

## **NGO submission**

### **identification**

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NGO

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#### **country**

Denmark

### **questions scope**

#### **problem definition**

Yes

#### **which option**

No change

### **additional comments**

Products should not be banned before a proper assessment of their health effects has been established. Some forms of oral tobacco have shown promise in both reducing the risk of tobacco use (Compared to smoking) and could maybe assist people in quitting smoking.

### **questions smokeless**

#### **problem definition**

Yes

#### **which option**

Lifting the ban on snus

### **additional comments**

As stated before, Snus is likely to be less harmful than many allowed tobacco products. Therefore it makes no sense to ban it. Also snus is available in loose forms in some markets while not allowed in portion packs. This kind of legislation is confusing to customers and makes the internal market for tobacco products much less transparent. Snus has shown promise in helping people quit the more dangerous habit of smoking and snus does not create a problem for non-users (Like second hand smoke may). Lastly snus is already imported into Denmark from Sweden in large quantities, making Danish retailers miss out on potential profits without actually preventing use.

### **questions consumer**

#### **problem definition**

No

### **explanations**

Proper information should be displayed on packs so that consumers can make an informed

choice. However the current warnings are sufficient and cannot possibly be ignored by consumers because of their size (30-40% is VERY visible). So-called plain packaging will prevent consumers from choosing their preferred product and will complicate the service at store level since it will be harder to recognize the brands. This means that it will take more time to service each customer adding yet another cost increase for the small shops. Finally it will make the job easier for criminals in copying legitimate products resulting in a loss for the state and the legitimate retailers. In a high tax country such as Denmark the illegitimate cigarette industry is already very lucrative and there is simply no point in making it easier as well.

**which option**

No change

**additional comments**

Proper information should be displayed on packs so that consumers can make an informed choice. However the current warnings are sufficient and cannot possibly be ignored by consumers because of their size (30-40% is VERY visible). So-called plain packaging will prevent consumers from choosing their preferred product and will complicate the service at store level since it will be harder to recognize the brands. This means that it will take more time to service each customer adding yet another cost increase for the small shops. Finally it will make the job easier for criminals in copying legitimate products resulting in a loss for the state and the legitimate retailers. In a high tax country such as Denmark the illegitimate cigarette industry is already very lucrative and there is simply no point in making it easier as well.

**questions on reporting**

**problem definition**

No

**explanations**

Generally we have no comments on this issue. However, establishing a common format makes sense in order to save time. Putting fees on private companies for the purpose of financing government research should not be the job of the EU – therefore we cannot agree with the problem definition.

**which option**

Establish a common compulsory reporting format

**additional comments**

There is no reason why a common standard should not be introduced to save both businesses and governments time and resources. However such standards should not mean extra burdens on private businesses.

**regulation of ingredients**

**problem definition**

No

**explanations**

Neither state nor EU should make it their business to define taste (attractiveness). Adults should be able to choose what they find attractive. Banning the use of ingredients would

effectively wipe out more than 90% of the cigarettes available in Denmark leaving only the “additive free” variants. Since these additive free packs clearly state that they are not less harmful than ordinary cigarettes, it will be very confusing to customers if bans or restrictions are imposed.

**which option**

No Change

**access to tobacco products**

**problem definition**

No

**explanations**

Banning the display of tobacco products would mean huge costs for our members. It would also make it much easier for the unorganized and illegitimate shops to sell illegal products without being caught. All this without any evidence that such a ban would have any effect on the number of smokers. All sales channels should follow the law on equal terms for competition to function. But no sales channel should be restricted or banned by default. Enforcement of age limit laws by the member state is essential to upholding a functioning market and to protect minors – adults should have the opportunity to choose for themselves without being subject to censorship.

**which option**

No change

**additional option**

In Denmark age restrictions prevent minors from buying tobacco products. These restrictions should be enforced on a national level for all sales channels. Today the law is not enforced in Denmark, resulting in unfair competition between legitimate retailers and the unorganized kiosks neglecting their responsibility. If adults/parents are choosing to provide tobacco products to minors an informational campaign should address this issue.

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Lithuania

**questions scope**  
**problem definition**  
Yes

**which option**  
No change

**questions smokeless**  
**problem definition**  
Yes

**which option**  
Lifting the ban on snus

**additional option**  
As scientific evidence on the far less harmful impact compared to cigarettes is available, this should be one of the proven data leading to lifting the ban on snus.

**questions consumer**  
**problem definition**  
No

**explanations**  
Actually, there is no evidence that the bigger size of the warning sign the higher the effectiveness of the seeaked result which, in this case, is improved public health or decreased number of illnessse related to smoking.

**which option**  
No change

**questions on reporting  
problem definition**

No

**explanations**

Well, manufacturers among the Member States already provide information and they alone should be liable for enforcement of the Directive.

**which option**

Establish a common compulsory reporting format

**regulation of ingredients**

**problem definition**

No

**explanations**

In this case, more attention should be paid to testing the inhalation toxicity of the ingredients and not to preparation of more positive or negative lists.

**which option**

No Change

**access to tobacco products**

**problem definition**

No

**which option**

No change

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**NGO submission**

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NGO

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24

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**questions scope**  
**problem definition**

Yes

**which option**

No change

**recommend option**

Lifting the ban on snus

**additional comments**

Snus is far less dangerous than cigarettes and scientific studies show that snus has the highest success rate for those trying to quit smoking. The current ban on snus not only has unfortunate health effects, but also restricts the freedom of those citizens wanting to use snus.

**questions smokeless**

**problem definition**

No

**comments**

There is no correlation between the size of health warnings on cigarette packs and smoking prevalence. People who smoke are already aware of the health effects, and disturbing pictures would be a symbolic measure, empty of real effect. Plain packaging will make it easier for criminals to copy packs, leading to illicit trade and eroding consumer protection.

**which option**

No change

**questions consumer**

**problem definition**

No

**explanations**

Member states already have the option of introducing fees and sanctions if they so desire. Enforcement is a matter for the member states, and the EU should remain focused on its core purpose of securing the free movement of people and goods.

**which option**

No change

**questions on reporting**

**problem definition**

No

**explanations**

Regulating the additives of cigarettes should be left to the member states, and should be limited to regulating those substances increasing the toxicity of cigarettes. Neither the EU nor individual member states should be regulating additives based on "attractiveness".

**which option**

No change

**regulation of ingredients****problem definition**

No

**explanations**

Online tobacco purchase takes place on a very limited scale, and does not require EU regulation. The task of regulating vending machines should be left to the member states, not the EU.

**which option**

No Change

**additional comments**

It is the opinion of Liberal Alliance Youth that the EU should remain focused on securing the free movement of people and goods within the EU. Although we support a transnational effort at combating infectious diseases, preventing lifestyle diseases such as smoking or overweight should not be a matter for the EU. On the national level, we are of the opinion that individuals should be free to take responsibility for their own life. Smokers are well aware of the dangers of smoking, and if they choose to take that risk, governments should not try to restrict their access to tobacco. Tobacco is already heavily taxed, insuring that smokers carry the associated health care costs themselves.

**access to tobacco products****problem definition**

No

**explanations**

Online tobacco purchase takes place on a very limited scale, and does not require EU regulation. The task of regulating vending machines should be left to the member states, not the EU.

**which option**

No change

**additional comments**

It is the opinion of Liberal Alliance Youth that the EU should remain focused on securing the free movement of people and goods within the EU. Although we support a transnational effort at combating infectious diseases, preventing lifestyle diseases such as smoking or overweight should not be a matter for the EU. On the national level, we are of the opinion that individuals should be free to take responsibility for their own life. Smokers are well aware of the dangers of smoking, and if they choose to take that risk, governments should not try to restrict their access to tobacco. Tobacco is already heavily taxed, insuring that smokers carry the associated health care costs themselves.

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**questions scope**

**problem definition**

Yes

**which option**

No change

**questions smokeless**

**problem definition**

Yes

**which option**

No change

**questions consumer**

**problem definition**

Yes

**which option**

No change

**questions on reporting**

**problem definition**

Yes

**which option**

No change



**regulation of ingredients****problem definition**

Yes

**which option**

No Change

**access to tobacco products****problem definition**

Yes

**which option**

No change

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**NGO submission****identification****affiliation**

NGO

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Lithuania / Lietuva

**questions scope****problem definition**

Yes

**which option**

No change

**additional comments**

We do not agree with the suggested ban of the novel forms of oral tobacco. If such ban would not be automatic, we would be in favor of extending the scope of the Directive. We believe that new forms of tobacco products should be evaluated before the decision of allowing them on the market or banning them is taken.

**questions smokeless****problem definition**

Yes

**which option**

Lifting the ban on snus

**questions consumer  
problem definition**

No

**explanations**

While we agree that adequate information about the harm of smoking tobacco products should be available and clearly visible on the packs of cigarettes, cigars, smoking tobacco and similar products, we do not support the notion that bigger health warnings are informing consumers better than the current ones. We also object to the proposal to introduce "generic packaging", as there is no proof that it will improve consumer information.

**which option**

No change

**additional comments**

"Generic packaging" means de facto ban of trademarks used by tobacco manufacturers, which contradicts principles of intellectual property protection; it would also lead to commoditization of tobacco products, thus harming competition in the market, while making tobacco products easier to counterfeit.

**questions on reporting  
problem definition**

Yes

**which option**

Establish a common compulsory reporting format

**regulation of ingredients**

**problem definition**

No

**explanations**

There is no proof that tobacco ingredients make the product more attractive. In addition, the term "attractiveness" is very much depending on its interpretation and therefore cannot form the basis for banning or allowing ingredients to be used.

**which option**

No Change

**additional comments**

Lithuania already has the negative list of ingredients that cannot be used in manufacturing of tobacco products, thus there is no need to create an additional system. Each Member State has full right to establish such lists and therefore we do not see how EU level directive could be of any help.

**access to tobacco products**

**problem definition**

No

**explanations**

The problem is not defined in the "Problem definition" part for this question. We do not see how functioning of the retail sales in each Member State can have any impact on Internal Market.

**which option**

No change

**additional comments**

Countries have all necessary means to establish retail rules and to control them. Retail of any product, especially of tobacco products, is very much local affairs, not affecting the free movement of goods principle in EU. There is no logical or legal justification for introducing european rules for the retail selling process.

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NGO

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Lithuania

**questions scope****problem definition**

Yes

**which option**

No change

**recommend option**

Disagree with prohibitions without scientific proof of evidence. In such a way it would be bias. Scope might be broader to regulate tobacco products such as oral or new forms.

**questions smokeless****problem definition**

Yes

**which option**

Lifting the ban on snus

**additional comments**

Sweden shall not be left exclusive for sales of snus. Internal market rules shall apply to all to facilitate competition and opportunities for job creation.

**questions consumer  
problem definition**

No

**explanations**

Plain packaging leads to easier operations of black market and counterfeiters. It would directly harm countries' economy. There is not evidence that plain packaging or extreme health warning sizes are leading to improvements of health issues. It would scrutinize internal EU market principles, decrease work places in legal businesses.

**which option**

No change

**additional comments**

Health objectives shall not be accurately analyzed against real but not theoretical impact; most importantly consistent and comprehensive education curriculum shall be implemented to decrease smoking among underage as well as providing information to adult smokers about health effects of tobacco product use. Prohibitory approach is not effective (ref: alcohol prohibition in USA).

**questions on reporting  
problem definition**

No

**explanations**

Sanctions and registration payments can be introduced by sovereign countries already now. It shall be the member states' right but not of the EU to choose the best regulatory principle that would work in specific environment.

**which option**

Establish a common compulsory reporting format

**additional options**

Establish a clear reporting uniformed standard so all countries can adhere to it.

**regulation of ingredients****problem definition**

No

**explanations**

Constituencies shall be THE cause. Ingredients testing shall be carried to analyze against increase in toxicity in smoke. Use of ingredients shall be regulated based on scientific evidence.

**which option**

No Change

**access to tobacco products****problem definition**

No

**explanations**

Problem is not stated when it comes to display regulation or/and vending machine sales. Ban introduction has no evidence behind in any aspect. Moreover, non-visible display of product will help and stimulate illegal product distribution through legal licensed selling outlets. Ban of access, display would lead to disruption of legal business entities and, in real terms, will give the green light to smugglers, proliferation of non-duty payed products. Legal jobs and business evolution would be threatened without proof of evidence to lead to the stated principle of the Directive; it works against principle of Lisbon Treaty.

**which option**

No change

**additional comments**

Access shall be limited to adults who choose to smoke and the Directive shall not be driving into the prohibitory path for legal industry, unless it's proven to be hazardous to people or country's development. It shall be supportive to the boost of the black, incontrollable market.

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**questions scope****problem definition**

Yes

**which option**

Extend the scope of the Directive

**questions smokeless**

**problem definition**

Yes

**which option**

Lifting the ban on snus

**questions consumer**

**problem definition**

Yes

**which option**

No change

**questions on reporting**

**problem definition**

Yes

**which option**

Establish a common compulsory reporting format

**regulation of ingredients**

**problem definition**

Yes

**which option**

Introducing the basic criteria on the EU level without a common list

**access to tobacco products**

**problem definition**

Yes

**which option**

Controlled supply and access

**which supply and access**

Access to vending machines to be restricted to adults

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NGO

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**questions scope****problem definition**

Yes

**which option**

No change

**questions smokeless****problem definition**

Yes

**which option**

Lifting the ban on snus

**questions consumer****problem definition**

Yes

**which option**

Improve consumer information

**which improvement**

Tar, nicotine and carbon monoxide levels to be replaced with general information on harmful substances in tobacco products

**questions on reporting****problem definition**

Yes

**which option**

Establish a common compulsory reporting format

**regulation of ingredients****problem definition**

Yes

**which option**

Establish a common list of tobacco ingredients

**which one**

Establish a positive common list of tobacco ingredients

**access to tobacco products**

**problem definition**

Yes

**which option**

Controlled supply and access

**which supply and access**

Age verification of buyers and other legal conditions to be set for cross-border retail sale

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**questions scope**

**problem definition**

Yes

**which option**

Extend the scope of the Directive

**questions smokeless**

**problem definition**

Yes

**which option**



No change

**questions consumer  
problem definition**

Yes

**which option**

No change

**questions on reporting  
problem definition**

Yes

**which option**

No change

**regulation of ingredients  
problem definition**

Yes

**which option**

No Change

**access to tobacco products  
problem definition**

Yes

**which option**

No change

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**NGO submission**

**identification**

**affiliation**

NGO

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**questions scope**  
**problem definition**

No

**explanations**

Beibehaltung der nationalen Gesetzgebung der einzelnen EU-Mitgliedsstaaten.

**which option**

No change

**recommend option**

Keine Änderungen.

**additional comments**

Innovative Produkte wie elektr. Zigaretten, Nikotindrinks oder zigarettenähnliche Erzeugnisse, die keinen Tabak enthalten – wie etwa Kräuterzigaretten – würden verboten. Erwachsene Konsumenten werden in Ihrer Wahlfreiheit eingeschränkt, da alternative nikotinhaltige und nikotinfreie Produkte, die den klassischen Tabakkonsum ergänzen, vom Markt genommen würden.

**questions smokeless**

**problem definition**

No

**comments**

Sämtliche Arten von rauchlosen Tabakerzeugnissen sollten in der EU frei vermarktet werden dürfen, vorbehaltlich möglicher Anforderungen an eine geeignete Verbraucherinformation wie zum Beispiel Gesundheitswarnhinweise und Einhaltung des Jugendschutzes.

**which option**

Lifting the ban on snus

**additional option**

Aufhebung des Verkaufsverbots von Snus in Teilen von Europa.

**additional comments**

Kein Kommentar.

**questions consumer**

**problem definition**

No

**explanations**

Durch eine Einheitspackung droht ein Einheits Sortiment von Tabakprodukten. Alle Produkte sehen gleich aus. Nur die Schockbilder stechen hervor. Die bestehenden Markenstrukturen in Deutschland würden vom Markt verschwinden. Es ist davon auszugehen, dass Einheitspackungen dazu führen würden, dass die Warenpräsentation im Tabakwaren-Facheinzelhandel entfällt und die Attraktivität des Sortimentes darunter leidet. Damit würden die Grundlagen für eine gute Beratung, aktiven Jugendschutz etc. weitgehend entfallen. Dem illegalen Handel würde Vorschub geleistet und Schmuggel und Fälschungen Tür und Tor

geöffnet werden. Künftig würden die Konsumenten nur noch preisorientiert kaufen. Dies würde nicht den gesundheitspolitischen Zielen dienen und durch die Abwanderung der Produkte in illegale Vertriebswege würde die Kontrolle des Marktes aufgegeben. Im Übrigen würden Einheitspackungen Markenrechte tangieren.

**which option**

No change

**additional option**

Keine Änderungen.

**additional comments**

Die Einführung von bildlichen Warnhinweisen bleibt in den Mitgliedsstaaten optional und unterschiedliche Etikettierungsmuster existieren auch weiterhin. Wasserpfeifen bleiben ohne Gesundheitswarnhinweise.

**questions on reporting**

**problem definition**

No

**explanations**

Für den Fall, dass der Händler selbst importiert, gilt er als Hersteller im Sinne des Gesetzes. Änderungen des Meldeverfahrens könnten gerade für kleine Hersteller/Händler zu hohen Kosten und damit zu erheblichen finanziellen Problemen einer rentablen Vermarktung der Tabakprodukte führen.

**which option**

No change

**additional options**

Keine Änderung.

**additional comments**

Eine weitere finanzielle Belastung für den selbst importierten Tabakwarenhandel würde zur Reduzierung der Angebotsvielfalt und den Verlust von Arbeitsplätzen führen.

**regulation of ingredients**

**problem definition**

No

**explanations**

Den Mitgliedsstaaten soll es weiterhin freistehen, die Zusatzstoffe von Tabakerzeugnissen selbst zu regulieren. Eine Erweiterung der EU-Kompetenzen ist nicht erforderlich

**which option**

No Change

**additional option**

Keine Änderungen.

**additional comments**

Zusatzstoffe, tragen zur Geschmacksvielfalt im Tabakwarensortiment bei. Eine Reduzierung der Zusatzstoffe führt zum Einheitsgeschmack im Tabakwarensortiment. Handel, Industrie und Endverbraucher in Deutschland verlieren eine über Jahre hinweg entstandene Geschmacksvielfalt der Produkte.

**access to tobacco products****problem definition**

No

**explanations**

Die Mitgliedsstaaten sollen weiterhin die Zuständigkeit für nationale Maßnahmen zur Begrenzung des Zugangs zu Tabakerzeugnissen behalten.

**which option**

No change

**additional option**

Keine Änderungen.

**additional comments**

Hiermit wäre eine existenzielle Einschränkung für den gesamten Einzelhandel verbunden. Es würde nur noch eine Warenverteilung stattfinden. Werbung und Produktpräsentation am Verkaufsort sind eine wichtige Entscheidungshilfe für den erwachsenen Konsumenten als Käufer. Ein Verbot würde dem aufgeklärten Verbraucher die Möglichkeit nehmen, zwischen verschiedenen Produkten zu wählen und den Wettbewerb zwischen den Anbietern unterbinden. Diese Maßnahme gefährdet Arbeitsplätze in der gesamten Tabakwirtschaft und trägt nicht zur besseren Aufklärung der Verbraucher bei. In Deutschland gibt es rund 100.000 Verkaufsstellen für Tabakwaren - seien es Fachgeschäfte, Tankstellen, Kioske oder Supermärkte. Die geplanten Maßnahmen betreffen den Tabakwarenhandel umfassend und sind in den Konsequenzen für den Tabakwaren-Facheinzelhandel existenzbedrohend.

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France

**questions scope**

**problem definition**

Yes

**which option**

Extend the scope of the Directive

**recommend option**

I share option to novel forms of oral tobacco, airbawls cigarets and electronic nicotine delivery system must be submitted to the same directive.

**additional comments**

I recommend that the list of all additives included cigarettes must be printed on the packet. If not, manufacturers must indicate a phone number wher the consumer is able to be informed of all products added in the tobacco he smokes. A food legislation exists, the same legislation must exist for inhaled products.

**questions smokeless****problem definition**

Yes

**which option**

Lifting the ban on snus

**additional option**

The list of additives printed on the packet

**questions consumer****problem definition**

No

**explanations**

The definition avoids additives . The place of additives is the same as TNCO . The place of additives, in my opinion, is before pictural warning.

**which option**

Improve consumer information

**which improvement**

Information on harmful substances in tobacco products that cannot be placed on the package would be placed inside the package

**additional option**

I prefer a generic packaging with information concerning TNCO and additives , no more.

**questions on reporting****problem definition**

Yes

**which option**

Introduce fees and sanctions

**additional options**

I recommend option 3 with obligations to the tobacco industries to declare the whole list of additives used, by respect to the consumer.

**regulation of ingredients****problem definition**

Yes

**which option**

Establish a common list of tobacco ingredients

**which one**

Establish a positive common list of tobacco ingredients

**access to tobacco products****problem definition**

Yes

**which option**

Ban

**which one2**

Promotion and displays in retail stores to be banned

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**NGO submission****identification****affiliation**

NGO

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**questions scope****problem definition**

Yes

**which option**

Extend the scope of the Directive

**recommend option**

All products containing nicotine must fall under the same Directive in order to address smoking effectively. There must also be the careful monitoring of products that market themselves as alternatives to smoking, and the public must be made adequately aware of their health implications.

**additional comments**

Health warnings on cigarette packets throughout the EU have been effective, but more needs to be done. The EU should consider an increase in the taxation of all products that contain nicotine and tobacco. A small increase in taxation can dramatically reduce consumption, particularly among young people who are most vulnerable. On a separate note, similar warnings should be put on alcoholic drinks and food that is high in fats. These labels should be standardised throughout the EU

**questions smokeless**

**problem definition**

Yes

**which option**

Ban on all types of smokeless tobacco products

**questions consumer**

**problem definition**

Yes

**which option**

Improve consumer information

**which improvement**

Picture warnings to become mandatory; Tar, nicotine and carbon monoxide levels to be replaced with general information on harmful substances in tobacco products; Information on harmful substances in tobacco products that cannot be placed on the package would be placed inside the package

**questions on reporting**

**problem definition**

Yes

**which option**

Introduce fees and sanctions

**regulation of ingredients**

**problem definition**

Yes

**which option**

Establish a common list of tobacco ingredients

**which one**

Establish a positive common list of tobacco ingredients

**access to tobacco products****problem definition**

Yes

**which option**

Ban

**which one2**

Cross-border retail sales of tobacco to be banned over the Internet; Vending machines to be banned; Promotion and displays in retail stores to be banned

**additional option**

The purchase of tobacco over the internet should be completely banned. The EU must ensure the assistance of European banks in order to ensure that tobacco products are not purchased over the internet. Tobacco products and vending machines undermine minimum age restrictions in EU Member States.

**additional comments**

There is also inconsistencies in smoking legislation across the EU which needs to be addressed. A minimum age of at least 18 needs to be established across the EU, smoking in public places must be completely banned. In Belgium smoking in bars continues due to inadequate legislation. Smoking in public places in the EU must be banned in order to protect public health.

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**country**

Spain

**questions scope****problem definition**

Yes



**which option**

No change

**questions smokeless**

**problem definition**

Yes

**which option**

Lifting the ban on snus

**questions consumer**

**problem definition**

Yes

**which option**

No change

**questions on reporting**

**problem definition**

Yes

**which option**

Establish a common compulsory reporting format

**regulation of ingredients**

**problem definition**

Yes

**which option**

No Change

**access to tobacco products**

**problem definition**

Yes

**which option**

No change

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**country**

Austria

**age**

40

**questions scope****problem definition**

No

**explanations**

Jedes Land soll für sich selbst entscheiden

**which option**

No change

**questions smokeless****problem definition**

No

**comments**

Jeder über 16 soll für sich selbst entscheiden

**which option**

No change

**questions consumer****problem definition**

No

**explanations**

soll so bleiben

**which option**

No change

**questions on reporting****problem definition**

No

**explanations**

kein problem

**which option**

No change

**regulation of ingredients**

**problem definition**

No

**explanations**

kein problem

**which option**

No Change

**access to tobacco products****problem definition**

No

**explanations**

kein problem

**which option**

No change

---

**NGO submission****identification****affiliation**

NGO

**name**

Skrdla Heidi

**email**

tt.skrdla@speed.at

**country**

Österreich

**age**

42

**gender**

female

**questions scope****problem definition**

Yes

**which option**

No change

**questions smokeless**

**problem definition**

Yes

**which option**

No change

**questions consumer**

**problem definition**

Yes

**which option**

No change

**questions on reporting**

**problem definition**

Yes

**which option**

No change

**regulation of ingredients**

**problem definition**

Yes

**which option**

No Change

**access to tobacco products**

**problem definition**

Yes

**which option**

No change

---

**NGO submission**

**identification**

**affiliation**

NGO

**name**

Michelle Sagmueller

**email**

sagmueller@gmx.at

**country**

Austria

**age**  
28

**gender**  
female

**questions scope**  
**problem definition**  
No

**explanations**  
Crudely legislating away personal freedom cannot be the answer

**which option**  
No change

**questions smokeless**  
**problem definition**  
No

**comments**  
...

**which option**  
No change

**questions consumer**  
**problem definition**  
No

**explanations**  
...

**which option**  
No change

**questions on reporting**  
**problem definition**  
No

**explanations**  
...

**which option**  
No change

**regulation of ingredients**  
**problem definition**  
No

**explanations**

...

**which option**

No Change

**access to tobacco products**

**problem definition**

No

**explanations**

...

**which option**

No change

---

**NGO submission**

**identification**

**affiliation**

NGO

**name**

daniel gomez romero

**email**

danigomer@hotmail.es

**country**

spain

**age**

36

**gender**

male

**questions scope**

**problem definition**

Yes

**which option**

No change

**questions smokeless**

**problem definition**

Yes

**which option**

Lifting the ban on snus

**questions consumer**

**problem definition**

No

**explanations**

educational campaigns are better

**which option**

No change

**questions on reporting**

**problem definition**

No

**explanations**

establish common reporting format in all EU countries

**which option**

Establish a common compulsory reporting format

**regulation of ingredients**

**problem definition**

No

**explanations**

it's as bad or as good anyway

**which option**

No Change

**access to tobacco products**

**problem definition**

No

**explanations**

consumers will not be have possibility to choose brands on sales

**which option**

No change

---

**NGO submission**

**identification**

**affiliation**

NGO

**name**

Tabakssyndicaat van de planters van west vlaanderen

**email**

info@tabakssyndicaat-wervik,be

**country**

Belgium

**age**

36

**gender**

female

**questions scope**

**problem definition**

Yes

**which option**

No change

**questions smokeless**

**problem definition**

Yes

**which option**

Lifting the ban on snus

**questions consumer**

**problem definition**

No

**explanations**

Educational campaigns are better way to inform consumers than graphic health warnings.

**which option**

No change

**questions on reporting**

**problem definition**

No

**explanations**

It is a good idea to establish an uniform format for registration of ingredients.

**which option**

Establish a common compulsory reporting format



**regulation of ingredients**

**problem definition**

No

**explanations**

Ban of ingredients will influence badly the tobacco growing across the Europe.

**which option**

No Change

**access to tobacco products**

**problem definition**

No

**explanations**

If all channels will be forbidden consumers may buy illegal products from unknown source.

**which option**

No change

---

**NGO submission**

**identification**

**affiliation**

NGO

**name**

beaudoin jacques

**email**

-

**country**

france

**questions scope**

**problem definition**

Yes

**which option**

No change

**questions smokeless**

**problem definition**

Yes

**which option**

No change

**questions consumer  
problem definition**

Yes

**which option**

No change

**questions on reporting  
problem definition**

Yes

**which option**

No change

**regulation of ingredients  
problem definition**

Yes

**which option**

No Change

**access to tobacco products  
problem definition**

Yes

**which option**

No change

---

**NGO submission**

**identification  
affiliation**

NGO

**name**

Herbert Mette

**email**

h-m@gmx.at

**country**

Austria

**age**

40

**gender**

male

**questions scope**

**problem definition**

Yes

**which option**

No change

**questions smokeless**

**problem definition**

No

**which option**

No change

**questions consumer**

**problem definition**

No

**explanations**

Stimme nicht zu !

**which option**

No change

**questions on reporting**

**problem definition**

No

**explanations**

Warum gibts des nur auf Englisch zum Beispiel? Es müsste in allen Europäischen Sprachen verständlich geschrieben werden !!!!

**which option**

No change

**regulation of ingredients**

**problem definition**

No

**explanations**

Warum gibts des nur auf Englisch zum Beispiel? Es müsste in allen Europäischen Sprachen verständlich geschrieben werden !!!!

**which option**

No Change

**access to tobacco products**

**problem definition**

No

**explanations**

Warum gibts des nur auf Englisch zum Beispiel? Es müsste in allen Europäischen Sprachen verständlich geschrieben werden !!!!

**which option**

No change

---

**NGO submission****identification****affiliation**

NGO

**name**

Ludwik Wachowicz

**email**

Nie posiadam

**country**

Polska

**questions scope****problem definition**

Yes

**which option**

No change

**questions smokeless****problem definition**

Yes

**which option**

Lifting the ban on snus

**questions consumer****problem definition**

No

**explanations**

Edukacja jest skuteczniejsza niz zmiana formy ostrzezen zdrowotnych.

**which option**

No change

**questions on reporting  
problem definition**

No

**explanations**

Wprowadzanie jednolitego formularza zgłaszania dodatkow w całej UE jest skutecznym rozwiązaniem.

**which option**

Establish a common compulsory reporting format

**regulation of ingredients**

**problem definition**

No

**explanations**

Brak dodatkow do produktow spowoduje pozbawienie plantatorow pracy, a także zmniejszenie dochodowosci uprawy tytoniu.

**which option**

No Change

**access to tobacco products**

**problem definition**

No

**explanations**

Konsument powinien mieć dostęp do wyrobów tytoniowych i prawo wyboru marki.

**which option**

No change

---

**NGO submission**

**identification**

**affiliation**

NGO

**name**

Jan Kwasniewski

**email**

Nie posiadam

**country**

Polska

**questions scope**  
**problem definition**  
Yes

**which option**  
No change

**questions smokeless**  
**problem definition**  
Yes

**which option**  
Lifting the ban on snus

**questions consumer**  
**problem definition**  
No

**explanations**  
Obrazkowe ostrzenia zdrowotne w mniejszym skutku niz kampanie edukacyjne informuja konsumentow.

**which option**  
No change

**questions on reporting**  
**problem definition**  
No

**explanations**  
Ujednolicenie zasad zgłaszania dodatkow przez wszystkie kraje UE.

**which option**  
Establish a common compulsory reporting format

**regulation of ingredients**  
**problem definition**  
No

**explanations**  
Zakaz stosowania dodatkow spowoduje obnizenie dochodowosci gospodarstw uprawiajacych tyton.

**which option**  
No Change

**access to tobacco products**  
**problem definition**  
No

**explanations**

Wyroby tytoniowe powinny byc dostępne i widoczne w sprzedaży.

**which option**

No change

---

**NGO submission****identification****affiliation**

NGO

**name**

Dorota Kuras

**email**

Nie posiadam

**country**

Polska

**questions scope****problem definition**

Yes

**which option**

No change

**questions smokeless****problem definition**

Yes

**which option**

Lifting the ban on snus

**questions consumer****problem definition**

No

**explanations**

Kampanie edukacyjne sa lepszym sposobem informowania konsumentow niz obrazkowe osterzenia zdrowotne.

**which option**

No change

**questions on reporting****problem definition**

No

**explanations**

Potrzebne byloby ujednoczenie formatu zgłaszania dodatkow.

**which option**

Establish a common compulsory reporting format

**regulation of ingredients**

**problem definition**

No

**explanations**

Zakaz stosowania dodatkow uniemozliwi wykorzystywanie tytoniu Burley. Doprowadzi to do zmniejszenie liczby miejsc pracy i dochodu wielu rodzin uprawiajacych tyton.

**which option**

No Change

**access to tobacco products**

**problem definition**

No

**explanations**

Ekspozycja wyrobow tytoniowych umozliwia wybor produktu.

**which option**

No change

---

**NGO submission**

**identification**

**affiliation**

NGO

**name**

Ryszard Szwarc

**email**

Nie posiadam

**country**

Polska

**questions scope**

**problem definition**

Yes



**which option**

No change

**questions smokeless****problem definition**

Yes

**which option**

Lifting the ban on snus

**questions consumer****problem definition**

No

**explanations**

Jednolite opakowania nie pozwalaja na odroznienie marek. Kampanie edukacyjne dostarczaja informacje o skutkach palenia.

**which option**

No change

**questions on reporting****problem definition**

No

**explanations**

Ujednolicenie formy zgłaszania dodatkow, wprowadzenie jednego formularza w UE.

**which option**

Establish a common compulsory reporting format

**regulation of ingredients****problem definition**

No

**explanations**

Bez dodatkow uprawa tytoniu Burley bedzie niemozliwa. Dodatki nadaja charakterystyczny smak.

**which option**

No Change

**access to tobacco products****problem definition**

No

**explanations**

Zakaz sprzedazy przez Internet, ale mozliwosc ekspozycji papierosow w punktach sprzedazy, zeby odroznic marki od siebie.

**which option**

No change

---

**NGO submission**

**identification**

**affiliation**

NGO

**name**

Kazimierz Kolodziej

**email**

Nie posiadam

**country**

Polska

**questions scope**

**problem definition**

Yes

**which option**

No change

**questions smokeless**

**problem definition**

Yes

**which option**

Lifting the ban on snus

**questions consumer**

**problem definition**

No

**explanations**

Kampanie edukacyjne informuja o skutkach palenia lepiej niz obrazkowe ostrzezenia zdrowotne.

**which option**

No change

**questions on reporting**

**problem definition**

No

**explanations**

Kady kraj członkowski UE powinien zgłaszać dodatki na takim samym formularzu.

**which option**

Establish a common compulsory reporting format

**regulation of ingredients**

**problem definition**

No

**explanations**

Bez dodatków wykorzystanie tytoniu Burley będzie niemożliwe.

**which option**

No Change

**access to tobacco products**

**problem definition**

No

**explanations**

Ekspozycja papierosów pozwala konsumentowi na odróżnienie marek w sprzedaży.

**which option**

No change

---

**NGO submission**

**identification**

**affiliation**

NGO

**name**

Jose Maria Ramos Lucas

**email**

jmaria.ramos@acorex.es

**country**

ESPANA

**age**

49

**gender**

male

**questions scope**

**problem definition**

Yes

**which option**

No change

**recommend option**

Es un sinsentido intentar atacar el problema de esta manera y una via muy peligrosa. hoy hablamos de tabaco, manana de que hablaremos?. Podemos coincidir en los peligros del tabaco y podemos tratarcon informacion de sus efectos, pero hacerlo sobre sus ingredientes, considerando una variedad como tal es cuando menos discutible. Creo que cuando no hay argumentos racionales, lo mejor es dejar las cosas como estan.

**questions smokeless**

**problem definition**

Yes

**which option**

No change

**additional option**

Reitero las mismas explocaciones.

**questions consumer**

**problem definition**

Yes

**which option**

Improve consumer information

**additional option**

Aqui como decia al principio aqui si creo que se debe y se puede hacer un esfuerzo por parte de todos , el cosumidor debe estar informado de todo lo que le afecta y como le afecta o puede afectar. Perola decision final es suya, el decide libremente. la libertad es lo mas saludable para el ser humano. No caigamos en la tentacion de decidir por el, porque no solo no le salvariamos, le aulariamos como ser humano y en esos errores ya cayeron otos.No volvamos al pasado. A veces vergonzoso pasado.

**questions on reporting**

**problem definition**

Yes

**which option**

Establish a common compulsory reporting format

**additional options**

Ningun comentario mas . reiterarme en lo dicho informacion total , prohibicion ninguna y libertad toda.

**regulation of ingredients**

**problem definition**

Yes

**which option**

Introducing the basic criteria on the EU level without a common list

**access to tobacco products**

**problem definition**

Yes

**which option**

No change

---

**NGO submission**

**identification**

**affiliation**

NGO

**name**

Mariola Madej

**email**

Nie posiadam

**country**

polska

**questions scope**

**problem definition**

Yes

**which option**

No change

**questions smokeless**

**problem definition**

Yes

**which option**

Lifting the ban on snus

**questions consumer**

**problem definition**

No

**explanations**

Najlepszym sposobem informowania konsumentow sa kampanie edukacyjne na temat palenia.

**which option**

No change

**questions on reporting****problem definition**

No

**explanations**

Zasady zgłaszania dodatkow powinny byc jednolite w calej UE.

**which option**

Establish a common compulsory reporting format

**regulation of ingredients****problem definition**

No

**explanations**

Zakaz dodatkow pozbawi zrodla dochodow plantatorow uprawiajacych tyton Burley.

**which option**

No Change

**access to tobacco products****problem definition**

No

**explanations**

Dalsze ograniczenia sprzedazy spowoduja wzrost nielegalnego handlu.

**which option**

No change

---

**NGO submission****identification****affiliation**

NGO

**name**

EU Hasser

**email**

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**country**

austria

**age**  
20

**gender**  
male

**questions scope**  
**problem definition**  
No

**explanations**  
All EU Kommisars are Assholers

**which option**  
No change

**recommend option**  
All Eu Politikers are assholes

**additional comments**  
Assholes

**questions smokeless**  
**problem definition**  
No

**comments**  
you wixer have shit in head

**which option**  
No change

**questions consumer**  
**problem definition**  
No

**explanations**  
Eu no- thanks

**which option**  
No change

**questions on reporting**  
**problem definition**  
No

**explanations**  
I have nothing te explain to Diktatory shit EU

**which option**

No change

**regulation of ingredients**

**problem definition**

No

**explanations**

Fuck yourself

**which option**

No Change

**access to tobacco products**

**problem definition**

No

**explanations**

Hope EU ist past soon

**which option**

No change

---

**NGO submission**

**identification**

**affiliation**

NGO

**name**

Bogdan Kamrowski

**email**

Nie posiadam

**country**

Polska

**questions scope**

**problem definition**

Yes

**which option**

No change

**questions smokeless**

**problem definition**

Yes



**which option**

Lifting the ban on snus

**questions consumer**

**problem definition**

No

**explanations**

Kampanie edukacyjne sa najlepszym sposobem informowania o skutkach palenia.

**which option**

No change

**questions on reporting**

**problem definition**

No

**explanations**

Powinien zostac wprowadzony jednolity formularz dla wszystkich krajow UE.

**which option**

Establish a common compulsory reporting format

**regulation of ingredients**

**problem definition**

No

**explanations**

Zakaz dodatkow zlikwiduje w niektórych rejonach plantacje tytoniu Burley, co doprowadzi do bezrobocia w tych rejonach.

**which option**

No Change

**access to tobacco products**

**problem definition**

No

**explanations**

Co zakazane bardziej zacheca.

**which option**

No change

---

**NGO submission**

**identification**

**affiliation**

NGO

**name**

Andrzej Radunski

**email**

ozpt@wp.pl

**country**

polska

**questions scope****problem definition**

Yes

**which option**

No change

**questions smokeless****problem definition**

Yes

**which option**

Lifting the ban on snus

**questions consumer****problem definition**

No

**explanations**

Konsument powinien miec moliwosc posiadania informacji o konkretnej marce.

**which option**

No change

**questions on reporting****problem definition**

No

**explanations**

Zasady zgłaszania dodatkow w Polsce sa jasne. Potrzebny jest w calej UE jednolity formularz.

**which option**

Establish a common compulsory reporting format

**regulation of ingredients****problem definition**

No

**explanations**

Zakaz dodatkow uniemozliwi przetwarzanie tytoniu Byurley. Papieros bez dodatkow to jak "kielbasa bez soli i ziol". Powinny byc uregulowane dodatki, ktore zwiekszaja szkodliwosc.

**which option**

No Change

**access to tobacco products****problem definition**

No

**explanations**

Poszerzanie obowiazujacych ograniczen sprzedazy spowoduje ograniczenie wolnosci handlu. Sprzedaz jest juz obecnie regulowana.

**which option**

No change

---

**NGO submission****identification****affiliation**

NGO

**name**

Klaipėdos apskrities darbdavių asociacija / Employers Association of Klaipeda District

**email**

verslas@vakarai.lt

**country**

Lietuva / Lithuania

**questions scope****problem definition**

Yes

**which option**

Extend the scope of the Directive

**additional comments**

We do not agree with any pre-emptive prohibitions, in this case with the idea of prohibiting new products for oral consumption. They may be less harmful.

**questions smokeless****problem definition**

Yes

**which option**

Lifting the ban on snus

**questions consumer****problem definition**

No

**explanations**

Too many different things connected in one topic - water pipes and generic packaging have very little common ground. We do not see any convincing arguments on why bigger warnings would help to quit smoking - no scientific prove available. Same for generic packaging.

**which option**

No change

**additional comments**

Poorly selected prohibition measures will do a lot of damage to the legal business, especially to small business. It should be proven that prohibitions work before introducing it.

**questions on reporting****problem definition**

Yes

**which option**

Establish a common compulsory reporting format

**regulation of ingredients****problem definition**

No

**explanations**

Prohibition of ingredients has to be based on scientific investigation and statistics. Now it is absolutely unclear how to measure what is attractive.

**which option**

No Change

**access to tobacco products****problem definition**

No

**explanations**

Too many different topics under one question. We think that shops selling cigarettes and cigars must be regulated by countries and not by EU. Country government know better how to deal with local issues.

**which option**

No change

**additional comments**

Proposals to hide cigarettes under the counter will be very expensive for the small and medium companies and will only help big shopping malls. We disagree with such discrimination and ask EU not follow this option.

---

**NGO submission****identification****affiliation**

NGO

**name**

Henryk Dworniczak

**email**

Nie posiadam

**country**

Polska

**questions scope****problem definition**

Yes

**which option**

No change

**questions smokeless****problem definition**

Yes

**which option**

Lifting the ban on snus

**questions consumer****problem definition**

No

**explanations**

Jednolite opakowania spowoduja poszerzenie szarej strefy

**which option**

No change

**questions on reporting****problem definition**

No

**explanations**

Skuteczne jest wprowadzenie wspolnego formularza raportowania

**which option**

Establish a common compulsory reporting format

**regulation of ingredients****problem definition**

No

**explanations**

Wladze zdrowotne powinny dazyc do zakazywania dodatkow, ktore zwiekszaja szkodliwosc, a nie wszystkich dodatkow.

**which option**

No Change

**access to tobacco products****problem definition**

No

**explanations**

Zakaz proponowany sprzez UE nie jest zgodny z zasadami wolnego handlu. Sprzedaz jest juz w tym momencie uregulowana.

**which option**

No change

---

**NGO submission****identification****affiliation**

NGO

**name**

Marek Maciurzynski

**email**

oktawiancia@wp.pl

**country**

polska

**questions scope****problem definition**

Yes

**which option**

No change

**recommend option**

Należy uregulować bezdymne wyroby tytoniowe

**questions smokeless**

**problem definition**

Yes

**which option**

Lifting the ban on snus

**questions consumer**

**problem definition**

No

**explanations**

Kampanie edukacyjne są wystarczająco skuteczne

**which option**

No change

**questions on reporting**

**problem definition**

No

**explanations**

Wprowadzenie wspólnego formularza rejestracyjnego

**which option**

Establish a common compulsory reporting format

**regulation of ingredients**

**problem definition**

No

**explanations**

Nie ma naukowego potwierdzenia, że papierosy z dodatkami są bardziej szkodliwe. Brak dodatków uniemożliwia stosowanie tytoniu Burley.

**which option**

No Change

**access to tobacco products**

**problem definition**

No

**explanations**

Zakaz sprzedaży jest zbyt daleko idącą propozycją

**which option**

No change

---

**NGO submission**

**identification**

**affiliation**

NGO

**name**

Strzeciwilk Andrzej

**email**

Nie posiadam

**country**

Polska

**questions scope**

**problem definition**

Yes

**which option**

No change

**questions smokeless**

**problem definition**

Yes

**which option**

Lifting the ban on snus

**questions consumer**

**problem definition**

No

**explanations**

Kampanie edukacyjne skuteczniejsze niz ostrzenia zdrowotne

**which option**

No change

**questions on reporting**

**problem definition**

No

**explanations**

Wprowadzenie wspolnego formularza do raportowania



**which option**

Establish a common compulsory reporting format

**regulation of ingredients****problem definition**

No

**explanations**

Zniesienie dodatkow uniemozliwia przetwarzanie tytoniu Burley, marki bede nierozpoznawalne

**which option**

No Change

**access to tobacco products****problem definition**

No

**explanations**

Sprzedaz wyrobow tytoniowych jest juz w tym momencie ograniczona. dlaszte restrykcje w sprzedazy spowoduja spadek sprzedazy legalnych wyrobow tytoniowych.

**which option**

No change

---

**NGO submission****identification****affiliation**

NGO

**name**

Michael Mair

**email**

sleddogpower2010@gmail.com

**country**

Austria

**questions scope****problem definition**

Yes

**which option**

No change

**questions smokeless  
problem definition**

No

**which option**

No change

**questions consumer  
problem definition**

No

**explanations**

Völliger Swachsinn..Wir lassen uns von der EU nichts vorschreiben

**which option**

No change

**questions on reporting  
problem definition**

Yes

**which option**

No change

**regulation of ingredients  
problem definition**

Yes

**which option**

No Change

**access to tobacco products  
problem definition**

Yes

**which option**

No change

---

**NGO submission**

**identification  
affiliation**

NGO

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**country**

Austria

**age**

43

**gender**

male

**questions scope**

**problem definition**

No

**explanations**

The problem is not the tobacco, but the CENSORSShip by the European Commission and the member staes

**which option**

No change

**recommend option**

YES, leave the decision to the CITIZEN. we are living in a FREE society and not in communism any more. This directive is a shame on the EU.

**additional comments**

YES, the European Commission should deal with more urgent issues instead of wasting money on the tobacco issue.

**questions smokeless**

**problem definition**

No

**comments**

FREEDOM for citizens.

**which option**

Lifting the ban on snus

**questions consumer**

**problem definition**

Yes

**which option**

No change

**questions on reporting**

**problem definition**

Yes

**which option**

Establish a common compulsory reporting format

**regulation of ingredients**

**problem definition**

Yes

**which option**

No Change

**access to tobacco products**

**problem definition**

Yes

**which option**

No change

---

**NGO submission**

**identification**

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NGO

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austria

**age**

47

**gender**

male

**questions scope**

**problem definition**

Yes

**which option**

Extend the scope of the Directive

**questions smokeless**

**problem definition**

Yes

**which option**

Ban on all types of smokeless tobacco products

**questions consumer**

**problem definition**

Yes

**which option**

Introduce generic or plain packaging

**questions on reporting**

**problem definition**

Yes

**which option**

Introduce fees and sanctions

**regulation of ingredients**

**problem definition**

Yes

**which option**

Introducing the basic criteria on the EU level without a common list

**access to tobacco products**

**problem definition**

Yes

**which option**

Ban

**which one2**

Cross-border retail sales of tobacco to be banned over the Internet; Vending machines to be banned; Promotion and displays in retail stores to be banned

---

**NGO submission**

**identification**

**affiliation**

NGO

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Germany

**age**  
22

**gender**  
male

**questions scope**  
**problem definition**  
Yes

**which option**  
Extend the scope of the Directive

**recommend option**  
Only a ban on tobacco products solves the problem. Inconsiderate smokers are otherwise continue smoking and harming others. Tobacco smoke is a poison without a use which is expensive for all. Tobacco is the only poison that can be sold publicly. Tobacco is the only product whose intended use leads to death. Smokers are unrepentant. Only a ban on tobacco products solves the problem.

**additional comments**  
Smoking neighbours in apartments harass their neighbors massively. They must be stopped !  
!!

**questions smokeless**  
**problem definition**  
Yes

**which option**  
Ban on all types of smokeless tobacco products

**additional option**  
so long have somokers cigarettes.. they smoke everywhere

**questions consumer**  
**problem definition**  
Yes

**which option**  
Improve consumer information; Introduce generic or plain packaging

**which improvement**  
Picture warnings to become mandatory; Tar, nicotine and carbon monoxide levels to be replaced with general information on harmful substances in tobacco products; Health warnings to be put on water pipes

**questions on reporting  
problem definition**

Yes

**which option**

Establish a common compulsory reporting format; Introduce fees and sanctions

**regulation of ingredients**

**problem definition**

Yes

**which option**

Establish a common list of tobacco ingredients

**which one**

Establish a positive common list of tobacco ingredients; Establish a negative common list of tobacco ingredients

**access to tobacco products**

**problem definition**

Yes

**which option**

Ban

**which one2**

Cross-border retail sales of tobacco to be banned over the Internet; Vending machines to be banned; Promotion and displays in retail stores to be banned

---

**NGO submission**

**identification**

**affiliation**

NGO

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NOSMOKE.GR

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info@nosmoke.gr

**country**

Greece

**questions scope**

**problem definition**

Yes

**which option**

Extend the scope of the Directive

**additional comments**

We do not have any further recommendations, however, there is one issue concerning the marketing and use of ENDS by the public. Specifically, if ENDS are intended to be used as cigarette supplements that will help smokers quit their habit (much like the claims regarding the use of ‘Snus’) their purpose and marketing rules should be changed as appropriate. That means that ENDS should be explicitly marketed as smoking cessation aids, and their marketing should be guided by the directives and ordinances applied to other pharmaceutical products used for the same purpose (i.e., smoking cessation). If ENDS are finally marketed as smoking cessation aids, then their effectiveness should be examined rigorously following the standard clinical trials procedures, and the findings from the clinical trials studies should be reported back to the scientific community for further scrutiny and replication.

**questions smokeless****problem definition**

Yes

**which option**

Ban on all types of smokeless tobacco products

**questions consumer****problem definition**

Yes

**which option**

Introduce generic or plain packaging

**additional comments**

We believe there are complementary measures to be taken so that Option 3 is more effectively applied. In particular, we recommend that: a) Any information regarding ‘light’ cigarettes is removed from cigarette packages, so that the only text used for marketing purposes is the label of the specific brand. However, in compliance with Option 3 the brand name should be colourless. b) In addition to text warning regarding the harmful effects of tobacco use, additional text should be added on packages that will remind smokers of the smoking bans in public places (e.g., “It is forbidden by the law to smoke in closed public places”). This reminder would be more relevant to Member States where smoking bans in public places are not yet implemented, or have been implemented very recently and smokers strongly oppose them (e.g., Greece). This measure will help Member States harmonize their practices in reducing exposure to SHS in public places, and will greatly benefit countries under accession, where smoke-free policies are not yet aligned with EU practices and the mandates of the FCTC.

**questions on reporting****problem definition**

Yes

**which option**

Introduce fees and sanctions



**regulation of ingredients****problem definition**

Yes

**which option**

Establish a common list of tobacco ingredients

**which one**

Establish a negative common list of tobacco ingredients

**additional comments**

We believe that there is one issue that needs to be addressed in the Revised Tobacco Products Directive that has not been tapped in the available options of the Public Consultation Document. Specifically, having a negative common list does not preclude the possibility that the ingredients in the positive list are used. This is problematic and may potentially hinder efforts to reduce tobacco consumption for the following reason. The purpose of using attractive substances (even if they are listed on the positive list) is to increase the purchase of tobacco products. If packages are intended to be colourless and out of sight in public venues, then the tobacco industry could use its last marketing strategy available (i.e., regulation of ingredients) to continue promoting tobacco products in order to recruit new smokers (typically adolescents and young people). In a few words, if a positive list is allowed to be used, the tobacco industry may provide substances that will make tobacco products more attractive and perhaps more addictive, and this obviously hinders the scope of the Tobacco Products Directive. Therefore, the recommendation of NOSMOKE.GR regarding the regulation of ingredients is that only a common negative list is used, and that the tobacco industry is not allowed to use any substance to make tobacco products more attractive and addictive.

**access to tobacco products****problem definition**

Yes

**which option**

Ban

**which one2**

Cross-border retail sales of tobacco to be banned over the Internet; Vending machines to be banned; Promotion and displays in retail stores to be banned

---

**NGO submission****identification****affiliation**

NGO

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**country**

nederland

**age**

63

**gender**

male

**questions scope****problem definition**

Yes

**which option**

No change

**questions smokeless****problem definition**

Yes

**which option**

Lifting the ban on snus

**questions consumer****problem definition**

Yes

**which option**

No change

**questions on reporting****problem definition**

Yes

**which option**

No change

**regulation of ingredients****problem definition**

Yes

**which option**

No Change

**access to tobacco products****problem definition**

Yes

**which option**

No change; Controlled supply and access

**which supply and access**

Tobacco display and promotion at points of sales to be restricted

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**NGO submission**

**identification**

**affiliation**

NGO

**name**

Polish Confederation of Private Employers Lewiatan (PKPP Lewiatan) is a nation-wide representation of employers to the state and trade unions. Today it is an organization of 55 sector and regional associations of private employers and 16 individual members. Thus in total there are about 3000 companies employing over 600000 workers. PKPP Lewiatan runs its own office and employs professionals experienced in a wide range of issues such as: labour relations, macroeconomics, small and medium-sized enterprises sector, and the European Union. We are a member of BUSINESSEUROPE. Warsaw Office 6 Klonowa Street 00-591 Warsaw Phone 48 (22) 8459550 Fax 48 (22) 8459551

**email**

lewiatan@pkpplewiatan.pl

**country**

Poland

**questions scope**

**problem definition**

No

**explanations**

The EU legislation fails today to regulate tobacco-related products (e.g electronic cigarettes - ENDS) or so called novel tobacco products. In Poland electronic cigarettes become increasingly popular. Undoubtedly, lack of common, EU regulation covering novel tobacco or tobacco-related products may lead to a distortion of the internal market and a failure to secure a proper level of public health protection in the EU Member States. However, we do not think that any new tobacco-related products or novel form of smokeless tobacco should be banned as a principle by the new directive. It would be against economic freedom to ban the potential products that can be introduced in the market only because they are new products. Any prohibition should be justified by clear evidence or scientific assessment that will prove that such products pose a significant risk for health of its consumers. The revision of Tobacco Products Directive should extend the scope of the Directive and introduce a set of requirements that new tobacco or tobacco related products will have to meet in order to get permission for their marketing.

**which option**

No change

**questions smokeless****problem definition**

No

**comments**

EU should establish the same equal requirements for all products and Member States

**which option**

Lifting the ban on snus

**questions consumer****problem definition**

No

**explanations**

We do not agree with the problem definition. We believe that most of the proposed options to improve consumer information will fail to bring any health effect. On the contrary, they will distort the internal market as well as will bring losses to national markets. We can not see clear and strong evidences supporting any of the proposed options to improve consumer information. Therefore we can not agree with the problem definition and the proposed options as in our opinion some of them are contrary to the basic principles of the European Community and even international and national legislation (e.g. protection of the intellectual property rights). Comments on enlarged obligatory picture warnings: The Rand Report suggests that the size of health warnings could be enlarged to 75% of the front panel of the packaging and 100% of the back panel. In practice this would mean that at least one side of the pack would not bear the trade mark and the placement of the trade mark on the front side would be significantly limited. We do not see clear evidence showing that such restrictive regulation would bring a real public health effect. According to the research conducted by the Eurobarometer in 2010, smoking prevalence in Belgium did not drop after introduction of picture warnings. On the contrary, the smoking prevalence increased in Belgium between 2006 and 2009. In Poland the most effective measures to reduce smoking consumption, according to the health authorities, proved to be: education and awareness campaigns. Comments on generic or plain packaging: This proposal clearly is against the basic principles of the protection of economic freedom and intellectual property rights protection. We have asked for the legal opinion the Patent Office of the Republic of Poland. According to their opinion plain or generic packaging would: Breach the international treaties such as the Paris Convention for the Protection of Industrial Property. The above mentioned Act does not provide for the possibility of restricting trademark applications related to any products, including the tobacco ones. Breach the principle of equality of entities applying for legal protection of a trademark. It could also give rise to allegations of the infringement of freedom of business activity guaranteed by the Constitution, the important element of which is the possibility to introduce the goods identified by the own trademark to the market. Trademark serves the purpose to distinguish goods from the goods of the same type manufactured by a different producer. Give rise to the allegation of defying the constitutional principle of protecting ownership rights and other property rights It could also breach the conditions of bilateral agreements on mutual support and protection of investment (e.g. the Treaty of 1990

on Trade and Economic Relationships between Poland and the United States) which refer to equal and fair treatment of investors in a state accepting an investment. The Plain packaging concept may be deemed as unfair treatment of tobacco trade investors due to the object of their of business activity. Plain or generic packaging would imply certain consequences from the point of view of competition conditions on the market: It would restrict the possibility for new entities to enter the market/new products to be launched on the market, It could give an unjustified competitive advantage to the established product brands. And last but not least, generic or plain packaging would make it easier and cheaper to counterfeit standardized, generic or plain packages, which would bring huge losses to legitimate entrepreneurs, national and EU budgets.

**which option**

No change

**questions on reporting**

**problem definition**

No

**explanations**

The national legislation already regulates reporting of ingredients, and sets sanctions for lack of compliance.

**which option**

No change

**regulation of ingredients**

**problem definition**

No

**explanations**

Any new, EU legislation that aims at regulating the production process and the content of the products sold within the EU, should be based on scientifically feasible evidence. The EU should regulate and restrict only these ingredients that increase the toxicity and harmfulness of the final product.

**which option**

No Change

**access to tobacco products**

**problem definition**

No

**explanations**

Tobacco products are legal goods that are already today subject to restrictive measures at points of sale. We do not find the rationales for further restricting or banning displays of tobacco products sufficient. There is no clear evidence that such restrictions will bring any health effect (breach of the constitutional principle of proportionality). Display ban could give rise to allegations of breaching the constitutional economic freedom as well as the principle of protecting ownership rights and other property rights.

**which option**

No change

---

**NGO submission****identification****affiliation**

NGO

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Venstres Ungdom (ref: Jakob Engel Schmidt)

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**country**

Denmark

**questions scope****problem definition**

Yes

**which option**

No change

**additional comments**

In Venstres Ungdom we don't believe that anyone should prohibit new tobacco-based products for the single reason that they are a new product. All tobacco legislation should be based on a respect for the individual freedom and responsibility. An important way to do so is by basing all decisions on thorough scientific evidence. When it comes to tobacco we have in many years seen politicians to eager to make laws just because they are against the product.

**questions smokeless****problem definition**

Yes

**which option**

Lifting the ban on snus

**additional comments**

A lot of studies show that smokeless products and especially snus are less harmful than traditional tobacco products. This is a situation where there is no scientific evidence showing a need for prohibition. We believe that consumers should have a choice in a free society and when there are potential health benefits we see no reason to continue a no novelty products-strategy within the EU. In Sweden the use of tobacco is almost the same as in Denmark but Sweden has none the less a lower cancer rate than Denmark. Studies have shown that one of the reasons could be the wide use of snus.

**questions consumer  
problem definition**

No

**explanations**

As we see it the report doesn't give any evidence that supports the problem definition. All smokers are aware of the health risk and no graphical setup can take the focus away from this. It is important that consumers are aware of the health risk, but as we see it, this is already covered by the legislation at hand today. In a free market all manufacturers of legal products have the rights to promote their specific brand, and a minimum must be that they can diverse in appearance. More so we believe that plain packaging will make it even easier for criminals to copy legitimate products and cause an explosion in the non-controlled market.

**which option**

No change

**additional comments**

We would like to add the fact that a plain packaging policy or similar will destroy the competition between different brands on the existing market. This will create a situation where price is the only factor in which each brand can distinguish themselves from the competition. Venstres Ungdom supports a fully functional market aimed at existing smokers. The existing warning are sufficient in order to provide consumers with important information on the health risk smoking involves.

**questions on reporting  
problem definition**

No

**explanations**

We disagree with the problem definition as member states already have the ability to introduce various methods of sanctions. It should be up to each individual member state to implement the necessary enforcement; this is not a job for EU.

**which option**

Establish a common compulsory reporting format

**additional comments**

In our view it could be a good idea to establish a common reporting format, provided that gathered information are protected sufficiently.

**regulation of ingredients**

**problem definition**

No

**explanations**

We oppose the statement that ingredients should be regulated based on attractiveness. We are against characteristic confectionary flavor but an overall legislation based solely on attractiveness is not the way forward. In our perspective ingredients should only be ban if it is possible to scientifically prove that a certain addictive increases the toxicity of the product. The current definition as well as the provided positive options doesn't allow such a view.

**which option**

No Change

**additional option**

As there might be good arguments for a common regulation, we do not believe that the proposed options make it possible to create such lists solely based on toxicity.

**access to tobacco products****problem definition**

No

**explanations**

There is no real evidence showing that the regulation aimed at the access to products should have any effect. A simple comparison between countries who have implemented such a legislation and countries that hasn't show that no health benefits can be linked to a regulation. It essential in a free market, that manufacturers can show their products to the customers in order to provide them with a choice. Tobacco products are create for adults, and such products should be allowed to be displayed. This is not the direction we would like to go, and we believe it is a slide towards a society where all products which in the specific time and place is looked down upon should be hidden under the counter. Furthermore we believe that a legislation banning the display of tobacco products will create a bigger market for illegal products as it is easier to hind the illegal products below the counter or in cabinets.

**which option**

No change

**additional comments**

The systematics of the free market and free access to products are essential values to Venstres Ungdom. Current legislation must make sure that only addults should be able exercise the righths og free choise and access.

---

**NGO submission****identification****affiliation**

NGO

**name**

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**country**

Magyar

**questions scope**



**problem definition**

Yes

**which option**

No change

**additional comments**

Ellentmondásos a tervezet, mert már a hatáskör definiálásakor tiltásokat fogalmaz meg bizonyos termékkörre, anélkül, hogy erre vonatkozó részletekkel szolgálna - legyen szó akár a bevezetőről, akár a konzultációs anyag egyéb fejezeteiről.

**questions smokeless****problem definition**

Yes

**which option**

Lifting the ban on snus

**additional comments**

Ennek a kérdéskörnek a szabályozását tagállami hatáskörben lenne érdemes meghagyni. Mindezekmellett úgy gondoljuk, hogy a snusszel kapcsolatos svéd példa alapján a füstmentes dohánytermékeket tiltás helyett inkább reklámozni kellene.

**questions consumer****problem definition**

No

**explanations**

Véleményünk szerint az egészségvédő feliratok méretének eltúlzása nincs arányban az elérni kívánt céllal. Az egyencsomagolás bevezetése egyértelműen utat nyit a feketekereskedelem növekedésének.

**which option**

No change

**questions on reporting****problem definition**

No

**explanations**

Tagállami szinten a kérdéskör megoldott és a tagállamok szuverinitásának fentartása szükséges, mivel a jelenlegi direktíva megfelelő alapot biztosít ehhez.

**which option**

No change

**regulation of ingredients****problem definition**

No

**explanations**

A tiltó jellegű szabályozásnak megfelelő tudományos alapokon kell nyugodnia, nem pedig szubjektív értékelésen. Az FCTC 9-10 cikkeinek vitái alalpján is látszik, hogy egy nem átgondolt tiltó szabályozás dohánytermelők munkahelyeit veszélyezteti, így Magyarországon 10,000 ember megélhetését tervezi ellehetetleníteni.

**which option**

No Change

**access to tobacco products****problem definition**

No

**explanations**

A túlzott szabályozás a feketekereskedelem kapuit nyitja tágabbra, és így a legális értékesítés csökkenésén keresztül a termelői érdekeket hátrányosan befolyásolja.

**which option**

No change

---

**NGO submission****identification****affiliation**

NGO

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**country**

HOLLAND

**age**

47

**gender**

male

**questions scope****problem definition**

Yes

**which option**

No change

**questions smokeless  
problem definition**  
Yes

**which option**  
Lifting the ban on snus

**questions consumer  
problem definition**  
Yes

**which option**  
No change

**questions on reporting  
problem definition**  
Yes

**which option**  
No change

**regulation of ingredients  
problem definition**  
Yes

**which option**  
No Change

**access to tobacco products  
problem definition**  
Yes

**which option**  
No change

---

**NGO submission**

**identification  
affiliation**  
NGO

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**country**

Hungary

**questions scope**  
**problem definition**

Yes

**which option**

No change

**recommend option**

We believe that these products included in the scope of the Directive should be regulated one by one.

**questions smokeless**

**problem definition**

Yes

**which option**

Lifting the ban on snus

**additional option**

Snus has proven to be a good alternative product in Scandinavian countries and it has helped people to quit smoking.

**questions consumer**

**problem definition**

No

**explanations**

We cannot imagine a "plain" packaging would improve the functioning of the internal market, although it could highly contribute to non-legal traffic in tobacco products.

**which option**

No change

**questions on reporting**

**problem definition**

No

**explanations**

We strongly believe in addressing issues at the local (Member State) level and finding solutions in national regulations.

**which option**

Establish a common compulsory reporting format

**regulation of ingredients**

**problem definition**

No

**explanations**

Any such future regulation should be based on scientific objective practices and measures.

**which option**

No Change

**access to tobacco products****problem definition**

No

**explanations**

In view of the overall objective of improving the internal market's function, these issues should be regulated at national level.

**which option**

No change

---

**NGO submission****identification****affiliation**

NGO

**name**

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**country**

Lithuania

**questions scope****problem definition**

Yes

**which option**

No change

**recommend option**

Tobacco directive shall regulate only tobacco products

**questions smokeless****problem definition**

Yes

**which option**

Lifting the ban on snus

**additional option**

All legally produced products shall be allowed for use in all EU countries. Snus in Sweden has been analyzed and proven as less harmful especially for non-smokers.

**questions consumer****problem definition**

No

**explanations**

generic package will make business conditions more difficult for any tobacco selling entity, causing burden for logistics and stock keeping practice. It is likely that competition from contraband cigarettes would significantly increase, which may lead to business closures.

**which option**

No change

**questions on reporting****problem definition**

Yes

**which option**

Establish a common compulsory reporting format

**regulation of ingredients****problem definition**

No

**explanations**

Ingredient regulation is extremely complex and sensitive, thus same standards shall apply as for the regulation of food ingredients. It is also important that testing is done before any decision to restrict or prohibit use of materials.

**which option**

No Change

**additional comments**

There is no standard or common base that objectively defines what is attractive. Many countries and cultures interpret it differently. National governments are in the best position to decide, therefore it should not be regulated by EU directive.

**access to tobacco products****problem definition**

No

**explanations**

Varying rules on how tobacco products are sold in different countries does not constitute a problem.

**which option**

No change

**additional comments**

Ban on visual display of tobacco products will inevitably lead to increase in fraud and tax evasion. Highly questionable benefit for public health can not counter-balance real and substentional loss for HORECA business.

---

**NGO submission**

**identification**

**affiliation**

NGO

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**age**

49

**gender**

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**questions scope**

**problem definition**

Yes

**which option**

No change

**questions smokeless**

**problem definition**

Yes

**which option**

Lifting the ban on snus

**questions consumer**

**problem definition**

Yes

**which option**

No change

**additional comments**

Europa wordt volstrekt ongeloofwaardig als dit soort regelgeving vanuit Europa komt

**questions on reporting**

**problem definition**

Yes

**which option**

No change

**regulation of ingredients**

**problem definition**

Yes

**which option**

No Change

**access to tobacco products**

**problem definition**

Yes

**which option**

No change

---

**NGO submission**

**identification**

**affiliation**

NGO

**name**

"Investors' Forum"

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**country**

Lithuania

**questions scope**

**problem definition**

Yes

**which option**

No change

**additional comments**



It would be acceptable to extend the scope of the Directive as proposed by the option No. 2, but this option includes automatic ban of novel form of oral tobacco. Preventive ban of new products without any assessment of their effect on consumers health is not acceptable.

**questions smokeless**

**problem definition**

Yes

**which option**

Lifting the ban on snus

**additional comments**

In addition to single market arguments, it is very difficult to understand why the product, which is no more harmful than cigarettes should be banned. Example of Sweden shows that snus is likely to reduce the level of tobacco related illnesses.

**questions consumer**

**problem definition**

No

**explanations**

The problem is described incorrectly. The issue arises because current Directive only sets minimum surface to be dedicated for the Health Warnings on the packs and not setting the maximum levels. One standard for all EU countries would really solve the issue. In addition, there is no link between internal market and introduction of the plain or generic packaging and hence - no reason introducing it.

**which option**

No change

**additional comments**

Plain packaging also carries the risk of increasing counterfeiting of tobacco product, as it makes it easier for criminals to copy the packs.

**questions on reporting**

**problem definition**

Yes

**which option**

Establish a common compulsory reporting format

**additional options**

Standardization of reporting may be valuable in the context of EU, as long as trade secrets and commercial interests of investors have substantial protection.

**regulation of ingredients**

**problem definition**

No

**explanations**

The term "attractiveness" is not clearly defined. As in any other industry, restriction of ingredients must be based on solid research results.

**which option**

Introducing the basic criteria on the EU level without a common list

**access to tobacco products**

**problem definition**

No

**explanations**

Different rules of selling tobacco products in different countries cannot have any impact on the functioning of EU internal market. Retail is very local and geography driven business and therefore should be governed by national laws and regulations.

**which option**

No change

**additional comments**

Radical restrictions that have no proven impact on reduction of smoking cannot be justified, as they bring immediate losses to retail and has negative impact on investment in the retail and other related sectors. Placing legal product on the same scale as counterfeit or contraband cigarettes undermines transparency of businesses. It harms competition and does not stimulate investments into national economies.

---

**NGO submission**

**identification**

**affiliation**

NGO

**name**

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**country**

Lithuania

**questions scope**

**problem definition**

Yes

**which option**

No change

**questions smokeless**

**problem definition**

Yes

**which option**

Lifting the ban on snus

**questions consumer  
problem definition**

No

**explanations**

Pictures may be useful to help visualize the effects of smoking, but they should not be oversized. Science does not prove direct relation between increased size of health warning label and information effectiveness and consumer behavior. Introduction of generic packaging will not help to improve functioning of internal market. There is no proof that it helps to achieve any public health objectives. Also it would be the case of infringement of IP rights.

**which option**

No change

**questions on reporting  
problem definition**

No

**explanations**

Enforcement of reporting requirements should be regulated at the level of each Member State. Consequently, there is no need to regulate that on the EU level.

**which option**

Establish a common compulsory reporting format

**regulation of ingredients  
problem definition**

No

**explanations**

Regulation of prohibition of ingredients can only be based on objective scientific criteria. Although toxicity and addictiveness can be objectively measured, this does not apply to the concept of attractiveness.

**which option**

No Change

**access to tobacco products  
problem definition**

No

**explanations**

Bans to display tobacco products in retail shops will not improve functioning of internal market. Experience of other countries shows that such radical restrictions doesn't help public

health objectives as well. This may create a more favorable environment for illicit trade.

**which option**

No change

---

**NGO submission**

**identification**

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NGO

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belgium

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62

**gender**

male

**questions scope**

**problem definition**

Yes

**which option**

Extend the scope of the Directive

**questions smokeless**

**problem definition**

Yes

**which option**

Ban on all types of smokeless tobacco products

**questions consumer**

**problem definition**

Yes

**which option**

Introduce generic or plain packaging

**questions on reporting**

**problem definition**

Yes

**which option**

Introduce fees and sanctions

**regulation of ingredients****problem definition**

Yes

**which option**

Establish a common list of tobacco ingredients

**which one**

Establish a negative common list of tobacco ingredients

**access to tobacco products****problem definition**

Yes

**which option**

Ban

**which one2**

Cross-border retail sales of tobacco to be banned over the Internet; Vending machines to be banned; Promotion and displays in retail stores to be banned

---

**NGO submission****identification****affiliation**

NGO

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Austria

**age**

35

**gender**

female

**questions scope**  
**problem definition**

Yes

**which option**

Extend the scope of the Directive

**questions smokeless**

**problem definition**

Yes

**which option**

Ban on all types of smokeless tobacco products

**questions consumer**

**problem definition**

Yes

**which option**

Improve consumer information

**which improvement**

Picture warnings to become mandatory; Tar, nicotine and carbon monoxide levels to be replaced with general information on harmful substances in tobacco products; Information on harmful substances in tobacco products that cannot be placed on the package would be placed inside the package; Health warnings to be put on water pipes

**questions on reporting**

**problem definition**

Yes

**which option**

Introduce fees and sanctions

**regulation of ingredients**

**problem definition**

Yes

**which option**

Establish a common list of tobacco ingredients

**which one**

Establish a negative common list of tobacco ingredients

**access to tobacco products**

**problem definition**

Yes

**which option**

Ban

**which one2**

Vending machines to be banned; Promotion and displays in retail stores to be banned

---

**NGO submission**

**identification**

**affiliation**

NGO

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Austria

**age**

38

**gender**

male

**questions scope**

**problem definition**

Yes

**which option**

Extend the scope of the Directive

**recommend option**

total prohibition of passive smoking in public and closed rooms.

**questions smokeless**

**problem definition**

No

**comments**

everything has been said by the Austrian Council on Smoking and Health

**which option**

Ban on all types of smokeless tobacco products

**questions consumer**

**problem definition**

No

**explanations**

see statement by Prof. Manfred Neuberger/Austrian Council on Smoking and Health  
([www.aerzteinitiative.at](http://www.aerzteinitiative.at))

**which option**

Introduce generic or plain packaging

**questions on reporting****problem definition**

No

**explanations**

see [www.aerzteinitiative.at](http://www.aerzteinitiative.at)

**which option**

Introduce fees and sanctions

**regulation of ingredients****problem definition**

No

**explanations**

see statement by Prof. Manfred Neuberger

**which option**

Establish a common list of tobacco ingredients

**which one**

Establish a positive common list of tobacco ingredients; Establish a negative common list of tobacco ingredients

**access to tobacco products****problem definition**

Yes

**which option**

Ban

**which one2**

Cross-border retail sales of tobacco to be banned over the Internet; Vending machines to be banned; Promotion and displays in retail stores to be banned

---

**NGO submission****identification****affiliation**

NGO



**name**

Kamp, Joachim, Dr. med., Sportler-pro-rauchfrei

**email**

joachimkamp@web.de

**country**

Deutschland

**age**

45

**gender**

male

**questions scope****problem definition**

Yes

**which option**

Extend the scope of the Directive

**recommend option**

Jede Vermarktung von Tabak und Tabakprodukten ist zu verbieten!

**additional comments**

Jede Vermarktung von Tabak und Tabakprodukten ist zu verbieten!

**questions smokeless****problem definition**

Yes

**which option**

Ban on all types of smokeless tobacco products

**additional option**

Jede Vermarktung von Tabak und Tabakprodukten ist zu verbieten!

**additional comments**

Jede Vermarktung von Tabak und Tabakprodukten ist zu verbieten!

**questions consumer****problem definition**

Yes

**which option**

Introduce generic or plain packaging

**additional option**

Jede Vermarktung von Tabak und Tabakprodukten ist zu verbieten!

**additional comments**

Jede Vermarktung von Tabak und Tabakprodukten ist zu verbieten!

**questions on reporting**

**problem definition**

Yes

**which option**

Introduce fees and sanctions

**additional options**

Jede Vermarktung von Tabak und Tabakprodukten ist zu verbieten!

**additional comments**

Jede Vermarktung von Tabak und Tabakprodukten ist zu verbieten!

**regulation of ingredients**

**problem definition**

Yes

**which option**

Establish a common list of tobacco ingredients

**which one**

Establish a negative common list of tobacco ingredients

**additional option**

Jede Vermarktung von Tabak und Tabakprodukten ist zu verbieten!

**additional comments**

Jede Vermarktung von Tabak und Tabakprodukten ist zu verbieten!

**access to tobacco products**

**problem definition**

Yes

**which option**

Ban

**which one2**

Cross-border retail sales of tobacco to be banned over the Internet; Vending machines to be banned; Promotion and displays in retail stores to be banned

**additional option**

Jede Vermarktung von Tabak und Tabakprodukten ist zu verbieten!

**additional comments**

Jede Vermarktung von Tabak und Tabakprodukten ist zu verbieten!

---

**NGO submission**

**identification**

**affiliation**

NGO

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Austria

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63

**questions scope**

**problem definition**

No

**explanations**

weil es ein schwachsinn ist

**which option**

No change

**questions smokeless**

**problem definition**

Yes

**which option**

No change

**questions consumer**

**problem definition**

No

**explanations**

schwachsinn

**which option**

No change

**questions on reporting**

**problem definition**

Yes

**which option**

No change

**regulation of ingredients**

**problem definition**

Yes

**which option**

No Change

**access to tobacco products**

**problem definition**

Yes

**which option**

No change

---

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NGO

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Germany

**age**

52

**gender**

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**questions scope**

**problem definition**

Yes

**which option**

Extend the scope of the Directive

**questions smokeless**

**problem definition**

Yes

**which option**

Ban on all types of smokeless tobacco products

**questions consumer**

**problem definition**

Yes

**which option**

Introduce generic or plain packaging

**questions on reporting**

**problem definition**

Yes

**which option**

Introduce fees and sanctions

**regulation of ingredients**

**problem definition**

Yes

**which option**

Establish a common list of tobacco ingredients

**which one**

Establish a positive common list of tobacco ingredients

**access to tobacco products**

**problem definition**

Yes

**which option**

Ban

**which one2**

Vending machines to be banned; Promotion and displays in retail stores to be banned

---

**NGO submission**

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NGO

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36

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male

**questions scope****problem definition**

Yes

**which option**

No change

**questions smokeless****problem definition**

Yes

**which option**

Lifting the ban on snus

**additional option**

no

**additional comments**

no

**questions consumer****problem definition**

Yes

**which option**

No change

**questions on reporting****problem definition**

Yes

**which option**

Introduce fees and sanctions

**additional options**

sdfgh

**additional comments**

srtgh

**regulation of ingredients**

**problem definition**

No

**explanations**

ysfgnj

**which option**

No Change

**additional option**

sfgn

**additional comments**

asdf

**access to tobacco products**

**problem definition**

No

**explanations**

asgh

**which option**

Controlled supply and access

**which supply and access**

Tobacco display and promotion at points of sales to be restricted

**additional option**

arghj

**additional comments**

agh

---

**NGO submission**

**identification**

**affiliation**

NGO

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33

**gender**  
male

**questions scope**  
**problem definition**  
No

**explanations**  
kein kommentar

**which option**  
No change

**questions smokeless**  
**problem definition**  
No

**comments**  
kein kommentar

**which option**  
No change

**questions consumer**  
**problem definition**  
No

**explanations**  
kein kommentar

**which option**  
No change

**questions on reporting**  
**problem definition**  
No

**explanations**  
kein kommentar

**which option**  
No change



**regulation of ingredients**

**problem definition**

No

**explanations**

kein kommentar

**which option**

No Change

**access to tobacco products**

**problem definition**

No

**explanations**

kein kommentar

**which option**

No change

---

**NGO submission**

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NGO

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52

**gender**

male

**questions scope**

**problem definition**

No

**explanations**

kein Kommentar

**which option**

No change

**questions smokeless**

**problem definition**

No

**comments**

kein Kommentar

**which option**

Lifting the ban on snus

**questions consumer**

**problem definition**

No

**explanations**

kein Kommentar

**which option**

No change

**questions on reporting**

**problem definition**

No

**explanations**

kein Kommentar

**which option**

No change

**regulation of ingredients**

**problem definition**

No

**explanations**

kein kommentar

**which option**

No Change

**access to tobacco products**

**problem definition**

No

**explanations**

kein kommentar

**which option**

No change

---

**NGO submission**

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**affiliation**

NGO

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**age**

33

**gender**

male

**questions scope**

**problem definition**

Yes

**which option**

No change

**questions smokeless**

**problem definition**

Yes

**which option**

Lifting the ban on snus

**questions consumer**

**problem definition**

Yes

**which option**

No change

**questions on reporting**

**problem definition**

Yes

**which option**

No change

**regulation of ingredients**

**problem definition**

Yes

**which option**

No Change

**access to tobacco products**

**problem definition**

Yes

**which option**

Ban

**which one2**

Cross-border retail sales of tobacco to be banned over the Internet

---

**NGO submission**

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**affiliation**

NGO

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**country**

Deutschland

**questions scope**

**problem definition**

Yes

**which option**

Extend the scope of the Directive

**questions smokeless**

**problem definition**

Yes

**which option**

Ban on all types of smokeless tobacco products

**questions consumer**

**problem definition**

Yes

**which option**

Introduce generic or plain packaging

**questions on reporting**

**problem definition**

Yes

**which option**

Introduce fees and sanctions

**regulation of ingredients**

**problem definition**

Yes

**which option**

Establish a common list of tobacco ingredients

**which one**

Establish a positive common list of tobacco ingredients

**access to tobacco products**

**problem definition**

Yes

**which option**

Ban

**which one2**

Vending machines to be banned; Promotion and displays in retail stores to be banned

---

**NGO submission**

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**affiliation**

NGO

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wendt

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deutschland

**age**  
46

**gender**  
female

**questions scope**  
**problem definition**  
Yes

**which option**  
No change

**questions smokeless**  
**problem definition**  
No

**comments**  
kein kommentar

**which option**  
No change

**questions consumer**  
**problem definition**  
No

**explanations**  
no coment

**which option**  
No change

**questions on reporting**  
**problem definition**  
No

**explanations**  
no coment

**which option**  
No change

**regulation of ingredients**  
**problem definition**  
Yes

**which option**

No Change

**access to tobacco products****problem definition**

No

**explanations**

kein kommentar

**which option**

No change

---

**NGO submission****identification****affiliation**

NGO

**name**

OKRĘGOWY ZWIĄZEK PLANTATORÓW TYTONIU W KRAKOWIE

**email**

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**country**

POLAND

**questions scope****problem definition**

Yes

**which option**

No change

**questions smokeless****problem definition**

Yes

**which option**

Lifting the ban on snus

**questions consumer****problem definition**

No

**explanations**

NO COMMENT

**which option**

No change

**questions on reporting  
problem definition**

No

**explanations**

NO COMMENT

**which option**

No change

**regulation of ingredients  
problem definition**

No

**explanations**

NO COMMENT

**which option**

No Change

**access to tobacco products  
problem definition**

No

**explanations**

NO COMMENT

**which option**

No change

---

**NGO submission**

**identification**

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NGO

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Germany



**age**  
64

**gender**  
male

**questions scope**  
**problem definition**  
Yes

**which option**  
Extend the scope of the Directive

**recommend option**  
option 2

**questions smokeless**  
**problem definition**  
Yes

**which option**  
Ban on all types of smokeless tobacco products

**questions consumer**  
**problem definition**  
Yes

**which option**  
Improve consumer information

**which improvement**  
Information on harmful substances in tobacco products that cannot be placed on the package would be placed inside the package

**questions on reporting**  
**problem definition**  
Yes

**which option**  
Introduce fees and sanctions

**regulation of ingredients**  
**problem definition**  
Yes

**which option**  
Establish a common list of tobacco ingredients

**which one**

Establish a positive common list of tobacco ingredients

**access to tobacco products**

**problem definition**

Yes

**which option**

Controlled supply and access

**which supply and access**

Tobacco display and promotion at points of sales to be restricted

---

**NGO submission**

**identification**

**affiliation**

NGO

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**age**

47

**gender**

male

**questions scope**

**problem definition**

Yes

**which option**

Extend the scope of the Directive

**questions smokeless**

**problem definition**

Yes

**which option**

Ban on all types of smokeless tobacco products

**questions consumer**

**problem definition**

Yes

**which option**

Introduce generic or plain packaging

**questions on reporting**

**problem definition**

Yes

**which option**

Introduce fees and sanctions

**regulation of ingredients**

**problem definition**

Yes

**which option**

Establish a common list of tobacco ingredients

**which one**

Establish a negative common list of tobacco ingredients

**access to tobacco products**

**problem definition**

Yes

**which option**

Ban

**which one2**

Cross-border retail sales of tobacco to be banned over the Internet; Vending machines to be banned; Promotion and displays in retail stores to be banned

---

**NGO submission**

**identification**

**affiliation**

NGO

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Germany

**questions scope**  
**problem definition**  
Yes

**which option**  
Extend the scope of the Directive

**questions smokeless**  
**problem definition**  
Yes

**which option**  
Ban on all types of smokeless tobacco products

**additional comments**  
Wenn sich das Verbot aller Formen von rauchlosen Tabak nicht durchsetzen lässt, sollte zumindest das Verbot für Snus aufrecht erhalten bleiben.

**questions consumer**  
**problem definition**  
Yes

**which option**  
Improve consumer information

**which improvement**  
Picture warnings to become mandatory; Tar, nicotine and carbon monoxide levels to be replaced with general information on harmful substances in tobacco products; Information on harmful substances in tobacco products that cannot be placed on the package would be placed inside the package

**additional option**  
Die Verpflichtung bildliche Warnhinweise auf die Packungen aufzubringen, hat für GMASH eine hohe Priorität.

**additional comments**  
Die Verpflichtung bildliche Warnhinweise auf die Packungen aufzubringen, hat für GMASH eine hohe Priorität. Die Entfernung der irreführenden Angaben zu den Gehalten von Teer, Nikotine und CO hält GMASH für absolut erforderlich. Die Glaubwürdigkeit der Richtlinie würde erheblich in Mitleidenschaft gezogen, wenn diese Angaben weiterhin von der EU-Kommission gefordert würden.

**questions on reporting**  
**problem definition**  
Yes

**which option**  
Establish a common compulsory reporting format; Introduce fees and sanctions

**additional comments**

GMASH hält Forderung nach einem einheitlichen verpflichtenden Berichtformat und die Einführung von Gebühren für die Bearbeitung der Berichte für selbstverständlich.

**regulation of ingredients****problem definition**

Yes

**which option**

Establish a common list of tobacco ingredients

**which one**

Establish a positive common list of tobacco ingredients

**additional comments**

The common list should only contain tobacco ingredients that are neither harmful nor contribute to the attractiveness and addictiveness of tobacco products.

**access to tobacco products****problem definition**

Yes

**which option**

Controlled supply and access; Ban

**which supply and access**

Age verification of buyers and other legal conditions to be set for cross-border retail sale; Access to vending machines to be restricted to adults; Tobacco display and promotion at points of sales to be restricted

**which one2**

Cross-border retail sales of tobacco to be banned over the Internet; Promotion and displays in retail stores to be banned

**additional comments**

GMASH befürwortet insbesondere das Verbot der Werbung für Tabakwaren am Verkaufsort.

---

**NGO submission****identification****affiliation**

NGO

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Hungary

**age**  
33

**gender**  
male

**questions scope**  
**problem definition**  
Yes

**which option**  
No change

**questions smokeless**  
**problem definition**  
Yes

**which option**  
Lifting the ban on snus

**additional comments**  
The control of this issue should be done by member states. Smokeless products, on the basis of Swedish experiences on snus, should be advertised instead of ban.

**questions consumer**  
**problem definition**  
No

**explanations**  
The size of warning signs is not close relation to the goal wanted to be achieved. Uniform packaging will help illegal trade.

**which option**  
No change

**questions on reporting**  
**problem definition**  
No

**explanations**  
This issue has been solved on member states level, and the sovereignty of member states should be sustained and the current directive makes a good ground of it.

**which option**  
No change

**regulation of ingredients****problem definition**

No

**explanations**

The ban should stand on a scientific basis not on subjective measures. On the debates of FCTC 9-10 chapters it can be seen that this controll is not a well worked out and the ban threatens the living of thousands of workers in tobacco farming - around 10.000 people in Hungary.

**which option**

No Change

**access to tobacco products****problem definition**

No

**explanations**

Too strict regulation increases illegal trade. By increasing illegal trade the legal trade decreases and it can be disadvantageous for the growers.

**which option**

No change

---

**NGO submission****identification****affiliation**

NGO

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Deutschland

**age**

42

**gender**

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**questions scope****problem definition**

No

**explanations**

Kein Kommentar

**which option**

No change

**questions smokeless**

**problem definition**

No

**comments**

Kein Kommentar

**which option**

Lifting the ban on snus

**questions consumer**

**problem definition**

No

**explanations**

Kein Kommentar

**which option**

No change

**questions on reporting**

**problem definition**

No

**explanations**

Kein Kommentar

**which option**

No change

**regulation of ingredients**

**problem definition**

No

**explanations**

Kein Kommentar

**which option**

No Change

**access to tobacco products**

**problem definition**

No



**explanations**

Kein Kommentar

**which option**

No change

---

**NGO submission****identification****affiliation**

NGO

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POLSKI ZWIĄZEK PLANTATORÓW TYTONIU - (POLISH TOBACCO GROWERS ASSOCIATION)

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POLAND

**questions scope****problem definition**

Yes

**which option**

No change

**questions smokeless****problem definition**

Yes

**which option**

Lifting the ban on snus

**questions consumer****problem definition**

No

**explanations**

NO COMMENT

**which option**

No change

**questions on reporting**

**problem definition**

No

**explanations**

NO COMMENT

**which option**

Establish a common compulsory reporting format

**regulation of ingredients****problem definition**

No

**explanations**

NO COMMENT

**which option**

No Change

**access to tobacco products****problem definition**

No

**explanations**

NO COMMENT

**which option**

No change

---

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NGO

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73

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**questions scope  
problem definition**

No

**explanations**

kein kommentar

**which option**

No change

**recommend option**

kein kommentar

**additional comments**

kein kommentar

**questions smokeless**

**problem definition**

No

**comments**

kein kommentar

**which option**

No change

**additional option**

kein kommentar

**questions consumer**

**problem definition**

No

**explanations**

kein kommentar

**which option**

No change

**additional option**

kein kommentar

**additional comments**

kein kommentar

**questions on reporting**

**problem definition**

No

**explanations**

kein kommentar

**which option**

No change

**additional options**

kein kommentar

**additional comments**

kein kommentar

**regulation of ingredients**

**problem definition**

No

**explanations**

kein kommentar

**which option**

No Change

**additional option**

kein kommentar

**additional comments**

kein kommentar

**access to tobacco products**

**problem definition**

No

**explanations**

kein kommentar

**which option**

No change

**additional option**

kein kommentar

**additional comments**

kein kommentar

---

**NGO submission**

**identification**

**affiliation**

NGO

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germany

**age**

61

**gender**

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**questions scope****problem definition**

Yes

**which option**

Extend the scope of the Directive

**questions smokeless****problem definition**

Yes

**which option**

Lifting the ban on snus

**questions consumer****problem definition**

Yes

**which option**

Improve consumer information

**which improvement**

Picture warnings to become mandatory

**questions on reporting****problem definition**

Yes

**which option**

Establish a common compulsory reporting format

**regulation of ingredients**

**problem definition**

Yes

**which option**

Introducing the basic criteria on the EU level without a common list

**access to tobacco products****problem definition**

Yes

**which option**

Controlled supply and access

**which supply and access**

Age verification of buyers and other legal conditions to be set for cross-border retail sale

---

**NGO submission****identification****affiliation**

NGO

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**age**

52

**gender**

male

**questions scope****problem definition**

No

**explanations**

Keinen Änderung für unser Land

**which option**

No change

**recommend option**

Eu ist ausreichend,

**additional comments**

Wir haben es schon schwierig genug und brauchen uns nicht noch weiter von der eu fertig machen lassen

**questions smokeless**

**problem definition**

No

**which option**

No change

**additional comments**

no kommentar alles so lassen wie es ist die menschen sind alt genug um selber für sich entscheiden zu lassen

**questions consumer**

**problem definition**

No

**explanations**

alles so lassen wie es ist

**which option**

No change

**questions on reporting**

**problem definition**

No

**explanations**

no kommentar

**which option**

No change

**additional options**

Wir kontrollieren auf grund des jugenschutzes sonst soll alles bleiben wie es ist

**regulation of ingredients**

**problem definition**

No

**explanations**

kein kommentar

**which option**

No Change

**additional option**

Alles so bleiben wie es ist

**access to tobacco products****problem definition**

No

**explanations**

no kommentar

**which option**

No change

**additional option**

alles so bleiben wie es ist die Menschen können sich selberentscheiden was sie wollen

---

**NGO submission****identification****affiliation**

NGO

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**age**

32

**gender**

male

**questions scope****problem definition**

Yes

**which option**

No change

**questions smokeless****problem definition**

Yes



**which option**

Lifting the ban on snus

**questions consumer**

**problem definition**

Yes

**which option**

Improve consumer information

**which improvement**

Tar, nicotine and carbon monoxide levels to be replaced with general information on harmful substances in tobacco products

**questions on reporting**

**problem definition**

Yes

**which option**

No change

**regulation of ingredients**

**problem definition**

Yes

**which option**

No Change

**access to tobacco products**

**problem definition**

Yes

**which option**

No change

---

**NGO submission**

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**country**

Slovenia

**age**

23

**gender**

female

**questions scope**

**problem definition**

Yes

**which option**

Extend the scope of the Directive

**additional comments**

Nicotine drinks and nicotine sweets should may be rather be taken as "drugs" not as "Foods". Also, electronic cigarettes should not be advertised and should only be available on doctor's receipt. Only in this way it would be a pharmaceutical product that would not promote smoking! For some people smoking electronic cigarettes is really cool and fancy and some avoid the smoke-free public places law with it! I personally think they should be forbidden! Or, very limited as mentioned above.

**questions smokeless**

**problem definition**

Yes

**which option**

Ban on all types of smokeless tobacco products

**additional comments**

Do not forget to provide information about why you are banning the smokeless tobacco, especially because it is "healthier" than cigarettes. What would be best accepted by the public, in my opinion, is just to strictly forbid smokeless tobacco advertising and to keep smokeless tobacco prohibited in the countries where it is already prohibited. In other countries stress should be put in other fields, otherwise smokers will really feel victims of health policies, as everything will suddenly be prohibited. After all, smokeless tobacco is not directly harmful to anyone around, there is no second hand smoke!

**questions consumer**

**problem definition**

Yes

**which option**

Introduce generic or plain packaging

**additional comments**

I also think the logo of the cigarette brand should be black and white, may be also the same type of letters as everything else. Definitely, there should also be a standard size of package - 20 cigarettes or more, not less!

**questions on reporting  
problem definition**

Yes

**which option**

Introduce fees and sanctions

**additional comments**

Heavy burden on manufactures? We should not forget that they are marketing a heavy drug that kills more people than any other product in the world. Also, no other thing to be consumed exists with NO available information about ingredients. At least not in Slovenia!

**regulation of ingredients**

**problem definition**

Yes

**which option**

Establish a common list of tobacco ingredients

**which one**

Establish a positive common list of tobacco ingredients

**additional comments**

The common list is easiest and cheapest to achieve. The stress should be put on the addictive substances that are used in tobacco products - except for nicotine (even though this is silly to say).

**access to tobacco products**

**problem definition**

Yes

**which option**

Ban

**which one2**

Cross-border retail sales of tobacco to be banned over the Internet; Vending machines to be banned; Promotion and displays in retail stores to be banned

**additional option**

I think tobacco should not be sold in the same shops as food or clothes. It should be sold in specialized shops to which only adults would have access.

**additional comments**

Cross border tobacco sale AND promotion should be forbidden!

---

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NGO

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**questions scope**  
**problem definition**  
No

**explanations**  
kein kommentar

**which option**  
No change

**recommend option**  
kein kommentar

**questions smokeless**  
**problem definition**  
No

**comments**  
kein kommentar

**which option**  
No change

**additional option**  
kein kommentar

**questions consumer**  
**problem definition**  
No

**explanations**

kein kommtar

**which option**

No change

**additional option**

kein kommentar

**questions on reporting**

**problem definition**

No

**explanations**

kein kommentar

**which option**

No change

**additional options**

kein kommentar

**regulation of ingredients**

**problem definition**

No

**explanations**

kein kommentar

**which option**

No Change

**additional option**

kein kommentar

**access to tobacco products**

**problem definition**

No

**explanations**

kein kommentar

**which option**

No change

**additional option**

kein kommentar

---

**NGO submission**

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NGO

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**questions scope**  
**problem definition**  
Yes

**which option**  
No change

**questions smokeless**  
**problem definition**  
Yes

**which option**  
No change

**questions consumer**  
**problem definition**  
Yes

**which option**  
No change

**questions on reporting**  
**problem definition**  
Yes

**which option**  
No change

**regulation of ingredients**  
**problem definition**

Yes

**which option**

Establish a common list of tobacco ingredients

**which one**

Establish a negative common list of tobacco ingredients

**access to tobacco products**

**problem definition**

Yes

**which option**

No change

---

**NGO submission**

**identification**

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NGO

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info@skatteborgerne.dk

**country**

Danmark

**questions scope**

**problem definition**

Yes

**which option**

No change

**recommend option**

We would like to emphasize the fact that EU's main competence on this area is to secure a functioning internal market also when it comes to tobacco products. In doing so we believe that measures such as proportionality and evidence based should be the key elements in all EU legislation. We see the same trend when it comes to taxation and especially excise taxation, where politicians focus on feelings or personal moral issues towards a product instead of looking at what really matters and giving people a free choice based on sufficient information about the product they are about to buy.

**questions smokeless**

**problem definition**

Yes

**which option**

Lifting the ban on snus

**additional option**

I can't see why citizens living in EU shouldn't have the option of buying and using snus. If the current prohibition scheme remains, it will only be due to a legislation based on emotions and fear of new types of tobacco based products. As I see it, there's no evidence supporting the current ban, on the other hand recent independent science show possible health effect if more smokers start to use snus instead of cigarettes.

**questions consumer**

**problem definition**

No

**explanations**

The current regulation provides sufficient information that in clear text explains the risk of smoking. I don't believe that the proposed measures will provide any improvements other than increasing administration costs and damage essential free market elements, such as brand appearance.

**which option**

No change

**additional option**

I'm particular against the proposed measures when it comes to generic packaging. I believe this is a trip down the wrong road, and will be extremely damaging to the internal market. The consumers have the right to available information about a certain product, as well as a functioning free market. The aim should be to find a way where this is possible, and I think we are there today. The current clear warnings provide the consumers with information and the company's right to distinguish themselves from each other through the design of logos and package ensures a competition on the market, which gives consumers better products. The problem occur when this turns into a trend where all products, which are perceived to be 'unhealthy' or 'bad for you' should be surrounded by warnings and pictures or even plain cardboard packaging. Lastly, I don't think anyone in Europe today are unaware of the fact that cigarettes are extremely unhealthy.

**questions on reporting**

**problem definition**

No

**explanations**

Member states today have the option of employing sanctions and whatever enforcement methods they find fitting. I think the EU should be wary of getting involved in this matter, which should rightly be left to the member states.

**which option**

Establish a common compulsory reporting format



**additional options**

A common reporting format would bring transparency to the tobacco market, thereby improving the internal market. This is something I think the EU should consider doing.

**regulation of ingredients****problem definition**

No

**explanations**

What I find missing in the definition is the consideration that regulation should be based on objective criteria, such as whether a certain substance makes a cigarette more harmful. The way the definition is currently written, the EU is asked to regulate on the basis of subjective criteria, such as whether a substance tastes good.

**which option**

No Change

**additional option**

It should be made clear that the EU will only be regulating on the basis of objective criteria.

**access to tobacco products****problem definition**

No

**explanations**

Limiting the free market is a serious thing and should only be done where the evidence shows that it will have a major improvement on the public health. But the problem definition simply does not provide any evidence that limiting the access to tobacco products will have such an effect. Also, the problem definition does not consider that as legal sellers are burdened with onerous regulation, the sale will move to the black market, harming consumer protection and leading to an increase in counterfitting.

**which option**

No change

**additional option**

I do not support any of the restrictions or bans mentioned. Take limiting or banning displays of tobacco products in stores. Those who already smoke will continue to smoke, whether or not they see cigarettes on display. And there is no evidence that people take up smoking because they see pretty cigarette packages.

---

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NGO

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Hungary

**gender**

male

**questions scope**

**problem definition**

Yes

**which option**

Extend the scope of the Directive

**questions smokeless**

**problem definition**

Yes

**which option**

No change

**questions consumer**

**problem definition**

Yes

**which option**

Improve consumer information

**which improvement**

Tar, nicotine and carbon monoxide levels to be replaced with general information on harmful substances in tobacco products

**questions on reporting**

**problem definition**

Yes

**which option**

Introduce fees and sanctions

**regulation of ingredients**

**problem definition**

Yes

**which option**

Introducing the basic criteria on the EU level without a common list

**access to tobacco products**

**problem definition**

Yes

**which option**

Ban

**which one2**

Cross-border retail sales of tobacco to be banned over the Internet; Vending machines to be banned; Promotion and displays in retail stores to be banned

---

**NGO submission**

**identification**

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NGO

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österreich

**questions scope**

**problem definition**

No

**explanations**

es gibt schon zu viele regelungen

**which option**

No change

**questions smokeless**

**problem definition**

No

**comments**

kein kommentar

**which option**

Lifting the ban on snus

**questions consumer**

**problem definition**

No

**explanations**  
kein kommentar

**which option**  
No change

**questions on reporting  
problem definition**  
No

**explanations**  
keine änderung

**which option**  
No change

**regulation of ingredients  
problem definition**  
No

**explanations**  
beibehaltung der vielfalt

**which option**  
No Change

**access to tobacco products  
problem definition**  
No

**which option**  
No change

---

**NGO submission**

**identification  
affiliation**  
NGO

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**country**

Magyar

**questions scope**  
**problem definition**

Yes

**which option**

No change

**questions smokeless**  
**problem definition**

Yes

**which option**

Lifting the ban on snus

**additional comments**

Ennek a kérdéskörnek a szabályozását tagállami hatáskörben lenne érdemes hagyni. Mindezek mellett úgy gondolom, hogy a snüsszel kapcsolatos svéd példa alapján a füstmentes dohánytermékeket tiltás helyett inkább reklámozni kellene

**questions consumer**  
**problem definition**

No

**explanations**

Az egészségvédő feliratok méretének eltulzása nincs arányban az elérni kívánt céllal. Az egyencsomagolás bevezetése egyértelműen utat nyit a feketekereskedelem növekedésének.

**which option**

No change

**questions on reporting**  
**problem definition**

No

**explanations**

Tagállami szinten a kérdéskör megoldott és a tagállamok szuverenitásának fenntartása szükséges, mivel a jelenlegi direktíva megfelelő alapot biztosít ehhez.

**which option**

No change

**regulation of ingredients**  
**problem definition**

No

**explanations**

A tiltó jellegű szabályozásnak megfelelő tudományos alapokon kell nyugodnia, nem pedig szubjektív értékelésen. Az FCTC 9-10 cikkelyeinek vitái alapján az is látszik, hogy egy nem

átgondolt tiltó szabályozás dohánytermelők munkahelyeit veszélyezteti, ez cégeknél körülbelül 1000 hátrányos helyzetű ember megélhetését teszi lehetetlenné.

**which option**

No Change

**access to tobacco products**

**problem definition**

No

**explanations**

A túlzott szabályozás a feketekereskedelem kapuit nyitja tágabbra, és így legális értékesítés csökkenésén a termelői érdekeket hátrányosan befolyásolja.

**which option**

No change

---

**NGO submission**

**identification**

**affiliation**

NGO

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Yorkshire & the Humber Trading Standards Group

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**country**

England

**age**

33

**gender**

male

**questions scope**

**problem definition**

Yes

**which option**

Extend the scope of the Directive

**additional comments**

The Yorkshire & the Humber Trading Standards Group (YAHTSG) would welcome an extension of the scope of the Directive to include all smoked products, including herbal

cigarettes. Current provisions do not take recognise that herbal cigarettes are smoked in the same way as nicotine cigarettes

**questions smokeless**

**problem definition**

Yes

**which option**

No change

**additional comments**

The YAHTSG believes that the current ban on snus should remain. At a time when member countries are developing strategies to de-normalise smoking and tobacco use, any change in relation to the ban on snus could cause confusion. The result could be dual use of cigarettes and smokeless tobacco which could undermine health objectives

**questions consumer**

**problem definition**

Yes

**which option**

Improve consumer information; Introduce generic or plain packaging

**which improvement**

Picture warnings to become mandatory; Tar, nicotine and carbon monoxide levels to be replaced with general information on harmful substances in tobacco products; Information on harmful substances in tobacco products that cannot be placed on the package would be placed inside the package; Health warnings to be put on water pipes

**additional comments**

The current situation with some Member States adopting picture warnings whilst others have not done so has created a discrepancy and uneven health protection across the EU. The YAHTSG would support any move to make picture health warnings mandatory to ensure optimum health protection for all EU citizens. From a personal perspective, my wife was influenced to quit smoking following the introduction of picture health warnings in the UK

**questions on reporting**

**problem definition**

Yes

**which option**

Establish a common compulsory reporting format; Introduce fees and sanctions

**additional comments**

The current situation which allows different formats and reporting mechanisms is unsatisfactory, making it difficult for authorities to compare and analyse the data. Tobacco companies should be required to use a standardised reporting format

**regulation of ingredients**

**problem definition**

Yes

**which option**

Establish a common list of tobacco ingredients

**access to tobacco products**

**problem definition**

Yes

**which option**

Ban

**which one2**

Vending machines to be banned; Promotion and displays in retail stores to be banned

**additional comments**

In relation to tobacco promotion and point of sale displays, the YAHTS would support an EU-wide adoption of a ban in relation to tobacco displays.

---

**NGO submission**

**identification**

**affiliation**

NGO

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Greece

**questions scope**

**problem definition**

Yes

**which option**

No change

**questions smokeless**

**problem definition**

Yes

**which option**

Lifting the ban on snus



**questions consumer  
problem definition**

No

**explanations**

European Citizens should make their own decisions freely without any enforcement.

**which option**

No change

**questions on reporting  
problem definition**

No

**explanations**

The situation should be reported separately by any of the EU member countries

**which option**

Establish a common compulsory reporting format

**regulation of ingredients**

**problem definition**

No

**explanations**

There is no document that prove the raising of addictiveness of the tobacco products.

**which option**

No Change

**access to tobacco products**

**problem definition**

Yes

**which option**

Controlled supply and access

**which supply and access**

Age verification of buyers and other legal conditions to be set for cross-border retail sale

---

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NGO

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55

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**questions scope****problem definition**

Yes

**which option**

No change

**questions smokeless****problem definition**

Yes

**which option**

No change

**questions consumer****problem definition**

Yes

**which option**

No change

**questions on reporting****problem definition**

Yes

**which option**

No change

**regulation of ingredients****problem definition**

Yes

**which option**

No Change

**access to tobacco products****problem definition**

Yes

**which option**

No change

---

**NGO submission**

**identification**

**affiliation**

NGO

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The Swedish National Association for Convenience stores and Fast Food

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**country**

Sweden

**questions scope**

**problem definition**

No

**explanations**

The Swedish National Association for Convenience stores and Fast Food does not have an opinion on the Scope of the directive.

**which option**

No change

**questions smokeless**

**problem definition**

No

**which option**

Lifting the ban on snus

**questions consumer**

**problem definition**

No

**explanations**

The Swedish National Association for Convenience stores and Fast Food is a trade organization mobilizing 3000? 1800? individual retailers in Sweden. We take an interest in some tobacco related issues as our members sell tobacco products and regulation often affects them – especially as we know that regulation sometimes result in unintended consequences such as an increase in the illegal trade with tobacco products, which is one of our members

biggest challenges. When it comes to consumer information we see a great risk that that implementing plain packaging would lead to an increase in the illegal trade as it would be much easier to copy standardized tobacco products and packages, and also harder for the consumers to recognize illegal products. We are convinced that an introduction of plain packaging would have serious consequences for our members, and as there is no clear evidence that such a regulation would have an impact on health, we question the relevance to include it as an alternative in this context. When it comes to the other suggestions regarding consumer information our organization does not have a standpoint.

**which option**

No change

**questions on reporting**

**problem definition**

No

**explanations**

The Swedish National Association for Convenience stores and Fast Food does not have an opinion on reporting and registration of ingredients

**which option**

No change

**regulation of ingredients**

**problem definition**

No

**explanations**

When it comes to ingredients we would once again like to warn for overregulation leading to an increase in illegal trade. Regulation should be well founded, and based on thorough impact assessments to ensure that it is proportionate and does not lead to unintended consequences. This aspect has to be considered also in the context of ingredients regulation, to make sure that the illegal trade does not increase, due to measures without public health impact.

**which option**

No Change

**access to tobacco products**

**problem definition**

No

**explanations**

The Swedish National Association for Convenience stores and Fast Food has been active in the debate regarding display ban in Sweden, as it has serious consequences for the trade without leading to any improved health effects. Statistics from countries that have tried a display ban do not demonstrate a reduction in tobacco consumption, but on the other hand shows serious unintended consequences such as increased smuggling and closure of small businesses. We are also concerned regarding the signal that such a ban will send to the consumer. Today there is a clear distinction between legal and illegal products, the limit is clear to the consumer as legal products are displayed, while illegal products are hidden under

the counter. By introducing a display ban you would introduce an entirely new product category, legal products that are not allowed to be displayed among other legal products. It is unreasonable to have products that are semi-legal. Products that are legal to sell, should also be legal to display in stores. We have looked into the effects of the display ban in a report that we are sending as a complement to this submission in an email. The main arguments against a display ban from our report: - In countries where the ban has been tested, retailers have been impacted negatively due to lost revenues and significant costs related to implementing the ban. In e.g. Canada many retailers have been shut down after the implementation of the ban. - In countries where the ban have been tested, the illegal trade with tobacco products has increased which has resulted in both lost revenues for retailers, and in increasing levels of crime which affects small retailers and society as a whole. - Selling tobacco from under the counter will make it harder for consumers to differentiate illegal products from legal ones, as the legal tobacco would have to be sold in the same way as the illegal one. - None of the countries that have implemented the ban seem to have shown better results than countries without display ban when it comes to smoking. In some cases there even seem to have been an increase in smoking incidence after the ban has been implemented.

**which option**

No change

---

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**questions scope**

**problem definition**

No

**explanations**

no

**which option**

No change

**recommend option**

no

**additional comments**

no

**questions smokeless  
problem definition**

No

**comments**

no

**which option**

No change

**additional option**

no

**additional comments**

no

**questions consumer  
problem definition**

No

**explanations**

no

**which option**

No change

**additional option**

no

**additional comments**

no

**questions on reporting  
problem definition**

No

**explanations**

no

**which option**

No change

**additional options**

no

**additional comments**

no

**regulation of ingredients**

**problem definition**

No

**explanations**

no

**which option**

No Change

**additional option**

no

**additional comments**

no

**access to tobacco products**

**problem definition**

No

**explanations**

no

**which option**

No change

**additional option**

no

**additional comments**

no

---

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NGO

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**questions scope**  
**problem definition**  
No

**explanations**  
kein kommentar

**which option**  
No change

**recommend option**  
kein kommentar

**additional comments**  
nein

**questions smokeless**  
**problem definition**  
No

**comments**  
kein kommentar

**which option**  
No change

**additional option**  
keinkommentar

**additional comments**  
nein

**questions consumer**  
**problem definition**  
No

**explanations**  
kein kommentar

**which option**  
No change



**additional option**

kein kommentar

**additional comments**

nen

**questions on reporting  
problem definition**

No

**explanations**

kein kommentar

**which option**

No change

**additional options**

kein kommentar

**additional comments**

nein

**regulation of ingredients  
problem definition**

Yes

**which option**

No Change

**access to tobacco products  
problem definition**

No

**explanations**

keine erklärung

**which option**

No change

**additional option**

kein kommentar

**additional comments**

nein, habe ich nicht

---

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**affiliation**  
NGO

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**questions scope**  
**problem definition**  
No

**explanations**  
Kein Kommentar

**which option**  
No change

**questions smokeless**  
**problem definition**  
No

**comments**  
Kein Kommentar

**which option**  
Lifting the ban on snus

**questions consumer**  
**problem definition**  
No

**explanations**  
Kein Kommentar

**which option**  
No change

**questions on reporting**

**problem definition**

No

**explanations**

Kein Kommentar

**which option**

No change

**regulation of ingredients****problem definition**

No

**explanations**

Kein Kommentar

**which option**

No Change

**access to tobacco products****problem definition**

No

**explanations**

Hat die EU wirklich nichts besseres zu tun als sinnlos Steuergelder von fleißigen Arbeitern und Steuerzahlern zu verschwenden.

**which option**

No change

---

**NGO submission****identification****affiliation**

NGO

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ASSOCIATION POUR LA DÉFENSE DES DROITS ET LIBERTÉS FONDAMENTALES  
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**questions scope****problem definition**

No

**explanations**

No comment

**which option**

No change

**questions smokeless**

**problem definition**

No

**comments**

no comment

**which option**

No change

**questions consumer**

**problem definition**

No

**explanations**

No comment

**which option**

No change

**questions on reporting**

**problem definition**

No

**explanations**

No Comment

**which option**

No change

**regulation of ingredients**

**problem definition**

No

**explanations**

Not necessary

**which option**

No Change

**access to tobacco products**

**problem definition**

No

**explanations**

No comment

**which option**

No change

---

**NGO submission**

**identification**

**affiliation**

NGO

**name**

manfred szlavich

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**country**

austria

**age**

50

**gender**

male

**questions scope**

**problem definition**

Yes

**which option**

Extend the scope of the Directive

**questions smokeless**

**problem definition**

Yes

**which option**

Ban on all types of smokeless tobacco products

**questions consumer**

**problem definition**

Yes

**which option**

Introduce generic or plain packaging

**questions on reporting**

**problem definition**

Yes

**which option**

Introduce fees and sanctions

**regulation of ingredients**

**problem definition**

Yes

**which option**

Establish a common list of tobacco ingredients

**which one**

Establish a negative common list of tobacco ingredients

**access to tobacco products**

**problem definition**

Yes

**which option**

Ban

**which one2**

Promotion and displays in retail stores to be banned

---

**NGO submission**

**identification**

**affiliation**

NGO

**name**

silvia Heek

**email**

no

**country**

Germany

**age**

54

**gender**

female

**questions scope  
problem definition**

No

**explanations**

kein kommentar

**which option**

No change

**recommend option**

kein kommentar

**additional comments**

kein kommentar

**questions smokeless**

**problem definition**

No

**comments**

kein kommentar

**which option**

No change

**additional option**

kein kommentar

**additional comments**

kein kommentar

**questions consumer**

**problem definition**

No

**explanations**

kein kommentar

**which option**

No change

**additional option**

kein kommentar

**additional comments**

kein kommentar

**questions on reporting  
problem definition**

No

**explanations**

kein kommentar

**which option**

No change

**additional options**

kein kommentar

**additional comments**

kein kommentar

**regulation of ingredients**

**problem definition**

No

**explanations**

kein kommentar

**which option**

No Change

**additional option**

kein kommentar

**additional comments**

kein kommentar

**access to tobacco products**

**problem definition**

No

**explanations**

kein kommentar

**which option**

No change

**additional option**

kein kommentar

**additional comments**

kein kommentar

---



**NGO submission**

**identification**

**affiliation**

NGO

**name**

Ziegler,Sandra

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Offenbach, Germany

**age**

32

**gender**

female

**questions scope**

**problem definition**

Yes

**which option**

No change

**questions smokeless**

**problem definition**

No

**comments**

kein Kommentar

**which option**

No change

**additional option**

kein Kommentar

**additional comments**

kein Kommentar

**questions consumer**

**problem definition**

No

**explanations**

kein kommentar

**which option**

No change

**additional option**

kein kommentar

**additional comments**

kein kommentar

**questions on reporting**

**problem definition**

No

**explanations**

kein kommentar

**which option**

No change

**additional options**

kein kommentar

**additional comments**

kein kommentar

**regulation of ingredients**

**problem definition**

No

**explanations**

kein kommentar

**which option**

No Change

**additional option**

kein kommentar

**additional comments**

kein kommentar

**access to tobacco products**

**problem definition**

No

**explanations**

kein kommentar

**which option**

No change

**additional option**

kein kommentar

**additional comments**

kein kommentar

---

**NGO submission****identification****affiliation**

NGO

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**email**

prekler.laszlo@agrarkamara.hu

**country**

HUNGARY

**gender**

male

**questions scope****problem definition**

Yes

**which option**

Extend the scope of the Directive

**questions smokeless****problem definition**

Yes

**which option**

No change

**questions consumer****problem definition**

Yes

**which option**

Improve consumer information

**which improvement**

Information on harmful substances in tobacco products that cannot be placed on the package would be placed inside the package

**questions on reporting**

**problem definition**

Yes

**which option**

Introduce fees and sanctions

**regulation of ingredients**

**problem definition**

Yes

**which option**

Establish a common list of tobacco ingredients

**which one**

Establish a positive common list of tobacco ingredients

**access to tobacco products**

**problem definition**

Yes

**which option**

No change

---

**NGO submission**

**identification**

**affiliation**

NGO

**name**

Lithuanian National Tobacco and Alcohol Control Coalition

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aurelijus.veryga@gmail.com

**country**

Lithuania

**age**

34

**gender**

male

**questions scope**  
**problem definition**  
Yes

**which option**  
Extend the scope of the Directive

**recommend option**  
1. Highest priority: stress the importance of large (80%) mandatory picture warnings at the front and back of all tobacco products (not only cigarette packs) in combination with standardised/plain packaging, 2. Highest priority: stress the importance of adding quit lines on the pack of all tobacco products. 3. Highest priority: stress the importance of the removal of misleading tar/nicotine/CO figures on all tobacco products. 4. High priority: Maintaining the ban on snus 5. High priority: banning of ingredients in accordance with article 9&10 of the FCTC

**questions smokeless**  
**problem definition**  
Yes

**which option**  
Ban on all types of smokeless tobacco products

**questions consumer**  
**problem definition**  
Yes

**which option**  
Introduce generic or plain packaging

**questions on reporting**  
**problem definition**  
Yes

**which option**  
Introduce fees and sanctions

**regulation of ingredients**  
**problem definition**  
Yes

**which option**  
Establish a common list of tobacco ingredients

**which one**  
Establish a negative common list of tobacco ingredients

**access to tobacco products**  
**problem definition**

Yes

**which option**

Ban

**which one2**

Cross-border retail sales of tobacco to be banned over the Internet; Vending machines to be banned; Promotion and displays in retail stores to be banned

---

**NGO submission**

**identification**

**affiliation**

NGO

**name**

Thomas Pichler

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**country**

Austria

**age**

30

**gender**

male

**questions scope**

**problem definition**

Yes

**which option**

No change

**questions smokeless**

**problem definition**

Yes

**which option**

Lifting the ban on snus

**questions consumer**

**problem definition**

Yes

**which option**

No change

**questions on reporting  
problem definition**

Yes

**which option**

No change

**regulation of ingredients  
problem definition**

Yes

**which option**

No Change

**access to tobacco products  
problem definition**

Yes

**which option**

No change

---

**NGO submission**

**identification  
affiliation**

NGO

**name**

Hungarian Alliance for Tobacco Control

**email**

mucsi.janos@tudobeteg.hu

**country**

Hungary

**age**

49

**gender**

male

**questions scope  
problem definition**

Yes

**which option**

Extend the scope of the Directive

**additional comments**

We would endorse the following option (Medium priority) New tobacco products and novel forms of oral tobacco would be banned similarly to snus. Herbal cigarettes and electronic nicotine delivery systems should be regulated by EU food and pharmaceutical legislation. If necessary, the inclusion in a reviewed tobacco product directive can be considered, but is not a priority.

**questions smokeless****problem definition**

Yes

**which option**

No change

**additional comments**

The prohibition on the marketing of tobacco for oral use ("snus") remains unchanged. (High priority)

**questions consumer****problem definition**

Yes

**which option**

Introduce generic or plain packaging

**additional comments**

- Mandatory pictorial health warnings on all tobacco products (including oral and water pipe tobacco) covering 80% of the front and the back of the packs towards the top, in combination with standardized packaging. (very high priority)
- Standardised packaging is the prohibition of the use of logos, colours, brand images or promotional information on the packaging of tobacco products. It allows the use of brand names and product names, which have to be displayed in a standard colour and font style. (very high priority)
- Tobacco companies should only be allowed to have one standardized presentation (as already exist in Uruguay) and package size per cigarette brand. (very high priority)
- Quit line on all packs of tobacco products
- No tar, nicotine or carbon monoxide levels on the packs.
- Package inserts are an option, but not a priority.

**questions on reporting****problem definition**

Yes

**which option**

Establish a common compulsory reporting format

**additional comments**

We would endorse Option 2: Establish a common compulsory reporting format (Medium



priority): Tobacco industry would be obliged to use one harmonized reporting format, ideally combined with the electronic submission of data.

**regulation of ingredients**

**problem definition**

Yes

**which option**

Establish a common list of tobacco ingredients

**which one**

Establish a positive common list of tobacco ingredients

**additional comments**

We would endorse a positive list of ingredients, flavorings and additives in tobacco products, which should not contain ingredients, flavorings or additives, which enhance attractiveness.

We endorse a yearly registration fee paid to national competent authorities in order to finance their data collection and analysis work on ingredients. Only registered products would be allowed on the market. (High priority)

**access to tobacco products**

**problem definition**

Yes

**which option**

Ban

**which one2**

Cross-border retail sales of tobacco to be banned over the Internet; Vending machines to be banned; Promotion and displays in retail stores to be banned

**additional comments**

We would endorse a ban of cross-border sales of tobacco products through internet by postal or any other mail delivery system (Medium priority) We would endorse a ban of vending machines and of tobacco displays by the most appropriate legal instrument, taken into consideration the EU legal competence in this field. (Medium priority)

---

**NGO submission**

**identification**

**affiliation**

NGO

**name**

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Magyar

**age**  
57

**gender**  
male

**questions scope**  
**problem definition**  
Yes

**which option**  
No change

**additional comments**  
Ellentmondásos a tervezet, mert már a hatáskör definiálásakor tiltásokat fogalmaz meg bizonyos termékkörre, anélkül, hogy erre vonatkozó részletekkel szolgálna - legyen szó akár a bevezetőről, akár a konzultációs anyag egyéb fejezeteiről.

**questions smokeless**  
**problem definition**  
Yes

**which option**  
Lifting the ban on snus

**additional comments**  
Ennek a kérdéskörnek a szabályozását tagállami hatáskörben lenne érdemes meghagyni. Mindezek mellett úgy gondoljuk, hogy a snüsszel kapcsolatos svéd példa alapján a füstmentes dohánytermékeket tiltás helyett inkább reklámozni kellene.

**questions consumer**  
**problem definition**  
No

**explanations**  
Véleményünk szerint az egészségvédő feliratok méretének eltúlzása nincs arányban az elérni kívánt céllal. Az egyencsomagolás bevezetése egyértelműen utat nyit a feketekereskedelem növekedésének.

**which option**  
No change

**questions on reporting**  
**problem definition**  
No

**explanations**

Tagállami szinten a kérdéskör megoldott és a tagállamok szuverenitásának fenntartása szükséges, mivel a jelenlegi direktíva megfelelő alapot biztosít ehhez.

**which option**

No change

**regulation of ingredients****problem definition**

No

**explanations**

A tiltó jellegű szabályozásnak megfelelő tudományos alapokon kell nyugodnia, nem pedig szubjektív értékelésen. Az FCTC 9-10 cikkelyeinek vitái alapján is látszik, hogy egy nem átgondolt tiltó szabályozás dohánytermelők munkahelyeit veszélyezteti, így Magyarországon 10,000 ember megélhetését tervezi ellehetetleníteni.

**which option**

No Change

**access to tobacco products****problem definition**

No

**explanations**

A túlzott szabályozás a feketekereskedelem kapuit nyitja tágabbra, és így a legális értékesítés csökkenésén keresztül a termelői érdekeket hátrányosan befolyásolja.

**which option**

No change

---

**NGO submission****identification****affiliation**

NGO

**name**

AGATHI VAXEVANI (PRESIDENT OF TOBACCO WORKERS ASSOCIATION OF KAVALA)

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TOBACWORKERSASSOCIATION@GMAIL.COM

**country**

GREECE

**gender**

female

**questions scope**  
**problem definition**

Yes

**which option**  
No change

**questions smokeless**  
**problem definition**

Yes

**which option**  
Lifting the ban on snus

**questions consumer**  
**problem definition**

No

**explanations**  
ΣΩΣΤΗ ΚΑΙ ΥΠΕΥΘΥΝΗ ΕΝΗΜΕΡΩΣΗ ΠΑΝΩ ΣΤΑ ΠΑΚΕΤΑ

**which option**  
No change

**questions on reporting**  
**problem definition**

No

**explanations**  
Η ΕΦΑΡΜΟΓΗ ΑΥΤΩΝ ΤΩΝ ΡΥΘΜΙΣΕΩΝ ΤΗΣ ΟΔΗΓΙΑΣ ΠΡΕΠΕΙ ΝΑ ΓΙΝΕΤΑΙ ΣΕ ΕΠΙΠΕΔΟ ΚΡΑΤΟΣ-ΜΕΛΟΥΣ ΚΑΙ ΟΧΙ Ε.Ε.

**which option**  
Establish a common compulsory reporting format

**regulation of ingredients**  
**problem definition**

No

**explanations**  
ΕΙΣΑΓΩΓΗ ΚΟΙΝΟΥ ΤΥΠΟΥ ΣΥΣΤΑΤΙΚΩΝ ΣΕ ΕΠΙΠΕΔΟ Ε.Ε.

**which option**  
No Change

**access to tobacco products**  
**problem definition**

Yes

**which option**

No change

---

**NGO submission**

**identification**

**affiliation**

NGO

**name**

Tabakfachgeschäft Erwin Kerschbaummayr

**email**

tabak.kerschbaummayr@aon.at

**country**

Austria

**age**

36

**gender**

male

**questions scope**

**problem definition**

No

**explanations**

Es kann nicht sein, dass die EU nur gegen das Rauchen ist und Alkohol usw. dabei vergisst.

**which option**

No change

**questions smokeless**

**problem definition**

Yes

**which option**

Lifting the ban on snus

**questions consumer**

**problem definition**

Yes

**which option**

No change

**questions on reporting**

**problem definition**

Yes

**which option**

No change

**regulation of ingredients**

**problem definition**

Yes

**which option**

No Change

**access to tobacco products**

**problem definition**

Yes

**which option**

No change

---

**NGO submission**

**identification**

**affiliation**

NGO

**name**

UAB "Saurida"

**email**

danguolem@saurida.lt

**country**

Lietuva

**questions scope**

**problem definition**

Yes

**which option**

No change

**recommend option**

Direktyvos apimtis galėtų būti praplėsta, tačiau neturėtų apimti draudimo naujiems oraliniams vartojimui skirtiems produktams

**questions smokeless  
problem definition**

Yes

**which option**

Lifting the ban on snus

**questions consumer  
problem definition**

No

**explanations**

Nėra mokslinių įrodymų, kad vienodos pakuotės ar itin didelio dydžio įspėjamieji ženklai yra efektyvesni informuojant vartotojus apie žalą sveikatai. Tai nepadedą efektyviau siekti užsibrėžto visuomenės sveikatos tikslo.

**which option**

No change

**questions on reporting  
problem definition**

No

**explanations**

Kiekviena ES šalis-narė gali pati laisvai spręsti dėl mokesčių ir sankcijų - ir nėra būtinybės to apibrėžti ES Direktyvoje.

**which option**

Establish a common compulsory reporting format

**regulation of ingredients**

**problem definition**

No

**explanations**

Ingredientai turėtų būti reguliuojami tiriant tai, kaip jie įtakoja tabako dūmų toksiškumą.

**which option**

No Change

**access to tobacco products**

**problem definition**

No

**explanations**

Nėra aiškiai apibrėžta, kodėl produktų rodymas prekybos vietose turėtų būti draudžiamas ar ribojamas. Nėra argumentų, kaip ši priemonė padėtų siekti viusomenės sveikatos tikslų ar prisidėtų prie efektyvaus bendros ES rinkos funkcionavimo. Be to, Lietuvos rinkoje tai gali gerokai padidinti kontrabandos ir nelegalios prekybos tabako gaminiais mastą.

**which option**

No change

---

**NGO submission****identification****affiliation**

NGO

**name**

Μουσείο Καπνού Δήμου Καβάλας

**email**

info@tobaccomuseum.gr

**country**

Ελλάδα

**questions scope****problem definition**

Yes

**which option**

No change

**recommend option**

Η κυκλοφορία των snus, όπως στη Σουηδία και τις ΗΠΑ.

**questions smokeless****problem definition**

Yes

**which option**

No change

**questions consumer****problem definition**

Yes

**which option**

Improve consumer information

**which improvement**

Information on harmful substances in tobacco products that cannot be placed on the package would be placed inside the package

**questions on reporting****problem definition**



Yes

**which option**

No change

**regulation of ingredients**

**problem definition**

Yes

**which option**

Establish a common list of tobacco ingredients

**which one**

Establish a positive common list of tobacco ingredients

**access to tobacco products**

**problem definition**

Yes

**which option**

No change

---

**NGO submission**

**identification**

**affiliation**

NGO

**name**

Bärbel Weyer

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Deutschland

**age**

52

**gender**

female

**questions scope**

**problem definition**

No

**explanations**

kein Kommentar

**which option**

No change

**questions smokeless**

**problem definition**

No

**comments**

kein Kommentar

**which option**

No change

**questions consumer**

**problem definition**

No

**explanations**

kein Kommentar

**which option**

No change

**questions on reporting**

**problem definition**

No

**explanations**

kein Kommentar

**which option**

No change

**regulation of ingredients**

**problem definition**

No

**explanations**

kein Kommentar

**which option**

No Change

**access to tobacco products**

**problem definition**

No

**explanations**

kein Kommentar

**which option**

No change

---

**NGO submission**

**identification**

**affiliation**

NGO

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Katharina Calenbach

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**country**

Deutschland

**age**

74

**gender**

female

**questions scope**

**problem definition**

Yes

**which option**

Extend the scope of the Directive

**questions smokeless**

**problem definition**

Yes

**which option**

No change

**questions consumer**

**problem definition**

Yes

**which option**

Improve consumer information

**questions on reporting**

**problem definition**

Yes

**which option**

No change

**regulation of ingredients**

**problem definition**

Yes

**which option**

No Change

**access to tobacco products**

**problem definition**

Yes

**which option**

No change

---

**NGO submission**

**identification**

**affiliation**

NGO

**name**

Ludwig ulrike

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**country**

Austria

**age**

52

**gender**

female

**questions scope**

**problem definition**

No

**explanations**

in der praxis schwer durchführbar, da in manchen betrieben nur ein verkäufer tätig

**which option**

No change

**recommend option**

beibehaltung der jetzigen durchführung

**questions smokeless****problem definition**

No

**comments**

alles was geheim und verboten wird, ist noch interessanter

**which option**

No change

**additional option**

aufklärung ist wirkungsvoller als verbote

**additional comments**

die durchführung ist nicht möglich, mehrkosten für umbau und anschließend mehrkosten für personal

**questions consumer****problem definition**

No

**explanations**

nicht durchführbar

**which option**

No change; Improve consumer information

**which improvement**

Tar, nicotine and carbon monoxide levels to be replaced with general information on harmful substances in tobacco products

**additional option**

nein

**additional comments**

nein

**questions on reporting****problem definition**

No

**explanations**

nein

**which option**

No change

**additional options**

----

**additional comments**

-----

**regulation of ingredients**

**problem definition**

No

**explanations**

-----

**which option**

No Change

**additional option**

-----

**additional comments**

-----

**access to tobacco products**

**problem definition**

No

**explanations**

-----

**which option**

No change

**additional option**

-----

**additional comments**

-----

---

**NGO submission**

**identification**

**affiliation**

NGO

**name**

Butiker Mot Smuggling (Retailers against illicit trade)

**email**

butikermotsmuggling@gmail.com

**country**

Sverige

**questions scope**

**problem definition**

No

**explanations**

No comment

**which option**

No change

**questions smokeless**

**problem definition**

No

**comments**

No comment

**which option**

No change

**questions consumer**

**problem definition**

No

**explanations**

No Comment

**which option**

No change

**questions on reporting**

**problem definition**

No

**explanations**

No comment

**which option**

No change

**regulation of ingredients**

**problem definition**

No

**explanations**

No comment

**which option**

No Change

**access to tobacco products**

**problem definition**

No

**explanations**

Butiker mot smuggling är en organisation som består av enskilda butiker som arbetar för påverka politikerna till att agera mot den utbredda tobakssmugglingen i Sverige. Smuggling slår hårt mot handeln och för små butiker innebär det dels stora förluster i inkomst samt större rånrisk då organiserad brottslighet leder till ökad kriminalitet i allmänhet. Vi vet sedan tidigare att överregleringar av tobak ofta leder till en ökning i smuggling och när organiserad brottslighet väl biter sig fast är den svår att hantera. Redan idag är var åttonde cigarett som röks illegal och vi är väldigt måna om att den siffran ska minska, inte öka. Exponeringsförbud mot tobak i butiker som här föreslås tror vi kommer leda till en ökning av smugglade cigaretter. Idag är det enkelt för konsumenter att förstå skillnaden mellan lagliga produkter i hyllan samt olagliga som ofta förvaras under disk. En lag som skulle flytta tobaksvaror från hyllorna till under disk skulle göra det svårare för konsumenter att urskilja produkterna. Vi tror också att ett exponeringsförbud skulle försvåra tillsynen och underlätta för fler att göra valet att sälja illegal tobak. Det finns även siffror från andra länder som visar att smugglingen ökar med ett exponeringsförbud. I delstaten Ontario i Kanada där exponeringsförbud införts uppgår smugglingen till 50 % vilket är en tydlig ökning från innan förbudet infördes.

**which option**

No change

---

**NGO submission**

**identification**

**affiliation**

NGO

**name**

Stefan Rau

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Deutschland

**age**



45

**gender**

male

**questions scope**

**problem definition**

No

**explanations**

Kein Kommentar

**which option**

No change

**questions smokeless**

**problem definition**

No

**comments**

Kein Kommentar

**which option**

No change

**additional option**

Kein Kommentar

**additional comments**

Kein Kommentar

**questions consumer**

**problem definition**

No

**explanations**

Kein Kommentar

**which option**

No change

**questions on reporting**

**problem definition**

No

**explanations**

Kein Kommentar

**which option**

No change

**regulation of ingredients****problem definition**

No

**explanations**

Kein Kommentar

**which option**

No Change

**access to tobacco products****problem definition**

No

**which option**

No change

---

**NGO submission****identification****affiliation**

NGO

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patrick.kast@pro-rauchfrei.de

**country**

Deutschland

**gender**

male

**questions scope****problem definition**

Yes

**which option**

Extend the scope of the Directive

**additional comments**

The aim of Pro Rauchfrei e.V. first of all is to protect all non-smokers from the harmful second hand smoke. In order to reach this, it is necessary to reduce the number of smokers and limit the access to nicotine containing products. Our experiences are clear: smokeless forms of nicotine do not reduce the problems. The consumer does not smoke less and perhaps,

many people even start smoking through this "mild" starting nicotine products. Furthermore, nicotine is one of the most dangerous drugs, with regard to addiction. It provides too much harm on the society and the environment. Only a multi-track approach will be able to reach our goals - smoke-free environments and workplaces - reduces access to tobacco products and reduces nicotine supply - no more advertising for such products

**questions smokeless**

**problem definition**

Yes

**which option**

Ban on all types of smokeless tobacco products

**questions consumer**

**problem definition**

Yes

**which option**

Improve consumer information; Introduce generic or plain packaging

**which improvement**

Picture warnings to become mandatory; Tar, nicotine and carbon monoxide levels to be replaced with general information on harmful substances in tobacco products; Health warnings to be put on water pipes

**questions on reporting**

**problem definition**

Yes

**which option**

Establish a common compulsory reporting format; Introduce fees and sanctions

**regulation of ingredients**

**problem definition**

Yes

**which option**

Establish a common list of tobacco ingredients

**which one**

Establish a positive common list of tobacco ingredients

**additional comments**

A positive common list will be much more effective because it will not be necessary to extend it from time to time.

**access to tobacco products**

**problem definition**

Yes

**which option**

Ban

**which one2**

Cross-border retail sales of tobacco to be banned over the Internet; Vending machines to be banned; Promotion and displays in retail stores to be banned

**additional comments**

Vending machines in Germany are more spread than in any other EU member state. The access to tobacco is possible nearly everywhere and anytime. This provides serious problems to people who want quit smoking and also provides for shure second hand smoke everywhere (for example on large public outdoor events). Nicotine is a dangerous drug and should be banned. Because this is not yet possible, there is a strong need to reduce the "normal appearance" of smoking and the number of consumers as much as possible. Nicotine, if it would be introduces as a totally new substance, would never gain a permission.

---

**NGO submission****identification****affiliation**

NGO

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**country**

Sweden

**age**

28

**gender**

male

**questions scope****problem definition**

No

**explanations**

No more regulations is needed. It's legal products, politicians should not regulate this area. If regulated, this should be done on a national level, not European level.

**which option**

No change

**questions smokeless  
problem definition**

No

**comments**

It says that snus can cause cancer. This has not been proven in Sweden.

**which option**

Lifting the ban on snus

**additional option**

Snus is a way to quit smoking. Lifting the ban on snus will help people in Europe to quit smoking.

**questions consumer  
problem definition**

Yes

**which option**

No change

**additional option**

Plain packaging is a reduction in the trade mark protection. It would also lead to competition on price, as the product would be generic. Making the product cheaper would not reduce smoking. Plain packaging would also make it easier for criminals to produce counterfeit goods.

**questions on reporting  
problem definition**

Yes

**which option**

No change

**additional options**

This should not be regulated on a European level. if perceived to be a problem, it can be regulated on a national level.

**regulation of ingredients  
problem definition**

Yes

**which option**

No Change

**access to tobacco products  
problem definition**

No

**explanations**

The EU is all about the free trade of goods. No cross-border limitations should be imposed.

**which option**

No change

**additional option**

A display ban is wrong. Tobacco products are legal. As long as they are legal, it should also be legal to display them in stores. This is a matter of principle - who should be allowed to decide on the display of legal goods in stores - politicians or storeowners? This time the EU focus is on tobacco - the next time it might be about potato chips, candy or soda. It's completely weird if legal products would not be allowed to be displayed.

---

**NGO submission**

**identification**

**affiliation**

NGO

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55

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male

**questions scope**

**problem definition**

No

**explanations**

Kein Kommentar

**which option**

No change

**questions smokeless**

**problem definition**

No

**comments**

No Chance

**which option**

No change

**questions consumer**

**problem definition**

No

**explanations**

No Chance

**which option**

No change

**questions on reporting**

**problem definition**

No

**explanations**

No Chance

**which option**

No change

**regulation of ingredients**

**problem definition**

No

**explanations**

No Chance

**which option**

No Change

**access to tobacco products**

**problem definition**

No

**explanations**

No Chance

**which option**

No change

---

**NGO submission**

**identification**

**affiliation**

NGO

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Lithuania

**questions scope****problem definition**

Yes

**which option**

No change

**questions smokeless****problem definition**

Yes

**which option**

Lifting the ban on snus

**questions consumer****problem definition**

No

**explanations**

There is no evidence that bigger warnings are more effective. There is no evidence that plain packaging would improve the functioning of the internal market or have any public health benefits.

**which option**

No change

**questions on reporting****problem definition**

Yes

**which option**

Establish a common compulsory reporting format

**regulation of ingredients****problem definition**

No

**explanations**



attractiveness is not scientifically defined

**which option**

No Change

**access to tobacco products**

**problem definition**

No

**explanations**

There is no evidence provided as to why bans would improve the functioning of the internal market or advance any public health objectives

**which option**

No change

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**NGO submission**

**identification**

**affiliation**

NGO

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Hungary

**age**

37

**gender**

male

**questions scope**

**problem definition**

Yes

**which option**

No change

**additional comments**

From the tobacco producer (crop producer) point of view, every restriction in the scope of current regulation at the end result lower demand for tobacco which endangers the jobs of tobacco producers, who generally live in rural and in many times disadvantageous areas.

**questions smokeless****problem definition**

Yes

**which option**

No change

**additional comments**

From the tobacco producer (crop producer) point of view, every restriction of current regulation at the end result lower demand for tobacco which endangers the jobs of tobacco producers, who generally live in rural and in many times disadvantageous areas. Other form of tobacco products than cigarettes serve a market for tobacco producers.

**questions consumer****problem definition**

Yes

**which option**

No change

**additional comments**

From the tobacco producer (crop producer) point of view, every restriction of current regulation at the end result lower demand for tobacco which endangers the jobs of tobacco producers, who generally live in rural and in many times disadvantageous areas. All changes on packaging results cost for the manufacturers, which at the end results lower price for raw tobacco. Generic and plain packaging results decrease in the demand for tobacco products, less demand means less production which endangers the job of tobacco producers.

**questions on reporting****problem definition**

Yes

**which option**

No change

**additional comments**

From the tobacco producer (crop producer) point of view, every restriction of current regulation at the end result lower demand for tobacco which endangers the jobs of tobacco producers, who generally live in rural and in many times disadvantageous areas. Introducing fees and sancions or comlicating reporting obligation will increase the cost of the manufacturers, which probably leads to the drop of the price of raw tobacco which endanger the living of tobacco producers.

**regulation of ingredients****problem definition**

Yes

**which option**

No Change

**additional comments**

From the tobacco producer (crop producer) point of view, every restriction of current regulation at the end result lower demand for tobacco which endangers the jobs of tobacco producers. Creating a common list of approved ingredients for the 27 member states is difficult to make. There are species which might not fulfill the new conditions, but maybe the given species the only one type which can be produced in given member state. This decision will endanger the future of the whole tobacco producer sector in the given member state. Positive and negative list of tobacco ingredients has the risk that the current production technology of the manufacturer cannot fulfill the new requirements, so it has to change its whole production line, which might not do it at all in a given member state, or it results such a high cost that it appears on the lower prices of raw tobacco.

**access to tobacco products****problem definition**

Yes

**which option**

No change

**additional comments**

From the tobacco producer (crop producer) point of view, every restriction of current regulation at the end result lower demand for tobacco which endangers the jobs of tobacco producers. Option 3 may result such a big drop on demand for cigarettes (tobacco products) that the manufacturers might not take, and this means the end of the production of raw tobacco on many rural areas.

---

**NGO submission****identification****affiliation**

NGO

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**country**

Slovakia

**age**

53

**gender**

male

**questions scope**  
**problem definition**  
Yes

**which option**  
No change

**recommend option**  
The proposal in Option 2 is limiting any potential introduction of new forms of oral tobacco. We believe that any product should be banned only on a basis of scientific research and proper examination. A preemptive ban is against principals of innovation and can be counterproductive.

**questions smokeless**  
**problem definition**  
Yes

**which option**  
Lifting the ban on snus

**questions consumer**  
**problem definition**  
No

**explanations**  
Retailers are facing a menace of illicit trade in many goods, but the cigarettes are a prominent case. We believe, that the EC proposal, as mentioned in Options 2 and 3, will create an unprecedented opportunity for organized crime. Plain packaging or even enlarged health warnings will make the manufacturing pprocess of fake cigarettes very simple and will thus put a lot of pressure on law obeying retailers. The ensuing consequences – decrease of the legal market and loss of control over significant size of cigarettes smoked in the EU – will go against declared health objectives and will, in the time of global economical crisis push retailers even more into the corner.

**which option**  
No change

**questions on reporting**  
**problem definition**  
No

**explanations**  
Member states can now use their power and establish a system of penalties for noncompliance with mandatory reporting. This should stay within powers of Member states.

**which option**  
Establish a common compulsory reporting format

**regulation of ingredients**  
**problem definition**

No

**explanations**

Ingredients regulation should be based solely on scientific assessment and therefore should operate with measurable criteria, e.g. increased toxicity and/or addictiveness of the tobacco smoke or product. Any measurement of attractiveness is according to our view, impossible and unscientific.

**which option**

No Change

**access to tobacco products**

**problem definition**

No

**explanations**

The proposed ban or restriction will lead to significant costs for law obeying retailers and potential loss of sales either to illegal sources, or to the pure fact, that an adult consumer will not know, that tobacco products are available in the shop.

**which option**

No change

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**NGO submission**

**identification**

**affiliation**

NGO

**name**

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**country**

The Slovak Republic

**questions scope**

**problem definition**

Yes

**which option**

No change

**recommend option**

We believe, that the scope of the directive should be enlarged, based on scientific assesment of other available tobacco and non-tobacco products e.g. electronic cigarettes. The regulator

should examine these products first, before banning them as such.

**questions smokeless**

**problem definition**

Yes

**which option**

Lifting the ban on snus

**questions consumer**

**problem definition**

No

**explanations**

We believe, that this measure will hand over a major part of the market into hands of criminal organizations, which will subsequently lead to loss of control over the content of tobacco products and thus endanger the health of EU citizens.

**which option**

No change

**questions on reporting**

**problem definition**

No

**explanations**

Member states can now use their power and establish a system of penalties for noncompliance with mandatory reporting. This should stay within powers of Member states.

**which option**

Establish a common compulsory reporting format

**regulation of ingredients**

**problem definition**

No

**explanations**

Ingredients regulation should be based solely on scientific assesment and therefore should operate with meassurable criteria, e.g. increased toxicity and/or addictivness of the tobacco smoke or product. Any measurement of attractivness, is according to our view, impossible and unscientific.

**which option**

No Change

**access to tobacco products**

**problem definition**

No

**explanations**

The proposed ban or restriction will lead to costs for retailers and unintended consequences in the form of increased illicit trade – as the ban or restriction will make it easier for illegal products to penetrate the market. It will also restrict the right of information for consumers.

**which option**

No change

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**NGO submission**

**identification**

**affiliation**

NGO

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Germany

**age**

29

**gender**

female

**questions scope**

**problem definition**

No

**explanations**

das problem wir so nicht gelöst, arbeitsplätze gehen verloren, jeder mensch sollte zu eigenverantwortlichem handeln erzogen werden und nicht durch den staat oder die eu bevormundet werden. man kann nicht alles reglementieren.

**which option**

No change

**recommend option**

aufklärung - vor allem auch bei eltern, damit diese ihr kinder zu eigenverantwortlichem handeln erziehen können

**questions smokeless**

**problem definition**

No

**which option**

No change

**questions consumer  
problem definition**

No

**explanations**

das problem existiert meiner ansicht nach nicht in dieser form

**which option**

No change

**questions on reporting  
problem definition**

No

**explanations**

das problem existiert so nicht

**which option**

No change

**regulation of ingredients  
problem definition**

No

**explanations**

das problem existiert so nicht in dieser form

**which option**

No Change

**access to tobacco products  
problem definition**

No

**explanations**

existiert so nicht

**which option**

No change

---

**NGO submission**

**identification  
affiliation**

NGO



**name**

Andreas Noack

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**country**

Deutschland

**age**

52

**gender**

male

**questions scope****problem definition**

Yes

**which option**

No change

**questions smokeless****problem definition**

Yes

**which option**

No change

**questions consumer****problem definition**

Yes

**which option**

No change

**questions on reporting****problem definition**

Yes

**which option**

No change

**regulation of ingredients****problem definition**

Yes

**which option**

No Change

**access to tobacco products**

**problem definition**

Yes

**which option**

No change

---

**NGO submission**

**identification**

**affiliation**

NGO

**name**

MOSZ (National Federation of Agricultural Cooperators and Producers)

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**country**

Hungary

**questions scope**

**problem definition**

Yes

**which option**

No change

**additional comments**

Th Directive is inconsistent, It contains prohibitions on some product (new type of tobacco for oral use) without any explanation of its details.

**questions smokeless**

**problem definition**

Yes

**which option**

Lifting the ban on snus

**additional comments**

The regulation of this issue should be left to the Member States.

**questions consumer**

**problem definition**

No

**explanations**

Introducing generic or plain packing would rise black-market.

**which option**

No change

**questions on reporting****problem definition**

No

**explanations**

This issue is solved on Member States' level.

**which option**

No change

**regulation of ingredients****problem definition**

No

**explanations**

Regulation by banning has to be based on scientific basics.

**which option**

No Change

**access to tobacco products****problem definition**

No

**explanations**

An extremely controlled supply and access can increase black-market, reduce legal sales.

**which option**

No change

---

**NGO submission****identification****affiliation**

NGO

**name**

Lasse Honoré Rasmussen, head of Young Conservatives

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**country**  
Denmark

**gender**  
male

**questions scope**  
**problem definition**  
Yes

**which option**  
No change

**recommend option**  
New tobacco products should be judged on a scientific assessment of their health effects. Young Conservatives does not support banning new tobacco products simply because they are new.

**questions smokeless**  
**problem definition**  
Yes

**which option**  
Lifting the ban on snus

**additional option**  
The ban on snus prevents the free movement of goods within the EU, as it can be sold in some countries and not in others. In Denmark, we have the absurd situation that Danish snus producers export portion-packed snus to Sweden, and then Danes go to Sweden to buy snus and bring it back home.

**questions consumer**  
**problem definition**  
No

**explanations**  
Denmark already has warnings on cigarette packs, and there is no evidence that bigger warnings will be more effective. There is also no evidence that the plain packaging of tobacco products will result in any health benefits. Young Conservatives also fears that plain packaging would create a slipping slope, leading to similar demands for alcohol and fast food products.

**which option**  
No change

**questions on reporting**  
**problem definition**  
No

**explanations**

Member states already have the possibility of introducing fees and sanctions, and many have already done so. Young Conservatives believe that this matter should be left to the member states.

**which option**

Establish a common compulsory reporting format

**regulation of ingredients**

**problem definition**

No

**explanations**

When it comes to ingredients, the EU should focus on ensuring that cigarettes do not contain toxic ingredients. The EU should not be regulating issues of attractiveness, whether it is regarding cigarettes or other products, such as alcohol or fast-food.

**which option**

No Change

**access to tobacco products**

**problem definition**

No

**explanations**

There is no evidence that those countries which have banned point-of-sales display of tobacco products have experienced a drop in the number of smokers.

**which option**

No change

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**NGO submission**

**identification**

**affiliation**

NGO

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Stefan Rogos

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Deutschland

**age**

32

**gender**  
male

**questions scope**  
**problem definition**  
Yes

**which option**  
No change

**additional comments**  
meiner meinung nach sollte man sich lieber um die schwarzmärkte kümmern als so einen schwachsinn in die welt zu setzen! die sollten mal darüber nachdenken wie viel mill. die an tabansteuer im jahr einnehmen.... und wenn diese gelder wegfallen sollten sehe ich schwarz für die eu. zumal mit der neuen regelung eine menge geschäfte pleite bekommt sprich ein paar hundert tausend arbeitslose mehr aber ansch ist es das was die eu will!! lasst alles so wie es ist und kümmert euch viel mehr um den schwarzmarkt da habt ihr genug arbeit mt!!

**questions smokeless**  
**problem definition**  
Yes

**which option**  
No change

**questions consumer**  
**problem definition**  
Yes

**which option**  
No change

**questions on reporting**  
**problem definition**  
Yes

**which option**  
No change

**regulation of ingredients**  
**problem definition**  
Yes

**which option**  
No Change

**access to tobacco products**  
**problem definition**  
Yes

**which option**

No change

---

**NGO submission****identification****affiliation**

NGO

**name**

Slovenske zdruzenie pre znackove vyrobky

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**country**

Slovakia

**questions scope****problem definition**

Yes

**which option**

No change

**recommend option**

The ambition of the Commission to enlarge the scope of the current directive is welcomed, however, we should discourage the approach, which leads to preemptive ban of any product without performing a proper scientific scrutiny first. Therefore, the Option 2 and its ban of any novel forms of tobacco is unacceptable.

**questions smokeless****problem definition**

Yes

**which option**

Lifting the ban on snus

**questions consumer****problem definition**

No

**explanations**

Trademarks, brands and names belong to legal business with consumer goods for centuries. Ability to place a logo, and/or a trademark on a product is one of the fundamental rights of every legal entrepreneur. Proposals, as indicated in options 2 and 3 of the DG Sanco proposal are completely removing this right from the tobacco manufacturers. This is, in our view, unacceptable. We also believe, that the right to differentiate between products is not only a

right of the manufacturer, but also a right of consumers. By accepting proposed removal of all trademarks from packaging, this right will be denied to every adult citizen of the EU. We also cannot accept the proposal for larger health warnings, as this will interfere with highly valuable trademarks and logos of cigarettes and other tobacco products. We believe, that other, proven measures for tackling youth smoking can be examined, including strict enforcement of legal age laws. To our knowledge, plain packaging and/or larger health warnings will have limited, if any impact on the consumptions and will provide excellent opportunity to anyone wanting to produce fake products. This can lead to a tsunami of illegal products flooding the EU. We believe, that this is not in line with objectives of not only our organization, but also the European Commission and all member states. Also, we believe, that rightful owners of trademarks will take their cause to the court, once their trademarks are removed from their products. Taking into account the value of some of the tobacco brands, which exceeds tens of billions of dollars, potential deny of their use can be very costly to the EU and its member states. We hope, that this is not an intention and therefore, introduction of larger health warnings and/or plain packaging should be not even considered as an option.

**which option**

No change

**questions on reporting**

**problem definition**

No

**explanations**

Member states can now use their power and establish a system of penalties for noncompliance with mandatory reporting. This should stay within powers of Member states.

**which option**

Establish a common compulsory reporting format

**regulation of ingredients**

**problem definition**

No

**explanations**

Ingredients regulation should be based solely on scientific assessment and therefore should operate with measurable criteria, e.g. increased toxicity and/or addictiveness of the tobacco smoke or product.

**which option**

No Change

**access to tobacco products**

**problem definition**

No

**explanations**

The proposed ban or restriction of the products display will significantly limit a right of legal producers to communicate their products with their customers. We believe, that this is one of key principles of the trade, that every producer of legal product has a right to show its product



to its existing customer or inform him/her about any innovation and/or new products. Restriction and/or display ban will harshly remove this right with no proven effects on the health objectives. We also understand, that these measures can impose new costs on retailers in the time of economical downturn. This is also not acceptable in our view.

**which option**

No change

---

**NGO submission**

**identification**

**affiliation**

NGO

**name**

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**country**

Austria

**age**

38

**gender**

male

**questions scope**

**problem definition**

No

**explanations**

The consultation process should be free of taboos and conservative-moralistic values and should rather focus on the holistic (!) approach in the overall and integrated context of public health-, drugs-, fiscal- and economical policies.

**which option**

Extend the scope of the Directive

**recommend option**

Yes, a thorough, rational and public health-oriented reform of the criminal justice system, fiscal policies and other intertwined areas of the EU. The objective: a clear-cut smoking prohibition in all closed spaces, where employees and the public are damaged or at risk through second- or third-hand smoke. Exception to the rule: one-man-smoking-shops with licence to sell cannabis-products and tobacco to persons above the age of 18...

**additional comments**

Yes, it's worth a multidisciplinary written scientifically based expertise, under my supervision.

**questions smokeless****problem definition**

No

**comments**

Primary prevention starting in elementary or junior high school, total ban on all all forms of advertising...

**which option**

Lifting the ban on snus

**additional option**

Rational drug-politics is urgently needed with all accompanying measures.

**additional comments**

Yes, a task force with (unbiased and industry-free) experts from all member states of EU is urgently necessary (expertise, effective actions from within the European Commission, Parliament etc.).

**questions consumer****problem definition**

No

**explanations**

The Directive unconsciously or intentionally ignores the root of the problems and should work out the question within a holistic context of public health, drugs, criminal law, fiscal policies, industry interests, societal acceptance and consumptions of psychoactive substances etc.

**which option**

Improve consumer information; Introduce generic or plain packaging

**which improvement**

Picture warnings to become mandatory; Tar, nicotine and carbon monoxide levels to be replaced with general information on harmful substances in tobacco products; Information on harmful substances in tobacco products that cannot be placed on the package would be placed inside the package; Health warnings to be put on water pipes

**additional option**

High price increase of all forms of tobacco products, total ban on advertising, sale only in licensed shops with access only to persons at age 18...

**additional comments**

Overall reform of the drug policies in all EU-countries...

**questions on reporting**

**problem definition**

No

**explanations**

The parameters on how you measure toxic, cancer-causing and genetically damaging combustion products have been skilfully manipulated by the tobacco industry for decades. For example, for decades, the tobacco industry have known the the Marlboro Lights are far more toxic and genetically damaging than the regular Red Marloboros. This internal knowledge was of course hidden from the public for good reasons...see internal docs of the tobacco industry ("Schwarzbuch Zigarette").

**which option**

Establish a common compulsory reporting format; Introduce fees and sanctions

**additional options**

Prohibit all chemical additives (including menthol!!!) in all cigarettes, unless proven to effectively minimize the health risk...

**additional comments**

Yes, a scientific EU-task force should have the power to enforce any changes necessary for the sake of public health!!!!!!

**regulation of ingredients****problem definition**

No

**explanations**

Pure tobacco without any chemical additives whatsoever, including menthol...

**which option**

Establish a common list of tobacco ingredients

**additional option**

Implement the scientific proposals made by real and industry-independent experts and insiders...

**additional comments**

Overall reform of all interconnected laws and regulations regarding drugs...

**access to tobacco products****problem definition**

Yes

**which option**

Ban

**which one2**

Cross-border retail sales of tobacco to be banned over the Internet

---

## **NGO submission**

### **identification**

#### **affiliation**

NGO

#### **name**

YANNIS PLAKOPOULOS PRESIDENT OF THE GREEK FEDERATION OF KIOSK OWNERS AND TOBACCO RETAILERS

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#### **country**

GREECE

### **questions scope**

#### **problem definition**

Yes

#### **which option**

No change

### **questions smokeless**

#### **problem definition**

Yes

#### **which option**

Lifting the ban on snus

### **questions consumer**

#### **problem definition**

No

### **explanations**

ΔΕΝ ΣΥΜΦΩΝΟΥΜΕ ΟΤΙ ΟΙ ΥΠΕΡΜΕΓΕΘΕΙΣ ΠΡΟΕΙΔΟΠΟΙΗΣΕΙΣ ΥΓΕΙΑΣ ΘΑ ΣΥΜΒΑΛΛΟΥΝ ΣΤΗΝ ΚΑΛΥΤΕΡΗ ΠΛΗΡΟΦΟΡΗΣΗ ΤΩΝ ΚΑΠΝΙΣΤΩΝ, ΑΦΟΥ ΕΙΝΑΙ ΗΔΗ ΓΝΩΣΤΟΙ ΟΙ ΚΙΝΔΥΝΟΙ ΓΙΑ ΤΗΝ ΥΓΕΙΑ ΑΠΟ ΤΟ ΚΑΠΝΙΣΜΑ.

#### **which option**

No change

### **additional option**

Η ΘΕΣΠΙΣΗ ΕΝΙΑΙΑΣ ΣΥΣΚΕΥΑΣΙΑΣ ΔΕΝ ΘΑ ΣΥΜΒΑΛΛΕΙ ΣΤΗΝ ΚΑΤΑΠΟΛΕΜΗΣΗ ΤΟΥ ΚΑΠΝΙΣΜΑΤΟΣ. ΑΝΤΙΘΕΤΑ, ΘΑ ΟΔΗΓΗΣΕΙ ΣΕ ΠΟΛΕΜΟ ΤΙΜΩΝ, ΜΕ ΑΠΟΤΕΛΕΣΜΑ ΝΑ ΜΕΙΩΘΟΥΝ ΑΚΟΜΗ ΠΕΡΙΣΣΟΤΕΡΟ ΤΑ ΠΕΡΙΘΩΡΙΑ ΚΕΡΔΟΥΣ ΜΑΣ, ΣΕ ΑΥΞΗΣΗ ΤΟΥ ΠΑΡΑΝΟΜΟΥ ΕΜΠΟΡΙΟΥ ΚΑΙ, ΕΝ ΤΕΛΕΙ, ΝΑ ΚΑΠΝΙΖΟΥΝ ΟΙ ΑΝΘΡΩΠΟΙ ΠΕΡΙΣΣΟΤΕΡΟ, ΑΦΟΥ ΤΑ ΤΣΙΓΑΡΑ ΘΑ ΓΙΝΟΥΝ ΦΤΗΝΟΤΕΡΑ Ή ΘΑ ΔΙΑΤΙΘΕΝΤΑΙ ΣΤΗΝ ΠΑΡΑΝΟΜΗ ΑΓΟΡΑ.

**questions on reporting  
problem definition**

No

**explanations**

ΔΕΝ ΕΧΟΥΜΕ ΑΛΛΑ ΣΧΟΛΙΑ.

**which option**

Establish a common compulsory reporting format

**regulation of ingredients**

**problem definition**

No

**explanations**

ΔΕΝ ΣΥΜΦΩΝΟΥΜΕ ΜΕ ΤΗΝ ΑΠΑΓΟΡΕΥΣΗ ΤΩΝ ΣΥΣΤΑΤΙΚΩΝ ΣΤΑ ΤΣΙΓΑΡΑ ΑΝ ΔΕΝ ΥΠΑΡΧΕΙ ΠΡΟΗΓΟΥΜΕΝΗ ΕΠΙΣΤΗΜΟΝΙΚΗ ΤΕΚΜΗΡΙΩΣΗ. ΔΕΝ ΜΠΟΡΕΙ ΝΑ ΑΠΑΓΟΡΕΥΕΤΑΙ ΕΝΑ ΚΑΤΑΝΑΛΩΤΙΚΟ ΠΡΟΪΟΝ ΜΕ ΒΑΣΗ ΥΠΟΚΕΙΜΕΝΙΚΑ ΣΤΟΙΧΕΙΑ. ΕΙΔΙΚΑ ΓΙΑ ΤΗΝ ΕΛΛΑΔΑ, ΤΑ ΤΣΙΓΑΡΑ ΠΟΥ ΧΡΗΣΙΜΟΠΟΙΟΥΝ ΣΥΣΤΑΤΙΚΑ ΑΝΤΙΣΤΟΙΧΟΥΝ ΣΤΟ 95%. ΑΝ ΑΠΑΓΟΡΕΥΤΟΥΝ, ΑΥΤΟ ΘΑ ΟΔΗΓΗΣΕΙ ΣΤΗΝ ΠΕΡΑΙΤΕΡΩ ΑΥΞΗΣΗ ΤΟΥ ΠΑΡΑΝΟΜΟΥ ΕΜΠΟΡΙΟΥ, ΑΦΟΥ ΘΑ ΕΞΑΚΟΛΟΥΘΗΣΕΙ ΝΑ ΥΠΑΡΧΕΙ ΖΗΤΗΣΗ ΓΙΑ ΑΥΤΑ ΤΑ ΤΣΙΓΑΡΑ.

**which option**

No Change

**access to tobacco products**

**problem definition**

No

**explanations**

ΠΩΣ ΕΙΝΑΙ ΔΥΝΑΤΟΝ ΝΑ ΣΥΜΦΩΝΗΣΟΥΜΕ ΜΕ ΤΗΝ ΑΠΑΓΟΡΕΥΣΗ ΤΟΠΟΘΕΤΗΣΗΣ ΤΩΝ ΚΑΠΝΙΚΩΝ ΠΡΟΪΟΝΤΩΝ ΣΤΑ ΜΑΓΑΖΙΑ ΜΑΣ, ΑΦΟΥ ΘΑ ΜΑΣ ΔΥΣΚΟΛΕΨΕΙ ΤΗΝ ΚΑΘΗΜΕΡΙΝΟΤΗΤΑ ΜΑΣ, ΘΑ ΜΑΣ ΔΗΜΙΟΥΡΓΗΣΕΙ ΠΡΟΣΘΕΤΑ ΠΡΟΒΛΗΜΑΤΑ ΣΤΙΣ ΣΥΝΑΛΛΑΓΕΣ ΜΑΣ ΚΑΙ ΘΑ ΜΑΣ ΑΝΑΓΚΑΣΕΙ ΝΑ ΑΛΛΑΞΟΥΜΕ ΤΟΝ ΤΡΟΠΟ ΔΟΥΛΕΙΑΣ ΜΑΣ (Π.Χ. ΠΡΟΣΘΕΤΑ ΜΕΤΡΑ ΑΣΦΑΛΕΙΑΣ), ΛΑΜΒΑΝΟΜΕΝΗΣ ΥΠΟΨΗ ΤΗΣ ΙΔΙΑΙΤΕΡΗΣ ΜΟΡΦΟΛΟΓΙΑΣ ΤΩΝ ΠΕΡΙΠΤΕΡΩΝ ΣΤΗΝ ΕΛΛΑΔΑ. ΠΑΡΑΛΛΗΛΑ, ΑΠΟ ΤΗΝ ΠΕΙΡΑ ΜΑΣ ΕΚΤΙΜΟΥΜΕ ΟΤΙ ΘΑ ΑΥΞΗΘΕΙ ΤΟ ΠΑΡΑΝΟΜΟ ΕΜΠΟΡΙΟ.

**which option**

No change

---

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**affiliation**

NGO

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Bremen, Germany

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50

**gender**

male

**questions scope**

**problem definition**

Yes

**which option**

No change

**questions smokeless**

**problem definition**

Yes

**which option**

No change

**questions consumer**

**problem definition**

Yes

**which option**

No change

**questions on reporting**

**problem definition**

Yes

**which option**

No change

**regulation of ingredients**

**problem definition**

Yes

**which option**

No Change

**access to tobacco products  
problem definition**

Yes

**which option**

No change

---

**NGO submission**

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**questions scope**

**problem definition**

No

**explanations**

kein kommentar

**which option**

No change

**questions smokeless**

**problem definition**

No

**comments**

kein Kommentar

**which option**

No change

**questions consumer  
problem definition**

No

**explanations**

kein kommentar

**which option**

No change

**questions on reporting  
problem definition**

No

**explanations**

kein kommentar

**which option**

No change

**regulation of ingredients**

**problem definition**

Yes

**which option**

Establish a common list of tobacco ingredients

**which one**

Establish a positive common list of tobacco ingredients

**access to tobacco products**

**problem definition**

Yes

**which option**

Controlled supply and access

**which supply and access**

Age verification of buyers and other legal conditions to be set for cross-border retail sale

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**NGO submission**

**identification**

**affiliation**

NGO



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Austria

**age**

49

**gender**

male

**questions scope****problem definition**

Yes

**which option**

Extend the scope of the Directive

**recommend option**

Raising tobacco taxes considerably

**additional comments**

Generally no smoking in restaurants, guest houses, pubs, hotels, theatres, shops and places which are used by everybody (busstations, trainstations, marketplaces etc.)

**questions smokeless****problem definition**

Yes

**which option**

Ban on all types of smokeless tobacco products

**questions consumer****problem definition**

Yes

**which option**

Introduce generic or plain packaging

**questions on reporting****problem definition**

Yes

**which option**

Introduce fees and sanctions

**regulation of ingredients****problem definition**

Yes

**which option**

Establish a common list of tobacco ingredients

**which one**

Establish a positive common list of tobacco ingredients

**access to tobacco products****problem definition**

Yes

**which option**

Ban

**which one2**

Cross-border retail sales of tobacco to be banned over the Internet; Vending machines to be banned; Promotion and displays in retail stores to be banned

---

**NGO submission****identification****affiliation**

NGO

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Germany

**age**

44

**gender**

male

**questions scope****problem definition**

No

**explanations**

vernichtet arbeitsplätze,forciert schwarzhandel

**which option**

No change

**questions smokeless**

**problem definition**

No

**comments**

vernichtet arbeitsplätze,forciert schwarzhandel,vernichtet notwendige steuereinnahmen

**which option**

No change

**questions consumer**

**problem definition**

No

**explanations**

siehe vorherige fragen

**which option**

No change

**questions on reporting**

**problem definition**

No

**explanations**

siehe vorherige fragen

**which option**

No change

**regulation of ingredients**

**problem definition**

No

**explanations**

siehe vorherige fragen

**which option**

No Change

**access to tobacco products**

**problem definition**

No

**explanations**

siehe vor fragen

**which option**

No change

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**NGO submission****identification****affiliation**

NGO

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france

**questions scope****problem definition**

Yes

**which option**

No change

**questions smokeless****problem definition**

No

**comments**

aucune étude scientifique ne prouve les risques concernant les produits du tabac sans fumée

**which option**

Lifting the ban on snus

**questions consumer****problem definition**

No

**explanations**

aucune étude sérieuse sur l'efficacité des paquets neutres aucune étude sérieuse sur l'efficacité des photos chocs aucune efficacité quant aux avertissements sanitaires mise en place des paquets neutres = guerre des prix du tabac photo chocs sur 2 faces ou paquets génériques = approvisionnement des clients sur les marchés parallèles (étranger, contrebande, internet) DE TELLES MESURES VONT PENALISER ECONOMIQUEMENT LES 28 000 BURALISTES FRANCAIS ORGANISES DANS UN RESEAU REGLEMENTE ET SOUS TUTELLE DE L ETAT.

**which option**

No change

**questions on reporting**

**problem definition**

Yes

**which option**

Establish a common compulsory reporting format

**regulation of ingredients**

**problem definition**

No

**explanations**

Cela risque d'entraîner une standardisation de la production avec comme conséquence une diminution de l'offre au fumeur adulte et responsable, et le risque de voir apparaître une augmentation des produits du tabac contrefaits.

**which option**

No Change

**access to tobacco products**

**problem definition**

Yes

**which option**

Controlled supply and access; Ban

**which supply and access**

Age verification of buyers and other legal conditions to be set for cross-border retail sale

**which one2**

Cross-border retail sales of tobacco to be banned over the Internet; Vending machines to be banned

**additional comments**

Il n'y a rien qui prouve que la disparition des linéaire tabac fera diminuer le tabagisme

---

**NGO submission**

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NGO

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FRANCE

**questions scope****problem definition**

Yes

**which option**

No change

**questions smokeless****problem definition**

Yes

**which option**

No change

**questions consumer****problem definition**

No

**explanations**

aucune étude ne prouve que la mise en place de photos chocs ou de paquet neutre soit efficace

**which option**

No change

**questions on reporting****problem definition**

Yes

**which option**

Establish a common compulsory reporting format

**regulation of ingredients****problem definition**

No

**explanations**

risque d'augmentation du tabac contrefait

**which option**

No Change

**access to tobacco products****problem definition**

Yes

**which option**

Controlled supply and access; Ban

**which supply and access**

Age verification of buyers and other legal conditions to be set for cross-border retail sale

**which one2**

Cross-border retail sales of tobacco to be banned over the Internet; Vending machines to be banned

---

**NGO submission**

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germany

**questions scope**

**problem definition**

Yes

**which option**

No change

**questions smokeless**

**problem definition**

No

**which option**

Ban on all types of smokeless tobacco products

**questions consumer**

**problem definition**

Yes

**which option**

No change

**questions on reporting  
problem definition**

Yes

**which option**

No change

**regulation of ingredients  
problem definition**

Yes

**which option**

No Change

**access to tobacco products  
problem definition**

Yes

**which option**

No change

---

**NGO submission**

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NGO

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United Kingdom

**gender**

male

**questions scope**

**problem definition**

No

**explanations**

The definition ignores the remit of the Tobacco Products Directive 2001/37/EC, which is ‘the manufacture, presentation and sale of tobacco products’. Electronic Nicotine Delivery Systems and herbal cigarettes do not contain tobacco and are not paraphernalia for the consumption of tobacco, and so cannot be considered ‘tobacco products’. The problem



definition implicitly extends the Tobacco Products Directive to include all products such as ENDS and herbal cigarettes which resemble cigarettes but do not contain tobacco.

**which option**

No change

**additional comments**

The current framework is limited to the regulation of tobacco products and a change in this would imply a shift in responsibility from supervision of tobacco towards a supervision of all unhealthy stimulants. This would be unwise for two reasons. One, it would undermine the focus of the Directive and create an impossibly broad regulatory scope that the Directive could not fulfil, detracting from its main responsibilities. Two, it would be an encroachment upon civil liberties, because ENDS and herbal cigarettes are not harmful to others. Regulation of these products would set the precedent of the EC controlling substances which pose no danger to others, undermining civil liberties and the autonomy of EU member states.

**questions smokeless**

**problem definition**

No

**comments**

The definition ignores the issue of civil liberties. The standard defence for tobacco control is the consequences of smoking on others – that is, the passive effects of smoking. Smokeless tobacco products are only harmful to the consumers of those products, so the ban on them is only justifiable on paternalistic grounds: ie, protecting adults from the consequences of their choices by stopping them from making those choices. Thus, the central problem is one of individual choice and whether the Tobacco Products Directive may restrict the choices of adults. The problem definition ignores this entirely.

**which option**

Lifting the ban on snus

**additional comments**

As argued above, the central question in the regulation of smokeless tobacco products is one of individual autonomy, because they are only harmful to the consumer of those products. Under Chapter II, Article 2 of the Charter of Fundamental Rights of the European Union, every citizen has the right to liberty of person, which the Directive must strive to uphold. With appropriate consumer information, adults can and should be free to make an informed decision about whether to use smokeless tobacco products themselves. The EC's responsibility is to protect people from the actions of others, not protect people from themselves.

**questions consumer**

**problem definition**

Yes

**which option**

No change

**additional option**

Lifting all EU-wide regulations on cigarette packaging and allowing member states to make their own regulations. Since there is currently no regulation on the use of picture warnings, disparities between states already exist with minimal problems. The marginal impact that packaging has on smokers' choices combined with the need to promote civil liberties presents a strong case that the European Commission should not regulate packaging at all.

**additional comments**

The cited May 2010 Eurobarometer poll's findings on the issue of packaging were that "the package appears to be the least influential factor of the four discussed, with only one in seven agreeing that the package influenced their choice" (Eurobarometer, May 2010, p. 75). The poll found that, on average, only 15% of smokers in the EU said that cigarette packaging influenced their choice of cigarettes. Consumer choice and commercial free speech are imperatives that must be weighed to protect civil liberties in accordance with the Charter of Fundamental Rights of the European Union. The proposals to introduce generic packaging would create a serious problem of dangerous contraband cigarette importation: branded packaging is the only effective barrier against deceptive labelling of cigarettes and consumer protection.

**questions on reporting**

**problem definition**

Yes

**which option**

No change

**additional comments**

Regulatory competition is a valuable asset of the European Union, as different states can experiment with different regulatory frameworks and emulate successful approaches. An EU-wide reporting format would inhibit regulatory innovation and impose a one-size-fits-all model to the EU's diverse tobacco industry, creating a regulatory environment with 'feet of clay' that cannot react quickly to developments in the tobacco industry. The imposition of fees and sanctions would compound this problem and add to the creation of inefficient government bureaucracies.

**regulation of ingredients**

**problem definition**

No

**explanations**

The definition does not acknowledge that the addition of 'attractive substances' to tobacco products is a result of consumer demand for these substances. It also makes a serious error in conflating substances that make smoking more enjoyable (such as liquorice or menthol) with substances which are harmful to smokers without their knowledge.

**which option**

No Change

**additional comments**

The EC must accept that, while a controlled industry, tobacco is nonetheless a popular substance that many EU citizens enjoy consuming. Innovations that enhance enjoyment of

tobacco should not be stifled unless the innovations themselves are directly harmful. Simply making smoking more enjoyable cannot constitute 'harm' if the smoker is informed about the dangers associated.

**access to tobacco products**

**problem definition**

Yes

**which option**

No change

**additional comments**

The integrity of the Single Market requires that cross-border flows of goods and services be upheld except in highly exceptional cases, and the Directive should not infringe on this lightly. Restrictions on cross-border trade would inhibit competition between tobacco companies, harming the consumer and reducing the consumer-driven pressure on the tobacco industry to develop less harmful products. Furthermore, as Mario Monti's 'Report on the future of the Single Market' (2009) argues, the Single Market is in danger of losing its relevance to EU citizens and potentially becoming politically vulnerable to calls for protectionism within the EU, undermining one of the core functions of the EU.

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NGO

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Deutschland

**questions scope**

**problem definition**

No

**explanations**

kein Kommentar

**which option**

No change

**questions smokeless**

**problem definition**

No

**comments**

kein Kommentar

**which option**

No change

**additional option**

kein Kommentar

**additional comments**

kein Kommentar

**questions consumer  
problem definition**

No

**explanations**

kein Kommentar

**which option**

No change

**additional option**

kein Kommentar

**additional comments**

kein Kommentar

**questions on reporting  
problem definition**

Yes

**which option**

No change

**additional options**

kein Kommentar

**additional comments**

kein Kommentar

**regulation of ingredients  
problem definition**

No

**explanations**

kein Kommentar

**which option**

No Change

**additional option**

kein Kommentar

**additional comments**

kein Kommentar

**access to tobacco products****problem definition**

No

**explanations**

kein Kommentar

**which option**

No change

**additional option**

kein Kommentar

**additional comments**

kein Kommentar

---

**NGO submission****identification****affiliation**

NGO

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germany

**age**

58

**gender**

male

**questions scope****problem definition**

Yes

**which option**

Extend the scope of the Directive

**questions smokeless**

**problem definition**

Yes

**which option**

No change

**questions consumer**

**problem definition**

Yes

**which option**

Improve consumer information

**which improvement**

Picture warnings to become mandatory

**questions on reporting**

**problem definition**

Yes

**which option**

Establish a common compulsory reporting format

**regulation of ingredients**

**problem definition**

Yes

**which option**

Introducing the basic criteria on the EU level without a common list

**access to tobacco products**

**problem definition**

Yes

**which option**

No change

---

**NGO submission**

**identification**

**affiliation**

NGO

**name**

CHAMBRE SYNDICALE DES BURALISTES DE LA SEINE-MARITIME (ROUEN)

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reynald.mamier@wanadoo.fr

**country**

FRANCE

**questions scope****problem definition**

Yes

**which option**

No change

**questions smokeless****problem definition**

No

**comments**

il n'y a pas d'études scientifiques efficaces prouvant les risques concernant les produits du tabac sans fumée.

**which option**

Lifting the ban on snus

**questions consumer****problem definition**

No

**explanations**

aucune étude ne prouve l'efficacité des paquets neutres. aucune étude ne prouve l'efficacité des photos chocs, ni même de plus grands avertissements sanitaire sur les paquets. la mise en place de paquets neutres risque d'entraîner une guerre des prix du tabac (puisque cela restera le seul moyen pour les fabricants de se différencier). la mise en place de photos chocs sur les 2 faces des paquets ou de paquets génériques va pousser les consommateurs français à aller s'approvisionner sur les marchés parallèles du tabac (achats à l'étranger ou de contrebande, ou sur internet. de telles mesures risquent de déstabiliser et pénaliser économiquement le réseau des 28 000 buralistes français organisés dans un réseau réglementé et sous tutelle de l'Etat.

**which option**

No change

**questions on reporting****problem definition**

Yes

**which option**

Establish a common compulsory reporting format

**regulation of ingredients**

**problem definition**

No

**explanations**

cela risque d'entraîner une standardisation de la production avec comme conséquence une diminution de l'offre au fumeur adulte et responsable, et le risque de voire apparaître une augmentation des produits du tabac contrefaits

**which option**

No Change

**access to tobacco products**

**problem definition**

Yes

**which option**

Controlled supply and access; Ban

**which supply and access**

Age verification of buyers and other legal conditions to be set for cross-border retail sale

**which one2**

Cross-border retail sales of tobacco to be banned over the Internet; Vending machines to be banned

**additional comments**

il n'y a pas de corrélation prouvée entre la disparition des linéaires tabac et la lutte contre le tabagisme. la france dispose d'un réseau de 28 000 buralistes, préposées de l'administration responsables et professionnels, seuls habilités à vendre du tabac. ce réseau est fortement réglementé par l'Etat ce qui permet déjà de contrôler efficacement l'accès au produit tabac.

---

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france



**questions scope**  
**problem definition**  
Yes

**which option**  
No change

**questions smokeless**  
**problem definition**  
No

**comments**  
Il n'y a pas d'études scientifiques efficaces prouvant les risques concernant les produits du tabac sans fumée. »

**which option**  
Lifting the ban on snus

**questions consumer**  
**problem definition**  
No

**explanations**  
« Aucune étude ne prouve l'efficacité des paquets neutres. Aucune étude ne prouve l'efficacité des photos chocs, ni même de plus grands avertissements sanitaires sur les paquets. La mise en place de paquets neutres risque d'entraîner une guerre des prix du tabac (puisque cela restera le seul moyen pour les fabricants de se différencier). La mise en place de photos chocs sur les 2 faces des paquets ou de paquets génériques va pousser les consommateurs français à aller s'approvisionner sur les marchés parallèles du tabac (achats à l'étranger ou de contrebande, ou sur internet. De telles mesures risquent de déstabiliser et pénaliser économiquement le réseau des 28 000 buralistes français organisés dans un réseau réglementé et sous tutelle de l'Etat. »

**which option**  
No change

**questions on reporting**  
**problem definition**  
Yes

**which option**  
Establish a common compulsory reporting format

**regulation of ingredients**  
**problem definition**  
No

**explanations**  
« Cela risque d'entraîner une standardisation de la production avec comme conséquence une

diminution de l'offre au fumeur adulte et responsable, et le risque de voire apparaitre une augmentation des produits du tabac contrefaits. »

**which option**

No Change

**access to tobacco products**

**problem definition**

Yes

**which option**

Controlled supply and access; Ban

**which supply and access**

Age verification of buyers and other legal conditions to be set for cross-border retail sale

**which one2**

Cross-border retail sales of tobacco to be banned over the Internet; Vending machines to be banned

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**NGO submission**

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NGO

**name**

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**country**

Austria

**age**

65

**gender**

male

**questions scope**

**problem definition**

Yes

**which option**

Extend the scope of the Directive

**questions smokeless**

**problem definition**

Yes

**which option**

Ban on all types of smokeless tobacco products

**questions consumer**

**problem definition**

Yes

**which option**

Introduce generic or plain packaging

**additional option**

Picture warnings to become mandatory Information on harmful substances in tobacco products that cannot be placed on the package would be placed inside the package Tar, nicotine and carbon monoxide levels to be placed with general information on harmful substances in tobacco products Health warnings to be put on water pipes

**questions on reporting**

**problem definition**

Yes

**which option**

Establish a common compulsory reporting format; Introduce fees and sanctions

**regulation of ingredients**

**problem definition**

Yes

**which option**

Establish a common list of tobacco ingredients

**which one**

Establish a negative common list of tobacco ingredients

**access to tobacco products**

**problem definition**

Yes

**which option**

Ban

**which one2**

Cross-border retail sales of tobacco to be banned over the Internet; Vending machines to be banned; Promotion and displays in retail stores to be banned

---

## **NGO submission**

### **identification**

#### **affiliation**

NGO

#### **name**

Brandau Monika

#### **email**

wbrandauqt-online.de

#### **country**

Germany

#### **age**

53

#### **gender**

female

#### **questions scope**

#### **problem definition**

No

#### **explanations**

Kein Kommentar

#### **which option**

No change

#### **questions smokeless**

#### **problem definition**

No

#### **comments**

Kein Kommentar

#### **which option**

No change

#### **questions consumer**

#### **problem definition**

No

#### **explanations**

Kein Kommentar

#### **which option**

No change

**questions on reporting  
problem definition**

No

**explanations**

kein Kommentar

**which option**

No change

**regulation of ingredients  
problem definition**

No

**explanations**

kein Kommentar

**which option**

No Change

**access to tobacco products  
problem definition**

No

**explanations**

kein Kommentar

**which option**

No change

---

**NGO submission**

**identification**

**affiliation**

NGO

**name**

Chambre syndicale des buralistes de l'herault

**email**

marie-therese.dechaume@orange.fr

**country**

france

**questions scope**

**problem definition**

Yes

**which option**

No change

**questions smokeless****problem definition**

No

**comments**

Il n'y a pas d'étude scientifique prouvant les risques du tabac sans fumée

**which option**

Lifting the ban on snus

**questions consumer****problem definition**

No

**explanations**

Aucune étude ne prouve l'efficacité des paquets neutres ainsi que les photos chocs. La mise en place des paquets neutres risque d'entraîner une guerre des prix des fabricants. La mise en place des photos chocs va pousser les consommateurs à l'étranger. De telles mesures risquent de déstabiliser et pénaliser l'économie du réseau des 28000 buralistes qui restent en France sous la tutelle de l'état.

**which option**

No change

**questions on reporting****problem definition**

Yes

**which option**

Establish a common compulsory reporting format

**regulation of ingredients****problem definition**

No

**explanations**

Cela risque d'entraîner une standardisation de la production avec pour conséquence une diminution de l'offre au fumeur adulte et responsable.

**which option**

No Change

**access to tobacco products****problem definition**

Yes

**which option**

No change

**additional comments**

Il n'y a pas de rapport prouvé entre la disparition des linéaires taac et la lutte contre le tabagisme La France dispose d'un réseau de 28000 buralistes préposés de l'administration responsables , seuls habilités à vendre du tabac. ce réseau est fortement réglementé par l'etat ce qui permet de contrôler efficacement l'accès au tabac

---

**NGO submission**

**identification**

**affiliation**

NGO

**name**

A.S.E.Z.A.R

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**country**

España

**questions scope**

**problem definition**

Yes

**which option**

No change

**questions smokeless**

**problem definition**

Yes

**which option**

Lifting the ban on snus

**questions consumer**

**problem definition**

No

**explanations**

la propia genuinidad del producto es su razón de ser

**which option**

No change

**questions on reporting  
problem definition**

Yes

**which option**

No change

**additional comments**

una persona puede fumar 5 cigarrillos de su marca favorita y sentirse bien por ello y no tiene que molestarse en ver imagenes desagradables

**regulation of ingredients**

**problem definition**

Yes

**which option**

No Change

**access to tobacco products**

**problem definition**

Yes

**which option**

No change

---

**NGO submission**

**identification**

**affiliation**

NGO

**name**

Lóránt Zoltán

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**country**

Magyarország

**age**

45

**gender**

male



**questions scope**  
**problem definition**

Yes

**which option**

No change

**additional comments**

Ellentmondásos a tervezet,mert már a hatáskör definiásakor tiltásokat forgalmaz meg bizonyos termékköre, anélkül,hogy erre vonatkozó részletekkel szolgálna, legyen szó akár a bevezetőről, akár a konzultációs anyag egyéb fejezeteiről.

**questions smokeless**

**problem definition**

Yes

**which option**

Lifting the ban on snus

**additional comments**

Ennek a kérdéskörnek a szabályozását tagállami hatáskörben lenne érdemes meghagyni. Mindezek mellett úgy gondoljuk, hogy a snüsszel kapcsolatos svéd példa alapján a füstmentes dohánytermékeket tiltás helyett inkább reklámozni kellene.

**questions consumer**

**problem definition**

Yes

**which option**

No change

**additional option**

Ne növeljük a fekete kereskedelmet.

**questions on reporting**

**problem definition**

No

**explanations**

Tagállami szinten a kérdéskör megoldott és a tagállamok szuverenitásának fenntartása szükséges, mivel a jelenlegi direktíva megfelelő alapot biztosít ehhez.

**which option**

No change

**regulation of ingredients**

**problem definition**

No

**explanations**

A tiltó jellegű szabályozásnak megfelelő tudományos alapokon kell nyugodnia, nem pedig szubjektív értékelésen. Az FCTC 9-10 cikkelyeinek vitái alapján is látszik, hogy egy nem átgondolt tiltó szabályozás a dohánytermelők munkahelyeit veszélyezteti így Magyarországon 10 000 ember megélhetését teszi tönkre.

**which option**

No Change

**access to tobacco products**

**problem definition**

No

**explanations**

A túlzott szabályozás a feketekereskedelem kapuit nyitja tágabbra, és így a legális értékesítésen keresztül a termelői érdekeket hátrányosan befolyásolja.

**which option**

No change

---

**NGO submission**

**identification**

**affiliation**

NGO

**name**

chambre syndicale des buralistes de loire atlantique

**email**

ch.sy.tabac.44@wanadoo.fr

**country**

france

**questions scope**

**problem definition**

Yes

**which option**

No change

**questions smokeless**

**problem definition**

No

**comments**

Aucunes études scientifiques efficaces prouvent les risques concernant les produits du tabac sans fumée.

**which option**

Lifting the ban on snus

**questions consumer****problem definition**

No

**explanations**

Aucune étude ne prouve l'efficacité des paquets neutres, des photos chocs, des grands avertissements sanitaires. La mise en place des paquets neutres risque d'entraîner une guerre des prix, les photos chocs sur les 2 faces des paquets ou de paquets génériques va pousser les consommateurs français à aller s'approvisionner sur les marchés parallèles du tabac (achats à l'étranger ou contrebande ou internet). De telles mesure risquent de déstabiliser le réseau des 28000 buralistes français organisés dans un réseau réglementé et sous tutelle de l'Etat.

**which option**

No change

**questions on reporting****problem definition**

Yes

**which option**

Establish a common compulsory reporting format

**regulation of ingredients****problem definition**

No

**explanations**

Cela risque d'entraîner une standardisation de la production avec comme conséquence une diminution de l'offre au fumeur adulte et responsable, et le risque de voire apparaître une augmentation du tabac contrefaits.

**which option**

No Change

**access to tobacco products****problem definition**

Yes

**which option**

Controlled supply and access; Ban

**which supply and access**

Age verification of buyers and other legal conditions to be set for cross-border retail sale

**which one2**

Cross-border retail sales of tobacco to be banned over the Internet; Vending machines to be

banned

**additional comments**

Il n'y a pas de corrélation prouvée entre la disparition des linéaires tabac et la lutte contre le tabagisme. La France dispose d'un réseau de 28000 buralistes, préposés de l'Administration responsables et professionnels, seuls habilités à vendre du tabac. Ce réseau est fortement réglementé par l'Etat ce qui permet déjà de contrôler efficacement l'accès au produit tabac.

---

**NGO submission**

**identification**

**affiliation**

NGO

**name**

CHAMBRE SYNDICALE DES BURALISTES DE LA GIRONDE

**email**

csgtdg@wanadoo.fr

**country**

France

**questions scope**

**problem definition**

Yes

**which option**

No change

**questions smokeless**

**problem definition**

No

**comments**

Il n'y a pas d'étude scientifique efficace prouvant les risques concernant les produits du tabac sans fumée

**which option**

Lifting the ban on snus

**questions consumer**

**problem definition**

No

**explanations**

aucune étude ne prouve l'efficacité des paquets neutre. aucune étude ne prouve l'efficacité des photos chocspas plus que l'agrandissement des mentions sanitaires sur les paquets la mise en

place de paquet neutres pourrait entrainer une guerre des prix du tabac(puisqu'il ne restera que cela aux fabricants de se différencier la mise en place de photos chocs de part et d'autre du paquetode paquets génériques va pousser les consommateurs à s'approvisionner sur les marchés parallèles de telles mesures vont déstabiliser et pénaliser le réseau des 28000 buralistes français organisée en réseauréglementé et sous tutelle de l'état.

**which option**

No change

**questions on reporting**

**problem definition**

Yes

**which option**

Establish a common compulsory reporting format

**regulation of ingredients**

**problem definition**

No

**explanations**

risque d'entrainer unestandardisation de la production doc une diminution de l'offre aux fumeursadultes et responsables et par conséquent une augmentation des tabacs de contrefaçon

**which option**

No Change

**access to tobacco products**

**problem definition**

Yes

**which option**

Controlled supply and access; Ban

**which supply and access**

Age verification of buyers and other legal conditions to be set for cross-border retail sale

**which one2**

Cross-border retail sales of tobacco to be banned over the Internet; Vending machines to be banned

**additional comments**

il n'y apas de corrélation prouvée entre la disparition des linéaires de tabac et la lutte contre le tabagisme la France dispose d'un réseau dr 28000 buralistes responsables et professionnels seuls habilités à vendre du tabac. Ce réseau est fortement encadré par l'état ce qui permet le controle efficace de l'accès aux produits du tabac.

---

**NGO submission**

**identification**  
**affiliation**  
NGO

**name**  
Poksrucker Rudolf

**email**  
poksrucker@hotmail.com

**country**  
Austria

**age**  
60

**gender**  
male

**questions scope**  
**problem definition**  
No

**explanations**  
Es gibt schon zu viele Regelungen

**which option**  
No change

**questions smokeless**  
**problem definition**  
No

**comments**  
kein Kommentar

**which option**  
No change

**questions consumer**  
**problem definition**  
No

**explanations**  
Enteignung der Markenrechte

**which option**  
No change

**questions on reporting  
problem definition**

No

**explanations**

Erhaltung der verschiedenen Geschmacke

**which option**

No change

**regulation of ingredients**

**problem definition**

No

**explanations**

erhalt der Geschmacksvielfalt

**which option**

No Change

**access to tobacco products**

**problem definition**

No

**explanations**

Freier Zugang zu legalen Produkten

**which option**

No change

---

**NGO submission**

**identification**

**affiliation**

NGO

**name**

Chambre syndicale des Buralistes de Maine et Loire

**email**

buralistes49@orange.fr

**country**

france

**questions scope**

**problem definition**

Yes

**which option**

No change

**questions smokeless****problem definition**

No

**comments**

Il ny a pas d'études scientifiques efficaces prouvant les risques concernant les produits du tabac sans fumée.

**which option**

Lifting the ban on snus

**questions consumer****problem definition**

No

**explanations**

Aucune étude ne prouve l'efficacité des paquets neutres. Aucune étude ne prouve l'efficacité des photos chocs, ni même de plus grands avertissements sanitaires sur les paquets. La mise en place de paquets neutres risquent d'entraîner une guerre des prix du tabac (puisque cela restera le seul moyen pour les fabricants de se différencier.) La Mise en place de photos chocs sur les 2 faces des paquets ou de paquets génériques va pousser les consommateurs français à aller s'approvisionner sur les marchés parallèles du tabac (achat à l'étranger ou de contrebande ou sur internet.) De telles mesures risquent de déstabiliser et de pénaliser économiquement le réseau des 28.000 buralistes français organisé dans un réseau réglementé et sous tutelle de l'état.

**which option**

No change

**questions on reporting****problem definition**

Yes

**which option**

Establish a common compulsory reporting format

**regulation of ingredients****problem definition**

No

**explanations**

Cela risque d'entraîner une standardisation de la production avec comme conséquence une diminution de l'offre aux fumeurs adultes et responsables, et le risque de voir apparaître une augmentation des produits du tabac contrefaits.

**which option**



No Change

**access to tobacco products**

**problem definition**

Yes

**which option**

Controlled supply and access

**which supply and access**

Age verification of buyers and other legal conditions to be set for cross-border retail sale

**additional option**

Il n'y a pas de corrélation prouvée entre la disparition tabac et la lutte contre le tabagisme; La France dispose d'un réseau de 28.000 buralistes, préposés de l'administration, responsables et professionnels, seuls habilités à vendre du tabac. Ce réseau est fortement réglementé par l'Etat ce qui permet déjà de contrôler efficacement l'accès aux produits tabac.

---

**NGO submission**

**identification**

**affiliation**

NGO

**name**

chambre syndicale des buralistes du cher

**email**

leklims@orange.fr

**country**

france

**questions scope**

**problem definition**

Yes

**which option**

No change

**questions smokeless**

**problem definition**

No

**comments**

aucune étude scientifiques prouvent les risques concernant les produits du tabac sans fumée

**which option**

Lifting the ban on snus

**questions consumer**

**problem definition**

No

**explanations**

aucune étude ne prouve l'efficacité des paquets neutres aucune études ne prouve l'efficacité des photos chocs la mise en place de paquets neutres risques d'entraîner une guerre des prix du tabac la mises en place de photos chocs sur les 2 faces des paquets ou de paquets génériques va pousser les consommateurs français à aller s'approvisionner sur les marchés parallèles( à l'étranger, contrebande) cela va déstabiliser et pénaliser le réseau des 28000 buralistes français organisés dans un réseau réglementé et sous tutelle de l'état.

**which option**

No change

**questions on reporting**

**problem definition**

Yes

**which option**

Establish a common compulsory reporting format

**regulation of ingredients**

**problem definition**

No

**explanations**

cela risque d'entraîner une standardisation de la production avec comme conséquence une diminution de l'offre au fumeur adulte et responsable, et risque de voire apparaître une augmentation des produits du tabac contrefaits

**which option**

No Change

**access to tobacco products**

**problem definition**

Yes

**which option**

Controlled supply and access; Ban

**which supply and access**

Age verification of buyers and other legal conditions to be set for cross-border retail sale;  
Tobacco display and promotion at points of sales to be restricted

**which one2**

Cross-border retail sales of tobacco to be banned over the Internet; Vending machines to be banned

---

## **NGO submission**

### **identification**

#### **affiliation**

NGO

#### **name**

Cirka Monika

#### **email**

monika.cirka@gmx.at

#### **country**

Austria

#### **age**

49

#### **gender**

female

#### **questions scope**

##### **problem definition**

No

#### **explanations**

Wir sind alt genug um selbst entscheiden zu können ob wir rauchen oder nicht! Wer findet für die Personen deren Arbeitsplatz verloren geht bzw. ersatzlos geschrichenen wird, neue Arbeit?

#### **which option**

No change

#### **recommend option**

Warum will man alles ändern!?

#### **additional comments**

Auf jeder Party erhält ein Jugendlicher Alkohol in rauhen Mengen zu kleinem Preis. Diese Thematik wäre woll wichtiger, denn Alkoholranke sind eine größere Belastung für die Gesellschaft als Raucher!

#### **questions smokeless**

##### **problem definition**

No

#### **comments**

Kein Kommentar

**which option**

No change

**questions consumer  
problem definition**

No

**explanations**

Kein Kommentar

**which option**

No change

**additional option**

Kein Kommentar

**additional comments**

Alkohol ist das größere Problem

**questions on reporting  
problem definition**

No

**explanations**

Kein Kommentar

**which option**

No change

**additional options**

Keine Änderung wir haben andere Probleme

**regulation of ingredients**

**problem definition**

No

**explanations**

Kein Kommentar

**which option**

No Change

**additional option**

Andere wichtigere Probleme in Angriff nehmen und nicht den mündigen Bürger bevormunden wollen!

**access to tobacco products**

**problem definition**

No

**explanations**

Kein Kommentar

**which option**

No change

**additional option**

Auch die Wrbebranche muß leben können

---

**NGO submission****identification****affiliation**

NGO

**name**

Confédération Nationale des Buralistes de France

**email**

laconfederation@buralistes.fr

**country**

France

**questions scope****problem definition**

Yes

**which option**

No change

**questions smokeless****problem definition**

No

**comments**

Il n'y a pas d'études scientifiques efficaces prouvant les risques concernant les produits du tabac sans fumée.

**which option**

Lifting the ban on snus

**questions consumer****problem definition**

No

**explanations**

Aucune étude ne prouve l'efficacité des paquets neutres. Aucune étude ne prouve l'efficacité

des photos chocs, ni même de plus grands avertissements sanitaires sur les paquets. La mise en place de paquets neutres risque d'entraîner une guerre des prix du tabac (puisque cela restera le seul moyen pour les fabricants de se différencier). La mise en place de photos chocs sur les 2 faces des paquets ou de paquets génériques va pousser les consommateurs français à aller s'approvisionner sur les marchés parallèles du tabac (achats à l'étranger ou de contrebande, ou sur internet. De telles mesures risquent de déstabiliser et pénaliser économiquement le réseau des 28 000 buralistes français organisés dans un réseau réglementé et sous tutelle de l'Etat.

**which option**

No change

**questions on reporting**

**problem definition**

Yes

**which option**

Establish a common compulsory reporting format

**regulation of ingredients**

**problem definition**

No

**explanations**

Cela risque d'entraîner une standardisation de la production avec comme conséquence une diminution de l'offre au fumeur adulte et responsable, et le risque de voire apparaitre une augmentation des produits du tabac contrefaits.

**which option**

No Change

**access to tobacco products**

**problem definition**

Yes

**which option**

Controlled supply and access; Ban

**which supply and access**

Age verification of buyers and other legal conditions to be set for cross-border retail sale

**which one2**

Cross-border retail sales of tobacco to be banned over the Internet; Vending machines to be banned

**additional option**

Il n'y a pas de corrélation prouvée entre la disparition des linéaires tabac et la lutte contre le tabagisme. La France dispose d'un réseau de 28 000 buralistes, préposés de l'administration responsables et professionnels, seuls habilités à vendre du tabac. Ce réseau est fortement réglementé par l'Etat ce qui permet déjà de contrôler efficacement l'accès au produit tabac.

---

**NGO submission**

**identification**

**affiliation**

NGO

**name**

Antonio Cuffaro

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tone@gmx.net

**country**

Germany

**questions scope**

**problem definition**

Yes

**which option**

No change

**questions smokeless**

**problem definition**

Yes

**which option**

Lifting the ban on snus

**questions consumer**

**problem definition**

Yes

**which option**

No change

**questions on reporting**

**problem definition**

Yes

**which option**

Establish a common compulsory reporting format

**regulation of ingredients**

**problem definition**

Yes

**which option**

Introducing the basic criteria on the EU level without a common list

**access to tobacco products**

**problem definition**

Yes

**which option**

No change

---

**NGO submission**

**identification**

**affiliation**

NGO

**name**

Winkler, Thorsten

**email**

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**country**

deutschland

**age**

54

**gender**

male

**questions scope**

**problem definition**

No

**explanations**

kein kommentar

**which option**

No change

**questions smokeless**

**problem definition**

No

**which option**

Lifting the ban on snus

**questions consumer**



**problem definition**

No

**explanations**

kein kommentar

**which option**

No change

**questions on reporting**

**problem definition**

No

**explanations**

kein kommentar

**which option**

No change

**regulation of ingredients**

**problem definition**

No

**explanations**

kein kommentar

**which option**

No Change

**access to tobacco products**

**problem definition**

No

**explanations**

kein kommentar

**which option**

No change

---

**NGO submission**

**identification**

**affiliation**

NGO

**name**

Sächsische Landesstelle gegen die Suchtgefahren

**email**

slsev@t-online.de

**country**

Germany

**questions scope**

**problem definition**

Yes

**which option**

No change

**questions smokeless**

**problem definition**

Yes

**which option**

No change

**questions consumer**

**problem definition**

Yes

**which option**

Introduce generic or plain packaging

**questions on reporting**

**problem definition**

Yes

**which option**

Introduce fees and sanctions

**regulation of ingredients**

**problem definition**

Yes

**which option**

Establish a common list of tobacco ingredients

**which one**

Establish a negative common list of tobacco ingredients

**access to tobacco products**

**problem definition**

Yes

**which option**

No change

---

## **NGO submission**

### **identification**

#### **affiliation**

NGO

#### **name**

CHAMBRE SYNDICALE DEPARTEMENTALE DES DEBITANTS DE TABAC DU PAS DE CALAIS OUEST

#### **email**

le.persan@wanadoo.fr

#### **country**

FRANCE

### **questions scope**

#### **problem definition**

Yes

#### **which option**

No change

### **questions smokeless**

#### **problem definition**

No

### **comments**

IL N'Y A PAS D'ETUDES SCIENTIFIQUES EFFICACES PROUVANT LES RISQUES CONCERNANT LES PRODUITS DU TABAC SANS FUMEE

#### **which option**

Lifting the ban on snus

### **questions consumer**

#### **problem definition**

No

### **explanations**

aucune étude ne prouve l'efficacité des paquets neutres. Aucune étude ne prouve l'efficacité des photos chocs, ni même de plus grands avertissements sanitaires sur les paquets. La mise en place de paquets neutres risque d'entraîner une guerre des prix du tabac (puisque cela restera le seul moyen pour les fabricants de se différencier). La mise en place de photos chocs sur les 2 faces des paquets ou de paquets génériques va pousser les consommateurs français à aller s'approvisionner sur les marchés parallèles du tabac (achats à l'étranger ou de contrebande, ou sur internet). De telles mesures risquent de déstabiliser et pénaliser économiquement le réseau des 28000 buralistes français organisés dans un réseau réglementé et sous tutelle de l'Etat.

**which option**

No change

**questions on reporting**

**problem definition**

Yes

**which option**

Establish a common compulsory reporting format

**regulation of ingredients**

**problem definition**

No

**explanations**

Cela risque d'entraîner une standardisation de la production avec comme conséquence une diminution de l'offre au fumeur adulte et responsable, et le risque de voir apparaître une augmentation des produits du tabac contrefaits.

**which option**

No Change

**access to tobacco products**

**problem definition**

Yes

**which option**

Controlled supply and access; Ban

**which supply and access**

Age verification of buyers and other legal conditions to be set for cross-border retail sale

**which one2**

Cross-border retail sales of tobacco to be banned over the Internet; Vending machines to be banned

**additional comments**

Il n'y a pas de corrélation prouvée entre la disparition des linéaires tabac et la lutte contre le tabagisme. La France dispose d'un réseau de 28000 buralistes, préposés de l'Administration responsables et professionnels, seuls habilités à vendre du tabac. Ce réseau est fortement réglementé par l'Etat ce qui permet déjà de contrôler efficacement l'accès au produit tabac.

---

**NGO submission**

**identification**

**affiliation**

NGO

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**country**

deutschland

**age**

54

**gender**

male

**questions scope****problem definition**

No

**explanations**

kein Kommentar

**which option**

No change

**questions smokeless****problem definition**

No

**comments**

kein Kommentar

**which option**

No change

**questions consumer****problem definition**

No

**explanations**

kein Kommentar

**which option**

No change

**questions on reporting****problem definition**

No

**explanations**  
kein Kommentar

**which option**  
No change

**regulation of ingredients**  
**problem definition**  
No

**explanations**  
kein Kommentar

**which option**  
No Change

**access to tobacco products**  
**problem definition**  
No

**explanations**  
kein Kommentar

**which option**  
No change

---

**NGO submission**

**identification**  
**affiliation**  
NGO

**name**  
Izba Przemysłowo-Handlowa w Krakowie ( The Cracow Chamber of Commerce and Industry). Izba jest organizacją samorządu gospodarczego; zapewnia wsparcie dla rozwoju małych i średnich przedsiębiorstw;

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**country**  
Polska

**questions scope**  
**problem definition**  
Yes

**which option**

No change

**questions smokeless  
problem definition**

Yes

**which option**

Lifting the ban on snus

**questions consumer  
problem definition**

No

**explanations**

Unijne przepisy, których celem jest regulowanie legalnie działających przedsiębiorstw, które dają zatrudnienie i które przyczyniają się do rozwoju lokalnej i krajowej gospodarki, powinny opierać się na jasnych i obiektywnych zasadach oraz stwarzać równe warunki funkcjonowania na rynku. Ujednolicenie opakowań wyrobów tytoniowych ( plain packaging) stanowiłoby jawne naruszenie przepisów polskiego prawa (konstytucyjne prawo do swobody prowadzenia działalności gospodarczej oraz Ustawa z dn. 30 czerwca 2000 r. Prawo własności przemysłowej).

**which option**

No change

**questions on reporting  
problem definition**

No

**explanations**

zasady raportowania powinny być takie same w całej UE, aby informacja jaka trafia następnie do konsumentów była spójna we wszystkich krajach UE.

**which option**

Establish a common compulsory reporting format

**regulation of ingredients**

**problem definition**

No

**explanations**

Przepisy regulujące produkcję i skład wyrobów tytoniowych powinny dążyć do ograniczenia użycia w produkcji dodatków, które zwiększają toksyczność i szkodliwość wyrobów tytoniowych. Pojęcie "atrakcyjności" nie powinno stanowić w żadnym przypadku miary oceny, czy dany produkt powinien być dostępny na rynku, czy nie. Ocena oparta na pojęciu "atrakcyjności" stworzy poważne trudnienia w implementacji takich zapisów do krajowego prawa, a następnie w ich egzekwowaniu.

**which option**

No Change

**access to tobacco products**

**problem definition**

No

**explanations**

Ograniczenie bądź całkowity zakaz pokazywania produktów tytoniowych w punktach sprzedaży detalicznej zaburzy warunki konkurencyjne na rynku: - w uprzywilejowanej pozycji znajdą się rozpoznawalne marki z ugruntowaną pozycją na rynku, - utrudniony zostanie dostęp do rynku mniejszych podmiotów bądź mniej rozpoznawalnych i nowych marek,

**which option**

No change

---

**NGO submission**

**identification**

**affiliation**

NGO

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D.Wieda

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wiida@hs-spedition.de

**country**

D

**age**

60

**gender**

male

**questions scope**

**problem definition**

No

**explanations**

kein Kommentar

**which option**

No change

**questions smokeless**

**problem definition**



No

**comments**

Kein Kommentar

**which option**

No change

**questions consumer  
problem definition**

No

**explanations**

kein Kommentar

**which option**

No change

**questions on reporting  
problem definition**

No

**explanations**

kein Kommentar

**which option**

No change

**regulation of ingredients  
problem definition**

No

**explanations**

kein Kommentar

**which option**

No Change

**access to tobacco products  
problem definition**

No

**explanations**

kein Kommentar

**which option**

No change

---

## **NGO submission**

### **identification**

#### **affiliation**

NGO

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#### **email**

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#### **country**

Luxembourg

### **questions scope**

#### **problem definition**

Yes

#### **which option**

Extend the scope of the Directive

### **recommend option**

ENDS: are marketed and often sold as Quit Smoking Aids, they should be labelled as pharmaceutical products and therefore comply with this regulatory framework (proven efficacy, safety and quality)

### **additional comments**

/

### **questions smokeless**

#### **problem definition**

Yes

#### **which option**

Ban on all types of smokeless tobacco products

### **additional option**

Maintaining the ban on snus is a high priority.

### **additional comments**

/

### **questions consumer**

#### **problem definition**

Yes

#### **which option**

Improve consumer information; Introduce generic or plain packaging

**which improvement**

Picture warnings to become mandatory; Tar, nicotine and carbon monoxide levels to be replaced with general information on harmful substances in tobacco products; Information on harmful substances in tobacco products that cannot be placed on the package would be placed inside the package; Health warnings to be put on water pipes

**additional option**

Highest priority : - pictorial health warnings should cover at least 80% of the total packaging surface on all (!) tobacco products. And it would be more effective if those 'fear inducing' pictures were to be changed regularly, so they would not lose its shocking impact -those pictorial warnings have to be mandatory in all member States, so that all European citizens are well aware of the risks of tobacco products and therefore are equally protected -plain packaging is of the highest priority, but must be combined with standardised size and shape of all cigarette packs. This will mostly prevent smoking promotion and marketing activities. - adding quit lines on all tobacco products packaging is a must, and most effective. -the misleading tar/CO /nicotine figures have to be absolutely removed on all tobacco products -it is important that water-pipes will be included, as they are mostly targeted to young people who are not aware of the hazardous nature of water-pipes tobacco.

**questions on reporting  
problem definition**

Yes

**which option**

Establish a common compulsory reporting format; Introduce fees and sanctions

**additional options**

/

**additional comments**

/

**regulation of ingredients****problem definition**

Yes

**which option**

Establish a common list of tobacco ingredients

**which one**

Establish a positive common list of tobacco ingredients

**additional option**

All ingredients and flavours which enhance the attractiveness of tobacco products have to be banned. This includes not only sugars, sweeteners, spices, herbs or flavouring substances, but also all ingredients which may be linked to energy (as caffeine) or health (vitamins). And no coloring should be allowed. Only registered products should be allowed on the market.

**access to tobacco products**

**problem definition**

Yes

**which option**

Ban

**which one2**

Cross-border retail sales of tobacco to be banned over the Internet; Vending machines to be banned; Promotion and displays in retail stores to be banned

---

**NGO submission****identification****affiliation**

NGO

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**country**

FRANCE

**questions scope****problem definition**

Yes

**which option**

No change

**questions smokeless****problem definition**

No

**comments**

Aucune étude scientifique efficace prouvant les risques concernant les produits de tabac sans fumée

**which option**

Lifting the ban on snus

**questions consumer****problem definition**

No

**explanations**

"Aucune étude ne prouve l'efficacité des paquets neutres Aucune étude ne prouve l'efficacité des photos chocs, ni même de plus grands avertissements sanitaires sur les paquets. La mise en place de paquets neutres risque d'entraîner une guerre des prix du tabac (puisque cela restera le seul moyen pour les fabricants de se différencier) La mise en place de photos chocs sur les 2 faces des paquets ou de paquets génériques va pousser les consommateurs français à aller s'approvisionner sur les marchés parallèles dutabac (achats à l'étranger ou de contrebande, ou sur internet). De telles mesures risquent de déstabiliser et pénaliser économiquement le réseau des 28 000 buralistes français organisés dans un réseau réglementé et sous tutelle de l'Etat".

**which option**

No change

**questions on reporting**

**problem definition**

Yes

**which option**

Establish a common compulsory reporting format

**regulation of ingredients**

**problem definition**

No

**explanations**

"Cela risque d'entraîner une standardisation de la production avec comme conséquence une diminution de l'offre au fumeur adulte et responsable, et le risque de voire apparaître une augmentation des produits du tabac contrefaits".

**which option**

No Change

**access to tobacco products**

**problem definition**

Yes

**which option**

Controlled supply and access; Ban

**which supply and access**

Age verification of buyers and other legal conditions to be set for cross-border retail sale

**which one2**

Cross-border retail sales of tobacco to be banned over the Internet; Vending machines to be banned

**additional comments**

"Il n'y a pas de corrélation prouvée entre la disparition des linéaires tabac et la lutte contre le tabagisme. La France dispose d'un réseau de 28 000 buralistes, préposés de l'administration

responsables et professionnels, seuls habilités à vendre du tabac. Ce réseau est fortement réglementé par l'Etat ce qui permet déjà de contrôler efficacement l'accès au produit tabac."

---

## **NGO submission**

### **identification**

#### **affiliation**

NGO

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chambre syndicale des débitants de tabac de la mayenne

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#### **country**

france

### **questions scope**

#### **problem definition**

Yes

#### **which option**

No change

### **questions smokeless**

#### **problem definition**

No

#### **comments**

« Il n'y a pas d'études scientifiques efficaces prouvant les risques concernant les produits du tabac sans fumée. »

#### **which option**

Lifting the ban on snus

### **questions consumer**

#### **problem definition**

No

### **explanations**

Aucune étude ne prouve l'efficacité des paquets neutres. Aucune étude ne prouve l'efficacité des photos chocs, ni même de plus grands avertissements sanitaires sur les paquets. La mise en place de paquets neutres risque d'entraîner une guerre des prix du tabac (puisque cela restera le seul moyen pour les fabricants de se différencier). La mise en place de photos chocs sur les 2 faces des paquets ou de paquets génériques va pousser les consommateurs français à aller s'approvisionner sur les marchés parallèles du tabac (achats à l'étranger ou de contrebande, ou sur internet. De telles mesures risquent de déstabiliser et pénaliser

économiquement le réseau des 28 000 buralistes français organisés dans un réseau réglementé et sous tutelle de l'Etat

**which option**

No change

**questions on reporting**

**problem definition**

Yes

**which option**

Establish a common compulsory reporting format

**regulation of ingredients**

**problem definition**

No

**explanations**

Cela risque d'entraîner une standardisation de la production avec comme conséquence une diminution de l'offre au fumeur adulte et responsable, et le risque de voire apparaitre une augmentation des produits du tabac contrefaits.

**which option**

No Change

**access to tobacco products**

**problem definition**

Yes

**which option**

Controlled supply and access; Ban

**which supply and access**

Age verification of buyers and other legal conditions to be set for cross-border retail sale

**which one2**

Cross-border retail sales of tobacco to be banned over the Internet; Vending machines to be banned

**additional comments**

Il n'y a pas de corrélation prouvée entre la disparition des linéaires tabac et la lutte contre le tabagisme. La France dispose d'un réseau de 28 000 buralistes, préposés de l'administration responsables et professionnels, seuls habilités à vendre du tabac. Ce réseau est fortement réglementé par l'Etat ce qui permet déjà de contrôler efficacement l'accès au produit tabac.

---

**NGO submission**

**identification**

**affiliation**

NGO

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**country**

Bundesrepublik Deutschland

**questions scope****problem definition**

No

**explanations**

Probleme und Marktverzerrungen entstehen keineswegs dadurch, dass entsprechende Produkte nicht der Tabakwarenrichtlinie unterliegen, sondern genau im Gegenteil rühren sie daher, dass die bereits erfassten Tabakwaren – in einer ihrem Konsum gegenüber feindlichen Weise (!) – in ein Korsett der Überregulierung gezwängt worden sind.

**which option**

No change

**recommend option**

Netzwerk Rauchen empfiehlt die Aufhebung der gesamten Richtlinie. Auf Ebene der EU findet eine besonders freiheitsfeindliche Bekämpfung des Tabakkonsums statt, da die Pläne des medizinisch-industriellen Komplexes bzw. der Anti-Tabak-Lobby in Brüssel auf fruchtbareren Boden fallen als in vielen Mitgliedsstaaten der EU. Wir lehnen Gleichschaltung durch einschlägige Verbote ab. Hilfsweise befürworten wir die grundlegende Überarbeitung der gesamten Richtlinie. Jeder Ansatz von Tabakbekämpfung hat aus ihr zu verschwinden und einem Bekenntnis zur Konsum- und Unternehmensfreiheit der Menschen in der EU zu weichen, das selbstverständlich auch Tabakwaren umfasst.

**additional comments**

Ein wesentlicher Teil der Anti-Tabak-Lobby sind die Pharmakonzerne, die Nikotinprodukte (und Psychopharmaka als Alternative zum Tabakkonsum) anbieten. Die EU-Kommission handelt in deren Interesse. Bestimmte Konkurrenzprodukte wie elektronische Zigaretten sollen deshalb verboten werden.

**questions smokeless****problem definition**

No

**comments**

Netzwerk Rauchen weist die Behauptung monokausaler Zusammenhänge zwischen dem Konsum von Tabakwaren und bestimmten Erkrankungen zurück. Wenn die EU-Organe ihr



Gerede von der Gefährlichkeit des Tabakrauchens und ihren blinden Glauben an die pseudowissenschaftliche multifaktorielle Epidemiologie ernst nähme, hätte ihre vermeintliche Mission zur Rettung von Menschenleben längst zur Aufhebung des Snus-Verbots geführt.

**which option**

Lifting the ban on snus

**additional option**

Netzwerk Rauchen lehnt nicht nur die bestehende weitreichende Snus-Prohibition ab, sondern auch die vielen kleinen Einzelstücke, aus denen sich das verhängnisvolle Mosaik der Prohibition bei den anderen Tabakwaren zusammensetzt. Ein bekannter Spruch auch zum Thema Prohibition lautet: „Small laws are pieced together into huge tyrannies“. Dies gilt z.B. für die Tabakproduktrichtlinie. Wir fordern daher eine Entfernung jeglicher prohibitionistischer Elemente aus der Richtlinie.

**additional comments**

Auch hier gilt unser Hinweis zu Punkt I. des Verfahrens, dass die in der Anti-Tabak-Lobby mächtigen einschlägigen Pharmakonzernen Snus als lästige Konkurrenz zu ihren eigenen Nikotinprodukten sehen.

**questions consumer**

**problem definition**

No

**explanations**

Privatwirtschaftlich hergestellte Produkte und ihre Verpackungen sind nicht Eigentum der Obrigkeit, die diese zur Projektionsfläche ihrer politischen und ideologischen Mitteilungen machen darf. Zudem handelt es sich bei den sog. Warnhinweisen um manipulative Lügen und Halbwahrheiten, mittels derer Rauchern wie Nichtrauchern ein monströses Zerrbild des Rauchens eingetrichtert werden soll. Durch den Nocebo-Effekt erhöht sich bei vielen Rauchern erst die Wahrscheinlichkeit eines Krankheitseintritts. Die EU-Organe machen sich auf diese Weise schuldig an zahllosen schweren Erkrankungen, sogar an Todesfällen in der EU. Noch größere Flächen auf Tabakverpackungen für staatliche Verunstaltung sowie irreführende Fotografien, auch „Gesundheitspornos“ genannt, würden diese verwerfliche Politik auf die Spitze treiben. „Plain Packaging“, wäre eine ästhetische Katastrophe durch Vernichtung kulturell wertvollen und beliebten Industriedesigns und außerdem eine tiefgreifende Verzerrung des Wettbewerbs zwischen verschiedenen Anbietern im Binnenmarkt. Einheitsverpackungen sind in Teilen Deutschlands noch aus der Zeit der kommunistischen DDR-Diktatur bekannt. Es stellt sich die Frage, ob die EU ihren Weg hin zu einer von Kritikern so bezeichneten „EUdSSR“ auch an diesem Punkt gehen möchte.

**which option**

No change

**additional option**

Netzwerk Rauchen fordert ein Ende jeglicher Warnhinweise und „Gesundheitspornos“ auf Tabakverpackungen sowie vergleichbarer Regulierung.

**additional comments**

1. Das vorgebliche Ziel, mit sog. Warnhinweisen und Abschreckungspropaganda die

Raucherraten nach unten zu drücken, hat die EU eindeutig verfehlt. Sie ist damit gescheitert, was nicht zuletzt gestiegene Zahlen rauchender Jugendlicher nach dem Inkrafttreten diverser Tabakkontroll-Maßnahmen in vielen Mitgliedsstaaten deutlich machen. 2. Die weitere Verunstaltung von Verpackungen wäre ein zusätzlicher Anreiz, Tabakwaren legal oder illegal aus dem außerEUropäischen Ausland zu beziehen.

**questions on reporting  
problem definition**

No

**explanations**

Kein Kommentar.

**which option**

No change

**additional options**

Zur Ersparnis von Aufwand und Kosten schlägt Netzwerk Rauchen vor, die EU-Ebene mit dieser Frage überhaupt nicht weiter zu belasten. EU-Bürger können sich darüber in ihren Mitgliedsstaaten und eigenen Sprachen informieren.

**additional comments**

Der Versuch, Informationen zu zentralisieren, mag zwar zum zentralplanwirtschaftlichen Denken in diesem Teil der EU-Bürokratie passen, bringt aber den Bürgern keinen Nutzen.

**regulation of ingredients**

**problem definition**

No

**explanations**

Für die Behauptung, bestimmte Zusätze und Zubereitungen in Tabakprodukten brächten größere gesundheitliche Risiken mit sich, gibt es keine belastbare wissenschaftliche Grundlage. Wäre dies so, müsste die EU übrigens konsequenterweise dafür Sorge tragen, dass Zusatzstofffreie Tabakprodukte als gesündere Alternative beworben werden dürfen, was in Mitgliedsstaat wie Deutschland derzeit untersagt ist. Die Attraktivität von Produkten zu attackieren, offenbart ein perverses Denken bei der EU-Kommission. Anbieter bemühen sich selbstverständlich um die Erstellung attraktiver Angebote, und der Konsument fragt diese nach. Regulierung, die Produkte bewusst und vorsätzlich unattraktiv machen soll, die EU-Bürgern also schlechtere Produkte aufzwingen will, muss sich von vornherein kategorisch verbieten.

**which option**

No Change

**additional option**

1. Bestimmte Zusatzstoffe sind notwendig bei der Entwicklung von sog. risikoreduzierten Tabakwaren, Stichwort: Safer Cigarette. Zusatzstoffverbote würden diese Bestrebungen, wie sie jüngst bei Tabakwarenherstellern wieder entbrannt sind, verunmöglichen. Damit hätte die EU-Kommission künftig selbst weitere der von ihre behaupteten „Tabaktoten“ auf dem Gewissen. Stattdessen wäre es angebracht, sich der Risikominimierung anzunehmen und

regulatorische Hemmnisse für solche Produktinnovationen abzubauen. Netzwerk Rauchen fordert einschlägige Aktivitäten sowohl von Herstellerfirmen wie von der EU und den Mitgliedsstaaten ein. 2. Netzwerk Rauchen fordert die Abschaffung der bestehenden Produktregulierung mit ihren Höchstwerten. Die EU-Kommission selbst ist ja offenbar der Auffassung, dass leichtere Zigaretten und -Tabake keine geringeren gesundheitlichen Risiken mit sich bringen, sonst hätte sie die Bezeichnung „Light“ nicht verboten. Daher bestand und besteht keine Rechtfertigung für das Verbot starker Tabakwaren.

#### **additional comments**

Am Markt zeigen sich zunehmende Nachfrage nach und Angebote von Zusatzstofffreien Tabakwaren. Europäische Konsumenten und in der EU tätige Hersteller finden ihren Geschmack, was die Zusammensetzung von Tabakwaren angeht, ganz alleine, ohne obrigkeitstaatliche Regulierung.

#### **access to tobacco products**

##### **problem definition**

No

##### **explanations**

Eine Marktwirtschaft zeichnet sich dadurch aus, dass den Menschen der Zugang zu von ihnen gewünschten Dienstleistungen und Produkten, hier: Tabakwaren, nicht durch staatliche Einflussnahme unnötig erschwert wird. Dass der Zugang, nicht die Zugangshemmnisse, von der EU-Kommission als Problem dargestellt wird, zeigt, wessen Geistes Kind diese ist, insbesondere im Gesundheitsbereich.

##### **which option**

No change

##### **additional option**

Zur Sicherung eines freien und fairen Wettbewerbs muss Tabakwerbung erlaubt sein. Von den bestehenden Werbeverböten haben in den vergangenen Jahrzehnten bereits die Marktführer, insbesondere der Philip-Morris-Konzern, profitiert. Netzwerk Rauchen fordert, dass Tabak wie jedes andere Produkt behandelt wird.

##### **additional comments**

1. Die EU sollte für möglichst freien grenzüberschreitenden Handel stehen. 2. Der Automatenverkauf ist gerade in Deutschland ein seit Generationen bewährtes und beliebtes Mittel zur Verbesserung der Versorgungslage der rauchenden Bevölkerung. 3. Die angedachte Degradierung von Tabak zur ‚Bückware‘ unter der Ladentheke beweist eine spießige Mentalität, die sich vor Jahrzehnten auf erotisches Schrifttum bezog und heutzutage von den brutalen Spießern des Volksgesundheitspropaganda und des rot-grünen Bürgertums nicht zuletzt auf Tabakwaren angewandt wird. In Zusammenspiel mit ‚Plain Packing‘ entspricht die Bückwarenvorschrift sogar einer Burkapflicht für Tabakwaren. Zudem hätten besonders die Einzelhändler unter der Verhüllung von Tabakwaren am Verkaufspunkt zu leiden. Als Kleinunternehmer sind diese leider ohnehin das Opfer einer Politik in der EU und den Mitgliedsstaaten, die sich an den mächtigen Interessen der Konzerne und Staatsbürokratien orientiert. Die Kosten für die Umgestaltung von Tabakgeschäften wären erheblich. Der Journalist Christopher Snowden hat 2009 anhand von nach dem britischen Informationsfreiheitsgesetz beschafften Informationen nachgewiesen, wie das Netz aus

Antitabaklobby und Regierungsbürokratie mit Falschinformationen über diese Kosten (sie wurden viel zu niedrig angesetzt) die politischen Entscheider gefüttert hat.

---

## **NGO submission**

### **identification**

#### **affiliation**

NGO

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Germany

### **questions scope**

#### **problem definition**

No

#### **explanations**

No comment

#### **which option**

No change

### **questions smokeless**

#### **problem definition**

No

#### **comments**

No comment

#### **which option**

Lifting the ban on snus

### **questions consumer**

#### **problem definition**

No

#### **explanations**

Wie an den bisherigen „Warnhinweisen“ erkennbar, betreibt die Europäische Union nicht Verbraucherinformation, sondern -desinformation.

#### **which option**

No change

**additional option**

Auf der Website und den Schriftstücken der Europäischen Kommission sollte folgender Warnhinweis vermerkt werden: „Die Europäische Union fügt Ihnen und den Menschen in Ihrer Umgebung erheblichen Schaden zu.“

**questions on reporting  
problem definition**

No

**explanations**

Aus Sicht von Rauchen NRW besteht hier kein Problem.

**which option**

No change

**additional comments**

Sowohl Tabakwaren mit Zusatzstoffen als auch zunehmend solche ohne werden stark nachgefragt. Beide haben ihren Platz und ihre Existenzberechtigung, nämlich durch den freiwilligen Konsum der Raucherinnen und Raucher.

**regulation of ingredients****problem definition**

No

**explanations**

Aus Sicht von Rauchen NRW besteht hier kein Problem.

**which option**

No Change

**additional comments**

Sowohl Tabakwaren mit Zusatzstoffen als auch zunehmend solche ohne werden stark nachgefragt. Beide haben ihren Platz und ihre Existenzberechtigung, nämlich durch den freiwilligen Konsum der Raucherinnen und Raucher.

**access to tobacco products****problem definition**

No

**explanations**

Rauchen NRW sieht im Zugang zu Tabakwaren nicht etwa ein Problem, sondern das Recht der Raucherinnen und Raucher.

**which option**

No change

**additional comments**

Rauchen NRW spricht sich für den Behalt von Zigarettenautomaten, in der Gastronomie und anderswo, aus. Rauchen NRW spricht sich zudem für möglichst freien grenzüberschreitenden

Handel, auch Internethandel, mit Tabakwaren aus. Rauchen NRW befürwortet Tabakwerbung, am Verkaufspunkt und anderswo, und verwahrt sich gegen die zusätzlichen Kosten, die Tabakhändlern dadurch auferlegt würden, dass sie ihre Ware unter dem Ladentisch verstecken müssten.

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## **NGO submission**

**identification**

**affiliation**

NGO

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Deutschland

**age**

48

**gender**

female

**questions scope**

**problem definition**

No

**explanations**

kein Kommentar“

**which option**

No change

**questions smokeless**

**problem definition**

No

**comments**

kein Kommentar“

**which option**

No change

**questions consumer**

**problem definition**

No

**explanations**  
kein Kommentar“

**which option**  
Improve consumer information

**questions on reporting**  
**problem definition**  
No

**explanations**  
kein Kommentar“

**which option**  
No change

**regulation of ingredients**  
**problem definition**  
No

**explanations**  
kein Kommentar“

**which option**  
No Change

**access to tobacco products**  
**problem definition**  
No

**explanations**  
kein Kommentar“

**which option**  
No change

---

**NGO submission**

**identification**  
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NGO

**name**  
CHAMBRE SYNDICALE DES BURALISTES DU MORBIHAN(56) FRANCE

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michel.guiffes@wanadoo.fr

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FRANCE

**questions scope**

**problem definition**

Yes

**which option**

No change

**recommend option**

AINSI IL Y A UNE CHANCE POPUR UNE LEGALISATION DES SNUS

**questions smokeless**

**problem definition**

No

**comments**

AUCUNE ETUDE SCIENTIFIQUE NE PROUVE LES RISQUES DU TABAC SANS FUMEE

**which option**

Lifting the ban on snus

**questions consumer**

**problem definition**

No

**explanations**

AUCUNE ETUDE NE DEMONTRE L'EFFICACITE DES PAQUETS NEUTRES  
AUCUNE ETUDE NE PROUVE L'EFFICACITE DES PHOTOS CHOCS, NI MEME DE PLUS GRANDS AVERTISSEMENTS SANITAIRES SUR LES PAQUETS. LA MISE EN PLACE DE PAQUETS NEUTRES RISQUE D'ENTRAINER UNE GUERRE DES PRIX DU TABAC(PUISQUE CELA RESTERA LE SEUL MOYEN POUR LES FABRICANTS DE SE DIFFERENCIER. LA MISE EN PLACE DE PHOTOS CHOCS SUR LES 2 FACES DES PAQUETS OU DE PAQUETS GENERIQUES VA POUSSER LES CONSOMMATEURS FRANCAIS A ALLER S4APPROVISIONNER SUR LES MARCHES PARALLELES DU TABAC( ACHATS A L4ETRANGER OU DE CONTREBANDE, OU SUR INTERNET). DE TELLES MESUREZS RISQUENT DE DESTABILISER ET PENALISER ECONOMIQUEMENT LE RESEAU DES 28 000 BURALISTES FRANCAIS ORGANISES DANS LE RESEAU REGLEMENTE ET SOUS TUTELLE DE L4ETAT.

**which option**

No change

**questions on reporting**

**problem definition**



Yes

**which option**

Establish a common compulsory reporting format

**regulation of ingredients**

**problem definition**

No

**explanations**

CELA VA ENTRAINER UNE STANDARDISATION DE LA PRODUCTION AVEC  
COMME CONSEQUENCE UNE DIMINUTION DE L'OFFRE AU FUMEUR ADULTE ET  
RESPONSABLE? ET LE RISQUE DE VOIR APPARAITRE UNE AUGMENTATION DES  
PRODUITS DU TABAC CONTREFAITS

**which option**

No Change

**access to tobacco products**

**problem definition**

Yes

**which option**

Controlled supply and access; Ban

**which supply and access**

Age verification of buyers and other legal conditions to be set for cross-border retail sale

**which one2**

Cross-border retail sales of tobacco to be banned over the Internet; Vending machines to be banned

**additional comments**

IL N'Y A PAS DE LIEN DIRECT PROUVE ENTRE LA DISPARITION DES LINEAIRES  
TABAC ET LA LUTTE CONTRE LE TABAGISME. LA FRANCE DISPOSE D'UN  
RESEAU DE 28 000 BURALISTES, PREPOSES DE L'ADMINISTRATION  
RESPONSABLES ET PROFESSIONNELS, SEULS HABILITES A VENDRE DU TABAC.  
CE RESEAU EST FORTEMENT REGLEMENTE PAR L'ETAT CE QUI PERMET DEJA  
DE CONTROLER EFFICACEMENT L'ACCES AU PRODUIT TABAC.

---

**NGO submission**

**identification**

**affiliation**

NGO

**name**

chambre syndicale de l'indre

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mr marandon denis

**age**

42

**gender**

male

**questions scope****problem definition**

Yes

**which option**

No change

**questions smokeless****problem definition**

No

**comments**

il n'y a pas d'etudes scientifiques efficaces prouvant les risques concernant les produits du tabac sans fumée

**which option**

Lifting the ban on snus

**questions consumer****problem definition**

No

**explanations**

Aucune étude ne prouve l'efficacité des paquets neutres. Aucune étude ne prouve l'efficacité des photos chocs, ni même de plus grands avertissements sanitaire sur les paquets. La mise en place de paquets neutres risque d'entraîner une guerre des prix de tabac ( puisque cela restera le seul moyen pour les fabricants de se différencier). La mise en place de photos chocs sur les 2 faces des paquets ou de paquets génériques va pousser les consommateurs français à aller s'approvisionner sur les marchés parallèles du tabac ( achats à l'étranger ou de contrebande, ou sur internet. De telles mesures risquent de déstabiliser et pénaliser économiquement le réseau de 28000 buralistes français organisés dans un réseau réglementé et sous tutelle de l'Etat.

**which option**

No change

**questions on reporting****problem definition**

Yes

**which option**

Establish a common compulsory reporting format

**regulation of ingredients**

**problem definition**

No

**explanations**

Cela risque d'entraîner une standardisation de la production avec comme conséquence une diminution de l'offre au fumeur adulte et responsable, et le risque de voire apparaître une augmentation des produits du tabac contrefaits.

**which option**

No Change

**access to tobacco products**

**problem definition**

Yes

**which option**

Controlled supply and access

**which supply and access**

Age verification of buyers and other legal conditions to be set for cross-border retail sale

---

**NGO submission**

**identification**

**affiliation**

NGO

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Germany

**questions scope**

**problem definition**

Yes

**which option**

No change

**questions smokeless****problem definition**

No

**which option**

No change

**questions consumer****problem definition**

No

**explanations**

there already exists a general awareness of the risks of smoking. Add a point of warning images on this increased awareness, the pics do not work merely predominantly repulsive without additional information to offer. packaging through the implementation of neutral counterfeiters will facilitate the work and the problem of smuggling is still deteriorating. this is the existence of purely nationally active wholesale and retail trade in Germany threatened. the introduction of neutral packaging focuses more on the marketing competition, the award. falling prices would be the consequences. this is in all respects (tax revenues youth protection, health protection, ...) counterproductive. there are sweepingly that the introduction of pictorial warnings on behavior that acts of smoking. There is currently no evidence from countries, which have been already introduced pictorial warnings compulsory.

**which option**

No change

**questions on reporting****problem definition**

Yes

**which option**

No change

**regulation of ingredients****problem definition**

Yes

**which option**

No Change

**access to tobacco products****problem definition**

No

**explanations**

tobacco products is a legal stimulant, the consumer - is associated with health risks - as well as alcohol and sweets. yet it is a legal product. measures proposed here are the fundamental rights restricted. this is not the risk relative to the actual. prohibiting the display or visibility of cigarettes in shops have no cross-border implications. proposed here relate to the measures do

not work within the European market, but they are alone motivated health policy. Health policy is not within the competence of the EU, but is regulated by the principle of subsidiarity at the national level alone. yes indeed exist in all countries and regulatory measures already. the individual at the national level, existing restrictions have worked well. pursued if further improvements of individual constraints at the national level, this leads to an increased aktzeptanz the arrangements for the citizens. The EU should not pose as the super-bureaucracy, living habits, the smallest of all people requires unifying. this will create eu-frustrating! not surprisingly, the Europeans can not start with the eu. organized crime and smuggling will fill the gap that results when disappear legal terms and provide outlets.

**which option**

No change

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**NGO submission**

**identification**

**affiliation**

NGO

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Deutschland

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57

**gender**

male

**questions scope**

**problem definition**

Yes

**which option**

Extend the scope of the Directive

**questions smokeless**

**problem definition**

Yes

**which option**

Ban on all types of smokeless tobacco products

**questions consumer  
problem definition**

Yes

**which option**

Introduce generic or plain packaging

**additional option**

Bildwarnhinweise für alle Mitgliedsstaaten Explizite und genaue Angaben über schädliche Inhaltsstoffe Gesundheitshinweise auch für Wasserpfeifen

**questions on reporting**

**problem definition**

Yes

**which option**

Introduce fees and sanctions

**regulation of ingredients**

**problem definition**

Yes

**which option**

Establish a common list of tobacco ingredients

**which one**

Establish a positive common list of tobacco ingredients

**access to tobacco products**

**problem definition**

Yes

**which option**

Ban

**which one2**

Cross-border retail sales of tobacco to be banned over the Internet; Vending machines to be banned; Promotion and displays in retail stores to be banned

---

**NGO submission**

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NGO

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Germany

**questions scope****problem definition**

Yes

**which option**

Extend the scope of the Directive

**questions smokeless****problem definition**

Yes

**which option**

Ban on all types of smokeless tobacco products

**questions consumer****problem definition**

Yes

**which option**

Improve consumer information; Introduce generic or plain packaging

**which improvement**

Picture warnings to become mandatory; Tar, nicotine and carbon monoxide levels to be replaced with general information on harmful substances in tobacco products; Information on harmful substances in tobacco products that cannot be placed on the package would be placed inside the package; Health warnings to be put on water pipes

**questions on reporting****problem definition**

Yes

**which option**

Establish a common compulsory reporting format; Introduce fees and sanctions

**regulation of ingredients****problem definition**

Yes

**which option**

Establish a common list of tobacco ingredients

**which one**

Establish a positive common list of tobacco ingredients

**access to tobacco products**

**problem definition**

Yes

**which option**

Ban

**which one2**

Cross-border retail sales of tobacco to be banned over the Internet; Vending machines to be banned; Promotion and displays in retail stores to be banned

---

**NGO submission**

**identification**

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NGO

**name**

CHAMBRE SYNDICALE DES BURALISES DE L'INDRE

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France

**questions scope**

**problem definition**

Yes

**which option**

No change

**questions smokeless**

**problem definition**

No

**comments**

Il n' y a pas d'études scientifiques efficaces prouvant les risques concernant les produits du tabac sans fumée

**which option**

Lifting the ban on snus

**questions consumer**

**problem definition**

No



**explanations**

Aucune études ne prouve l'efficacité des paquets neutres. Aucune études ne prouve l'efficacité des photos chocs, ni même de plus grands avertissements sanitaires sur les paquets. La mise en place de paquets neutres risque d'entraîner une guerre des prix du tabac (puisque cela restera le seul moyen pour les fabricants de se différencier). La mise en place de photos chocs sur les deux faces des paquets génériques va pousser les consommateurs français à aller s'approvisionner sur les marchés parallèles du tabac (achats à l'étranger ou de contrebande, ou sur internet). De telles mesures risquent de déstabiliser et pénaliser économiquement le réseau des vingt huit mille buralistes français organisés dans un réseau réglementé et sous tutelle de l'Etat.

**which option**

No change

**questions on reporting****problem definition**

Yes

**which option**

Establish a common compulsory reporting format

**regulation of ingredients****problem definition**

No

**explanations**

Cela risque d'entraîner une standardisation de la production avec comme conséquence une diminution de l'offre au fumeur adulte responsable, et le risque de voir apparaître une augmentation des produits du tabac contrefaits.

**which option**

No Change

**access to tobacco products****problem definition**

Yes

**which option**

Controlled supply and access; Ban

**which supply and access**

Age verification of buyers and other legal conditions to be set for cross-border retail sale

**which one2**

Cross-border retail sales of tobacco to be banned over the Internet; Vending machines to be banned

**additional option**

Il n'y a pas corrélation prouvée entre la disparition des linéaires tabac et la lutte contre le tabagisme. La France dispose d'un réseau de vingt huit mille buralistes, préposés de

l'administration et professionnels,seuls habilités à vendre du tabac.Ce réseau est fortement réglementé par l'Etat ce qui permet déjà de contrôler efficacement l'accès au produit tabac.

---

## **NGO submission**

### **identification**

#### **affiliation**

NGO

#### **name**

Chambre syndicale des buralistes de l'AIN

#### **email**

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#### **country**

FRANCE

#### **gender**

female

### **questions scope**

#### **problem definition**

Yes

#### **which option**

No change

### **questions smokeless**

#### **problem definition**

No

#### **comments**

" il n'y a pas d'études scientifiques efficaces prouvant les risques concernant les produits du tabac sans fumée"

#### **which option**

Lifting the ban on snus

### **questions consumer**

#### **problem definition**

No

### **explanations**

- AUCUNE ETUDE NE PROUVE L'EFFICACITE DES PAQUETS NEUTRES " Aucune étude ne prouve l'efficacité des photos chocs, ni même des plus grands avertissements sanitaires sur les paquets " " La mise en place de paquets neutres risque d'entraîner une guerre des prix du tabac (puisque cela restera le seul moyen pour les fabricants de se différencier "

"La mise en place de photos chocs sur les 2 faces des paquets ou de paquets génériques va pousser les consommateurs français à aller s'approvisionner sur les marchés parallèles du tabac (achats à l'étranger ou de contrebande, ou sur Internet " " De telles mesures risquent de déstabiliser et pénaliser économiquement le réseau des 28 000 buralistes français organisés dans un réseau réglementé et sous tutelle de l'Etat "

**which option**

No change

**questions on reporting**

**problem definition**

Yes

**which option**

Establish a common compulsory reporting format

**regulation of ingredients**

**problem definition**

No

**explanations**

" Cela risque d'entraîner une standardisation de la production avec comme conséquence une diminution de l'offre au fumeur adulte et responsable, et le risque de voir apparaître une augmentation des produits du tabac contrefaits "

**which option**

No Change

**access to tobacco products**

**problem definition**

Yes

**which option**

Controlled supply and access; Ban

**which supply and access**

Age verification of buyers and other legal conditions to be set for cross-border retail sale

**which one2**

Cross-border retail sales of tobacco to be banned over the Internet; Vending machines to be banned

**additional comments**

" Il n'y a pas de corrélation prouvée entre la disparition des linéaires tabac et la lutte contre le tabagisme" La France dispose d'un réseau de 28 000 buralistes, préposés de l'administration responsables et professionnels, seuls habilités à vendre les produits du tabac. Ce réseau est fortement règlementé par l'Etat ce qui permet déjà de contrôler efficacement l'accès aux produits tabac "

---

## **NGO submission**

### **identification**

#### **affiliation**

NGO

#### **name**

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#### **country**

deutsch

### **questions scope**

#### **problem definition**

No

### **explanations**

kein Kommentar

### **which option**

No change

### **questions smokeless**

#### **problem definition**

No

### **comments**

kein Kommentar

### **which option**

No change

### **questions consumer**

#### **problem definition**

No

### **explanations**

kein Kommentar

### **which option**

No change

### **questions on reporting**

#### **problem definition**

No

**explanations**  
kein Kommentar

**which option**  
No change

**regulation of ingredients**  
**problem definition**  
No

**explanations**  
kein Kommentar

**which option**  
No Change

**additional option**  
kein Kommentar

**access to tobacco products**  
**problem definition**  
No

**explanations**  
kein Kommentar

**which option**  
No change

**additional option**  
kein Kommentar

---

**NGO submission**

**identification**  
**affiliation**  
NGO

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COPAGRI - Confederazione Produttori Agricoli (Vice Presidente Alessandro Ranaldi)

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Italia

**questions scope**

**problem definition**

Yes

**which option**

No change

**additional comments**

Non reputiamo necessario un allargamento dell'ambito della Direttiva ad altre categorie di prodotti. Seppure riteniamo interessante controllare il mercato delle sigarette senza tabacco, non si può accettare il divieto proposto per tutte le forme di tabacco senza fumo tra cui lo "snus" che rappresenta sbocchi interessanti per alcuni Paesi, non essendo stata dimostrata scientificamente una nocività di questi prodotti analoga a quella degli altri prodotti del tabacco.

**questions smokeless****problem definition**

No

**comments**

La spiegazione dettagliata è nello spazio relativo alla scelta dell'opzione.

**which option**

Lifting the ban on snus

**additional comments**

Riteniamo ingiusto che la commercializzazione del tabacco umido in polvere per uso orale (c.d. "snus") sia consentita in un solo Stato dell'UE, ovvero la Svezia, e vietata in tutti gli altri Stati. Il divieto di vendita non è basato su prove scientifiche ed andrebbe rimosso. La nostra posizione è sostenuta anche dal fatto che, in Svezia, diverse ricerche scientifiche dimostrano la riduzione dell'incidenza delle patologie correlate al fumo rispetto alla media UE proprio grazie all'utilizzo dello "snus". Inoltre, anche la percentuale dei fumatori sul totale della popolazione è inferiore alla media UE. Tale dato dimostrerebbe l'efficacia dello "snus" come potenziale strumento di supporto per smettere di consumare prodotti da fumo. Ci auguriamo, quindi, che lo "snus" venga liberamente commercializzato in tutti gli Stati Membri del mercato unico europeo.

**questions consumer****problem definition**

No

**explanations**

La spiegazione dettagliata è nello spazio relativo alla scelta dell'opzione.

**which option**

No change

**additional comments**

Non esistono più fumatori che ignorano i pericoli del consumo. Le foto non hanno dato la prova della loro efficienza. La consapevolezza dei rischi sanitari connessi al prodotto, come sostenuto da più ricerche scientifiche, non aumenta con l'utilizzo di ulteriori avvertenze

speciali. A nostro avviso, quindi, la possibilità di inserire avvertenze sotto forma di fotografie a colori o altre illustrazioni dovrebbe essere lasciata alla libera iniziativa degli Stati Membri, come previsto dalla Direttiva attuale. Inoltre, l'introduzione di restrizioni sul pacchetto (es. il c.d. pacchetto generico che riteniamo un'aberrazione per un prodotto da banco e il rischio di mascherare il prodotto a discapito della qualità del tabacco), come suggerito dall'opzione 3, a nostro avviso, mina seriamente la sopravvivenza stessa dell'industria legale a causa del rischio di incremento della contraffazione dei prodotti che va a tutto vantaggio del commercio illecito e delle organizzazioni criminali, rendendo il prodotto più accessibile ai giovani.

**questions on reporting**

**problem definition**

Yes

**which option**

Establish a common compulsory reporting format

**regulation of ingredients**

**problem definition**

No

**explanations**

La spiegazione dettagliata è nello spazio relativo alla scelta dell'opzione.

**which option**

No Change

**additional comments**

Il rischio che alcuni o anche tutti gli ingredienti, vengano vietati, senza fondamento scientifico, è troppo grande. A nostro avviso, la regolamentazione degli ingredienti inseriti nei prodotti del tabacco dovrebbe rimanere competenza degli Stati Membri, come già previsto dall'attuale Direttiva. Questo anche in virtù dei risultati del rapporto del Comitato SCENIHR, incaricato dalla Commissione Europea/DG SANCO di valutare il ruolo degli ingredienti utilizzati in riferimento all'attrattività e all'assuefazione degli stessi. Il rapporto conferma che l'attrattività è un concetto assolutamente soggettivo. L'eventuale divieto di uso degli ingredienti avrebbe gravissime ripercussioni economiche ed occupazionali per il settore del tabacco greggio in Italia. Queste misure, infatti, renderebbero non più economicamente conveniente la coltivazione di alcune varietà di tabacco utilizzato per la produzione di sigarette di tipo American blend e la sopravvivenza dell'intero settore della coltivazione e della prima trasformazione del tabacco in Italia, che occupano circa 60.000 addetti, verrebbe seriamente minata.

**access to tobacco products**

**problem definition**

Yes

**which option**

Controlled supply and access

**which supply and access**

Age verification of buyers and other legal conditions to be set for cross-border retail sale;

Access to vending machines to be restricted to adults

**additional comments**

Riteniamo opportuno una discussione sull'accesso controllato, ma non attraverso un approccio di restrizioni globali globale all'interno delle tabaccherie e di internet, che è difficilmente controllabile. A nostro avviso, la determinazione delle misure che stabiliscono i limiti all'accesso ai prodotti a base di tabacco dovrebbe rimanere competenza degli Stati Membri. In particolare, siamo contrari ad ulteriori ed ingiustificate restrizioni, come il divieto totale di esposizione dei prodotti, in quanto determinano una sorta di criminalizzazione del consumo di un prodotto legale, con gravi ripercussioni su tutta la filiera produttiva. Peraltro, auspichiamo che la Direttiva adotti la regolamentazione già presente in Italia, in particolare per quanto riguarda la verifica dell'età dell'acquirente e l'installazione di distributori automatici provvisti di sistema di verifica anagrafica. Infine, supportiamo le restrizioni prospettate per le vendite via internet poiché tali misure, a nostro avviso, preservano il livello qualitativo del prodotto garantito, in Italia, dal sistema di concessione delle licenze ai prodotti del tabacco tutelando, quindi, anche la salute del consumatore.

---

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**affiliation**

NGO

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Deutschland

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45

**gender**

male

**questions scope**

**problem definition**

Yes

**which option**

No change

**questions smokeless**

**problem definition**

Yes



**which option**

No change

**questions consumer  
problem definition**

Yes

**which option**

No change

**questions on reporting  
problem definition**

Yes

**which option**

No change

**regulation of ingredients  
problem definition**

Yes

**which option**

No Change

**access to tobacco products  
problem definition**

Yes

**which option**

No change

---

**NGO submission**

**identification**

**affiliation**

NGO

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Shell Station Hellweg

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Germany

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53

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**questions scope**

**problem definition**

No

**explanations**

kein kommentar

**which option**

No change

**questions smokeless**

**problem definition**

No

**comments**

kein kommentar

**which option**

No change

**questions consumer**

**problem definition**

No

**explanations**

kein kommentar

**which option**

No change

**questions on reporting**

**problem definition**

No

**explanations**

kein kommentar

**which option**

No change

**additional options**

kein kommentar

**regulation of ingredients**

**problem definition**

No

**explanations**

kein kommentar

**which option**

No Change

**additional option**

kein kommentar

**access to tobacco products**

**problem definition**

No

**which option**

No change

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**NGO submission**

**identification**

**affiliation**

NGO

**name**

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**country**

Deutschland

**questions scope**

**problem definition**

No

**explanations**

Kein Kommentar

**which option**

No change

**questions smokeless**

**problem definition**

No

**comments**

Kein Kommentar

**which option**

No change

**questions consumer**

**problem definition**

No

**explanations**

Kein Kommentar

**which option**

No change

**questions on reporting**

**problem definition**

No

**explanations**

Kein Kommentra

**which option**

No change

**regulation of ingredients**

**problem definition**

No

**explanations**

Kein Kommentar

**which option**

No Change

**access to tobacco products**

**problem definition**

No

**explanations**

Kein Kommentar

**which option**

No change

---

**NGO submission**

**identification**

**affiliation**

NGO

**name**

UILA - Unione Italiana dei Lavori Agroalimentari (Segretario Nazionale Pietro Pellegrini)

**email**

uilanazionale@uila.it

**country**

Italia

**questions scope****problem definition**

Yes

**which option**

No change

**additional comments**

Non reputiamo necessario un allargamento dell'ambito della Direttiva ad altre categorie di prodotti. Seppure riteniamo interessante controllare il mercato delle sigarette senza tabacco, non si può accettare il divieto proposto per tutte le forme di tabacco senza fumo tra cui lo "snus" che rappresenta sbocchi interessanti per alcuni Paesi, non essendo stata dimostrata scientificamente una nocività di questi prodotti analoga a quella degli altri prodotti del tabacco.

**questions smokeless****problem definition**

No

**comments**

La spiegazione dettagliata è nello spazio relativo alla scelta dell'opzione.

**which option**

Lifting the ban on snus

**additional comments**

Riteniamo ingiusto che la commercializzazione del tabacco umido in polvere per uso orale (c.d. "snus") sia consentita in un solo Stato dell'UE, ovvero la Svezia, e vietata in tutti gli altri Stati. Il divieto di vendita non è basato su prove scientifiche ed andrebbe rimosso. La nostra posizione è sostenuta anche dal fatto che, in Svezia, diverse ricerche scientifiche dimostrano la riduzione dell'incidenza delle patologie correlate al fumo rispetto alla media UE proprio grazie all'utilizzo dello "snus". Inoltre, anche la percentuale dei fumatori sul totale della popolazione è inferiore alla media UE. Tale dato dimostrerebbe l'efficacia dello "snus" come potenziale strumento di supporto per smettere di consumare prodotti da fumo. Ci auguriamo, quindi, che lo "snus" venga liberamente commercializzato in tutti gli Stati Membri del mercato unico europeo.

**questions consumer**

**problem definition**

No

**explanations**

La spiegazione dettagliata è nello spazio relativo alla scelta dell'opzione.

**which option**

No change

**additional comments**

Non esistono più fumatori che ignorano i pericoli del consumo. Le foto non hanno dato la prova della loro efficienza. La consapevolezza dei rischi sanitari connessi al prodotto, come sostenuto da più ricerche scientifiche, non aumenta con l'utilizzo di ulteriori avvertenze speciali. A nostro avviso, quindi, la possibilità di inserire avvertenze sotto forma di fotografie a colori o altre illustrazioni dovrebbe essere lasciata alla libera iniziativa degli Stati Membri, come previsto dalla Direttiva attuale. Inoltre, l'introduzione di restrizioni sul pacchetto (es. il c.d. pacchetto generico che riteniamo un'aberrazione per un prodotto da banco e il rischio di mascherare il prodotto a discapito della qualità del tabacco), come suggerito dall'opzione 3, a nostro avviso, mina seriamente la sopravvivenza stessa dell'industria legale a causa del rischio di incremento della contraffazione dei prodotti che va a tutto vantaggio del commercio illecito e delle organizzazioni criminali, rendendo il prodotto più accessibile ai giovani.

**questions on reporting****problem definition**

Yes

**which option**

Establish a common compulsory reporting format

**regulation of ingredients****problem definition**

No

**explanations**

La spiegazione dettagliata è nello spazio relativo alla scelta dell'opzione.

**which option**

No Change

**additional comments**

Il rischio che alcuni o anche tutti gli ingredienti, vengano vietati, senza fondamento scientifico, è troppo grande. A nostro avviso, la regolamentazione degli ingredienti inseriti nei prodotti del tabacco dovrebbe rimanere competenza degli Stati Membri, come già previsto dall'attuale Direttiva. Questo anche in virtù dei risultati del rapporto del Comitato SCENIHR, incaricato dalla Commissione Europea/DG SANCO di valutare il ruolo degli ingredienti utilizzati in riferimento all'attrattività e all'assuefazione degli stessi. Il rapporto conferma che l'attrattività è un concetto assolutamente soggettivo. L'eventuale divieto di uso degli ingredienti avrebbe gravissime ripercussioni economiche ed occupazionali per il settore del tabacco greggio in Italia. Queste misure, infatti, renderebbero non più economicamente conveniente la coltivazione di alcune varietà di tabacco utilizzato per la produzione di

sigarette di tipo American blend e la sopravvivenza dell'intero settore della coltivazione e della prima trasformazione del tabacco in Italia, che occupano circa 60.000 addetti, verrebbe seriamente minata.

**access to tobacco products**

**problem definition**

Yes

**which option**

Controlled supply and access

**which supply and access**

Age verification of buyers and other legal conditions to be set for cross-border retail sale;  
Access to vending machines to be restricted to adults

**additional comments**

Riteniamo opportuno una discussione sull'accesso controllato, ma non attraverso un approccio di restrizioni globali globale all'interno delle tabaccherie e di internet, che è difficilmente controllabile. A nostro avviso, la determinazione delle misure che stabiliscono i limiti all'accesso ai prodotti a base di tabacco dovrebbe rimanere competenza degli Stati Membri. In particolare, siamo contrari ad ulteriori ed ingiustificate restrizioni, come il divieto totale di esposizione dei prodotti, in quanto determinano una sorta di criminalizzazione del consumo di un prodotto legale, con gravi ripercussioni su tutta la filiera produttiva. Peraltro, auspichiamo che la Direttiva adotti la regolamentazione già presente in Italia, in particolare per quanto riguarda la verifica dell'età dell'acquirente e l'installazione di distributori automatici provvisti di sistema di verifica anagrafica. Infine, supportiamo le restrizioni prospettate per le vendite via internet poiché tali misure, a nostro avviso, preservano il livello qualitativo del prodotto garantito, in Italia, dal sistema di concessione delle licenze ai prodotti del tabacco tutelando, quindi, anche la salute del consumatore.

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**NGO submission**

**identification**

**affiliation**

NGO

**name**

The Roy Castle Lung Cancer Foundation

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**country**

UK

**questions scope**

**problem definition**

Yes

**which option**

Extend the scope of the Directive

**recommend option**

No

**additional comments**

• The directive should be expanded to include herbal (tobacco-free and/or nicotine-free) smoked products. • The existing ban on oral tobacco should be maintained. • E-cigarettes and other non-smoked, non-tobacco nicotine products (such as gels or drinks) should be regulated at some level, however we believe this should be achieved through regulation as a pharmaceutical product (as was recently consulted on in the UK by the Medicines and Healthcare Regulatory Agency (MHRA)) Most of the harm to health caused by tobacco is due to the fact that tobacco products are typically smoked. Tobacco products that are not smoked tend to be significantly less harmful, though not harmless (Royal College of Physicians, 2008). Given this and considering emerging evidence that some types of herbal, non-tobacco or non-nicotine cigarettes are likely to be injurious to health in a similar manner to conventional tobacco cigarettes (Jorgensen et al, 2010; Gan et al 2009) it is appropriate to include such products within the Directive. Novel nicotine products that do not contain tobacco and are not combusted but which deliver nicotine to the user (such as electronic cigarettes) are relatively recent additions to the nicotine market. Because the method of administering nicotine in these products does not involve combustion or tobacco, they are likely to be significantly safer than smoked tobacco. These products are largely unregulated at present throughout the Member States, and there are concerns over inconsistencies in the manufacturing process which may result in the vapour delivered to the user varying from product to product. Because of this, regulation of these products would have several advantages, ensuring that e-cigarettes and other novel nicotine products are demonstrably safe and effective as a tobacco alternative. However, as these products are conceptually more similar to pharmaceutical nicotine products than smoked tobacco, RCLCF believes the most appropriate means to achieve suitable regulation should be as pharmaceuticals (as a recent consultation by the UK's Medicines and Healthcare Regulatory Agency discussed). The outcome and background of the MHRA consultation may be useful for the Commission to consider in order to inform its decision. Royal College of Physicians. Harm reduction in nicotine addiction: helping people who can't quit. A report by the Tobacco Advisory Group of the Royal College of Physicians. London: RCP, 2007. Jorgensen ED, Zhao H, Traganos F, Albino AP, Darzynkiewicz Z. DNA damage response induced by exposure of human lung adenocarcinoma cells to smoke from tobacco- and nicotine-free cigarettes. Cell Cycle. 2010 Jun 22;9(11). Gan Q, Yang J, Yang G, Goniewicz M, Benowitz NL, Glantz SA. Chinese "herbal" cigarettes are as carcinogenic and addictive as regular cigarettes. Cancer Epidemiol Biomarkers Prev. 2009 Dec;18(12):3497-501.

**questions smokeless****problem definition**

Yes

**which option**

No change

**additional option**



No

**additional comments**

RCLCF recommends that other smokeless tobacco products that are currently marketed within the Union (such as those more commonly used by black and minority ethnic communities, e.g. gutka) should be subject to tighter regulation to ensure accurate communication of the health risks of use, in a similar manner to other tobacco products. Cessation professionals should also be trained to effectively help individuals who use these products to quit. However extending the ban on oral tobacco to these products may be counterproductive as it could make it more difficult to engage with the communities that use them to offer education and cessation support.

**questions consumer  
problem definition**

Yes

**which option**

Improve consumer information; Introduce generic or plain packaging

**which improvement**

Picture warnings to become mandatory; Tar, nicotine and carbon monoxide levels to be replaced with general information on harmful substances in tobacco products; Information on harmful substances in tobacco products that cannot be placed on the package would be placed inside the package; Health warnings to be put on water pipes

**additional option**

The minimum size of health warnings should be increased to 80% of the front and back surfaces of all tobacco packaging.

**additional comments**

Picture warnings Research (e.g. Hammond et al, 2006) consistently demonstrates graphic warnings to be superior to text-only warnings. Smokers who read, think about, and discuss the implications of graphic labels are more likely to quit, reduce consumption or make a quit attempt. We recommend that picture warnings should become mandatory and they should, by regulation, occupy the largest possible area on the pack. We recommend picture warnings should take up 80% of both the front and back of all tobacco products. The current situation of text-only warnings at the EU level gives inconsistent health protection to residents in Member States, with picture warnings currently having limited uptake. Mandatory health warnings through the Directive are vital to standardise health protection across Member States, and will also assist some EU countries, currently dealing with the threat of tobacco industry legal action to delay warnings, in implementing them swiftly. Hammond D, Fong GT, McNeill A, Borland R, Cummings KM. Effectiveness of cigarette warning labels in informing smokers about the risks of smoking: findings from the International Tobacco Control (ITC) Four Country Survey. *Tob Control*. 2006 Jun;15 Suppl 3:iii19-25. Emission information Consumers associate lower tar, nicotine and CO levels (TNCO) with reduced harm. This has been demonstrated repeatedly in the literature, and results in the misperception that some brands of cigarettes are quantifiably safer (in terms of long-term health outcomes) than others. Because of the very-well established evidence that current machine-measured TNCO values are misleading to the consumer, we support the removal of TNCO emissions from the Directive, and suggest they are replaced with qualitative information on the

hazardous effects of tobacco emissions, and are required to include information on quitting smoking. Health warnings on water pipes The health effects of waterpipe smoking have not been studied to as great an extent as cigarette smoking. However the World Health Organisation (WHO, 2005) concluded that initial research suggests waterpipe smoking may involve similar health hazards to cigarette use. A more recent systematic review (Akl et al, 2010) concluded that waterpipe tobacco smoking is associated with lung cancer, respiratory illness, low birth-weight and periodontal disease. Given this, and the fact there are typically very few warnings on waterpipes or their accessories it is important that hazards are communicated to consumers through the inclusion of health warnings on waterpipes and on tobacco sold for use in waterpipes. Additional information on harmful substances in tobacco products We support proposals to include additional information on the health effects of tobacco consumption on pack inserts. This should include information on quitting smoking. Plain packaging We recommend the introduction of standardised packaging. Note that this refers to packaging where the format (shape, type of opening etc) is defined by regulation in addition to prohibiting the use of colour, branding and other design features. Tobacco packaging is a marketing tool that serves to promote tobacco (though branding, design, pack innovation and features like price marking), undermine health warnings, and foster misconceptions in smokers around harm differences between products through descriptors (such as 'smooth', 'slims' etc) and colour (Moodie et al, 2009). The pack is a powerful marketing opportunity, particularly as it is, in contrast to other overt forms of marketing, part of the consumer's everyday life. The removal of all branding through standardised packaging will remove this marketing opportunity and, in combination with the other measures described in this section, also increase the prominence and salience of health warnings. Moodie C, Hastings G & Ford A. A brief review of plain packaging research for tobacco products. Report prepared for the Department of Health. 2009.

#### **questions on reporting**

##### **problem definition**

Yes

##### **which option**

Establish a common compulsory reporting format; Introduce fees and sanctions

##### **additional options**

No

##### **additional comments**

The current situation which allows different formats and reporting mechanisms is unsatisfactory, making it difficult for authorities to compare and analyse the data. Tobacco companies should be required to use a standardised reporting format. Additionally the companies should be required to pay a yearly registration fee to cover the costs of administering this data collection. The above measures should be compliant with Articles 9 & 10 of the Framework Convention on Tobacco Control (FCTC).

#### **regulation of ingredients**

##### **problem definition**

Yes

##### **which option**

Establish a common list of tobacco ingredients

**which one**

Establish a positive common list of tobacco ingredients

**additional comments**

We support the adoption of a positive common list of tobacco ingredients. Tobacco products are highly toxic and addictive; their contents should therefore be regulated in order to achieve high standards of health protection. A positive common list would ensure that only registered products, with ingredients, flavourings and additives that appear on the positive list would be permitted on the EU market. Currently, EU citizens are not subject to the same level of health protection and a common list of permitted ingredients would go some way towards addressing this anomaly. The tobacco industry uses a range of additives to alter the composition of tobacco products. These can make the product more palatable to children or increase the addictiveness of the product. Therefore any flavourings that may be used to enhance the addictiveness or attractiveness of tobacco products should be banned. The revised Product Directive should be fully compliant with the guidelines on Articles 9 & 10 adopted at the fourth Conference of the Parties of the FCTC on 20th November 2010.

**access to tobacco products****problem definition**

Yes

**which option**

Ban

**which one2**

Cross-border retail sales of tobacco to be banned over the Internet; Vending machines to be banned; Promotion and displays in retail stores to be banned

**additional option**

No

**additional comments**

Internet. The principle of preventing cross-border promotion of tobacco products in order to protect public health was enshrined in the Tobacco Advertising directive (2001/0119). It is logical, therefore, to extend that principle to the sale of tobacco products between member states via the Internet. We support the prohibition of tobacco sales via the Internet. Vending machines. The majority of member states (22 out of 27) already prohibit the sale of tobacco products from vending machines in order to deter young people accessing cigarettes from this source. We support this measure. Point of Sale. We support an EU-wide adoption of a ban on the display of tobacco products at the point of sale. Across the EU, most forms of tobacco advertising are now prohibited but the tobacco industry continues to market its products by the use of attractive packaging. Research shows that point of sale displays of tobacco have a direct impact on young people's intention to smoke. Furthermore, there is a growing body of evidence to show that putting tobacco products out of sight in retail outlets can reduce youth smoking. To date, this measure has been adopted by Ireland and Finland (as well as Iceland and Norway) and is going through the parliamentary process in the UK. Point of Sale Display of Tobacco Products. The Centre for Tobacco Control Research. University of Stirling, 2008. Tobacco displays at the point of sale. ASH Briefing, Nov. 2010

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## **NGO submission**

### **identification**

#### **affiliation**

NGO

#### **name**

Città del Tabacco - Associazione Italiana dei Paesi e delle Città del Tabacco, aderente a Res Tipica/ANCI - Associazione Nazionale Comuni Italiani, Presidente Fernanda Cecchini

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#### **country**

Italia

#### **questions scope**

##### **problem definition**

Yes

#### **which option**

No change

#### **additional comments**

Non reputiamo necessario un allargamento dell'ambito della Direttiva ad altre categorie di prodotti. Seppure riteniamo interessante controllare il mercato delle sigarette senza tabacco, non si può accettare il divieto proposto per tutte le forme di tabacco senza fumo tra cui lo "snus" che rappresenta sbocchi interessanti per alcuni Paesi, non essendo stata dimostrata scientificamente una nocività di questi prodotti analoga a quella degli altri prodotti del tabacco.

#### **questions smokeless**

##### **problem definition**

No

#### **comments**

La spiegazione dettagliata è nello spazio relativo alla scelta dell'opzione.

#### **which option**

Lifting the ban on snus

#### **additional comments**

Riteniamo ingiusto che la commercializzazione del tabacco umido in polvere per uso orale (c.d. "snus") sia consentita in un solo Stato dell'UE, ovvero la Svezia, e vietata in tutti gli altri Stati. Il divieto di vendita non è basato su prove scientifiche ed andrebbe rimosso. La nostra posizione è sostenuta anche dal fatto che, in Svezia, diverse ricerche scientifiche dimostrano la riduzione dell'incidenza delle patologie correlate al fumo rispetto alla media UE proprio grazie all'utilizzo dello "snus". Inoltre, anche la percentuale dei fumatori sul totale della

popolazione è inferiore alla media UE. Tale dato dimostrerebbe l'efficacia dello "snus" come potenziale strumento di supporto per smettere di consumare prodotti da fumo. Ci auguriamo, quindi, che lo "snus" venga liberamente commercializzato in tutti gli Stati Membri del mercato unico europeo.

**questions consumer**

**problem definition**

No

**explanations**

La spiegazione dettagliata è nello spazio relativo alla scelta dell'opzione.

**which option**

No change

**additional comments**

Non esistono più fumatori che ignorano i pericoli del consumo. Le foto non hanno dato la prova della loro efficienza. La consapevolezza dei rischi sanitari connessi al prodotto, come sostenuto da più ricerche scientifiche, non aumenta con l'utilizzo di ulteriori avvertenze speciali. A nostro avviso, quindi, la possibilità di inserire avvertenze sotto forma di fotografie a colori o altre illustrazioni dovrebbe essere lasciata alla libera iniziativa degli Stati Membri, come previsto dalla Direttiva attuale. Inoltre, l'introduzione di restrizioni sul pacchetto (es. il c.d. pacchetto generico che riteniamo un'aberrazione per un prodotto da banco e il rischio di mascherare il prodotto a discapito della qualità del tabacco), come suggerito dall'opzione 3, a nostro avviso, mina seriamente la sopravvivenza stessa dell'industria legale a causa del rischio di incremento della contraffazione dei prodotti che va a tutto vantaggio del commercio illecito e delle organizzazioni criminali, rendendo il prodotto più accessibile ai giovani.

**questions on reporting**

**problem definition**

Yes

**which option**

Establish a common compulsory reporting format

**regulation of ingredients**

**problem definition**

No

**explanations**

La spiegazione dettagliata è nello spazio relativo alla scelta dell'opzione.

**which option**

No Change

**additional comments**

Il rischio che alcuni o anche tutti gli ingredienti, vengano vietati, senza fondamento scientifico, è troppo grande. A nostro avviso, la regolamentazione degli ingredienti inseriti nei prodotti del tabacco dovrebbe rimanere competenza degli Stati Membri, come già previsto dall'attuale Direttiva. Questo anche in virtù dei risultati del rapporto del Comitato SCENIHR,

incaricato dalla Commissione Europea/DG SANCO di valutare il ruolo degli ingredienti utilizzati in riferimento all'attrattività e all'assuefazione degli stessi. Il rapporto conferma che l'attrattività è un concetto assolutamente soggettivo. L'eventuale divieto di uso degli ingredienti avrebbe gravissime ripercussioni economiche ed occupazionali per il settore del tabacco greggio in Italia. Queste misure, infatti, renderebbero non più economicamente conveniente la coltivazione di alcune varietà di tabacco utilizzato per la produzione di sigarette di tipo American blend e la sopravvivenza dell'intero settore della coltivazione e della prima trasformazione del tabacco in Italia, che occupano circa 60.000 addetti, verrebbe seriamente minata.

### **access to tobacco products**

#### **problem definition**

Yes

#### **which option**

Controlled supply and access

#### **which supply and access**

Age verification of buyers and other legal conditions to be set for cross-border retail sale;  
Access to vending machines to be restricted to adults

#### **additional comments**

Riteniamo opportuno una discussione sull'accesso controllato, ma non attraverso un approccio di restrizioni globali globale all'interno delle tabaccherie e di internet, che è difficilmente controllabile. A nostro avviso, la determinazione delle misure che stabiliscono i limiti all'accesso ai prodotti a base di tabacco dovrebbe rimanere competenza degli Stati Membri. In particolare, siamo contrari ad ulteriori ed ingiustificate restrizioni, come il divieto totale di esposizione dei prodotti, in quanto determinano una sorta di criminalizzazione del consumo di un prodotto legale, con gravi ripercussioni su tutta la filiera produttiva. Peraltro, auspichiamo che la Direttiva adotti la regolamentazione già presente in Italia, in particolare per quanto riguarda la verifica dell'età dell'acquirente e l'installazione di distributori automatici provvisti di sistema di verifica anagrafica. Infine, supportiamo le restrizioni prospettate per le vendite via internet poiché tali misure, a nostro avviso, preservano il livello qualitativo del prodotto garantito, in Italia, dal sistema di concessione delle licenze ai prodotti del tabacco tutelando, quindi, anche la salute del consumatore.

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### **NGO submission**

#### **identification**

##### **affiliation**

NGO

##### **name**

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**country**

Belgium

**questions scope****problem definition**

Yes

**which option**

Extend the scope of the Directive

**questions smokeless****problem definition**

Yes

**which option**

No change

**questions consumer****problem definition**

Yes

**which option**

Improve consumer information; Introduce generic or plain packaging

**which improvement**

Picture warnings to become mandatory; Tar, nicotine and carbon monoxide levels to be replaced with general information on harmful substances in tobacco products; Information on harmful substances in tobacco products that cannot be placed on the package would be placed inside the package; Health warnings to be put on water pipes

**additional comments**

Picture warnings to become mandatory; tar, nicotine and carbon monoxide levels to be replaced with general information on harmful substances in tobacco products; health warnings to be put on water pipes and introduction of generic or plain packaging are high priority

**questions on reporting****problem definition**

Yes

**which option**

Establish a common compulsory reporting format

**regulation of ingredients****problem definition**

Yes

**which option**

Establish a common list of tobacco ingredients

**which one**

Establish a positive common list of tobacco ingredients

**access to tobacco products**

**problem definition**

Yes

**which option**

Ban

**which one2**

Cross-border retail sales of tobacco to be banned over the Internet; Vending machines to be banned; Promotion and displays in retail stores to be banned

**additional comments**

This is a very high priority

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**NGO submission**

**identification**

**affiliation**

NGO

**name**

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**country**

Germany

**questions scope**

**problem definition**

Yes

**which option**

Extend the scope of the Directive

**additional comments**

[http://www.dkfz.de/de/tabakkontrolle/download/Publikationen/RoteReihe/Band\\_16\\_Tobacco\\_Product\\_Directive\\_en.pdf](http://www.dkfz.de/de/tabakkontrolle/download/Publikationen/RoteReihe/Band_16_Tobacco_Product_Directive_en.pdf)

**questions smokeless**

**problem definition**

Yes

**which option**

Ban on all types of smokeless tobacco products



**additional comments**

[http://www.dkfz.de/de/tabakkontrolle/download/Publikationen/RoteReihe/Band\\_16\\_Tobacco\\_Product\\_Directive\\_en.pdf](http://www.dkfz.de/de/tabakkontrolle/download/Publikationen/RoteReihe/Band_16_Tobacco_Product_Directive_en.pdf)

[http://www.dkfz.de/de/tabakkontrolle/download/Publikationen/AdWfP/AdWfdP\\_Snus\\_en.pdf](http://www.dkfz.de/de/tabakkontrolle/download/Publikationen/AdWfP/AdWfdP_Snus_en.pdf)

[http://www.dkfz.de/de/tabakkontrolle/download/Publikationen/AdWfP/Literatur\\_Snus\\_en.pdf](http://www.dkfz.de/de/tabakkontrolle/download/Publikationen/AdWfP/Literatur_Snus_en.pdf)

**questions consumer****problem definition**

Yes

**which option**

Improve consumer information; Introduce generic or plain packaging

**which improvement**

Picture warnings to become mandatory; Tar, nicotine and carbon monoxide levels to be replaced with general information on harmful substances in tobacco products; Information on harmful substances in tobacco products that cannot be placed on the package would be placed inside the package; Health warnings to be put on water pipes

**additional comments**

[http://www.dkfz.de/de/tabakkontrolle/download/Publikationen/RoteReihe/Band\\_16\\_Tobacco\\_Product\\_Directive\\_en.pdf](http://www.dkfz.de/de/tabakkontrolle/download/Publikationen/RoteReihe/Band_16_Tobacco_Product_Directive_en.pdf)

[http://www.dkfz.de/de/tabakkontrolle/download/Publikationen/RoteReihe/Kombinierte\\_Warnhinweise\\_Band\\_10.pdf](http://www.dkfz.de/de/tabakkontrolle/download/Publikationen/RoteReihe/Kombinierte_Warnhinweise_Band_10.pdf)

[http://www.dkfz.de/de/tabakkontrolle/download/Publikationen/AdWfP/AdWfP\\_Standardisierte\\_Verpackungen.pdf](http://www.dkfz.de/de/tabakkontrolle/download/Publikationen/AdWfP/AdWfP_Standardisierte_Verpackungen.pdf)

[http://www.dkfz.de/de/tabakkontrolle/download/Publikationen/FzR/FzR\\_Carcinogens.pdf](http://www.dkfz.de/de/tabakkontrolle/download/Publikationen/FzR/FzR_Carcinogens.pdf)

[http://www.dkfz.de/de/tabakkontrolle/download/Publikationen/FzR/FzR\\_Wasserpfeife.pdf](http://www.dkfz.de/de/tabakkontrolle/download/Publikationen/FzR/FzR_Wasserpfeife.pdf)

[http://www.dkfz.de/de/tabakkontrolle/download/Publikationen/FzR/Literatur\\_FzR\\_Wasserpfeife.pdf](http://www.dkfz.de/de/tabakkontrolle/download/Publikationen/FzR/Literatur_FzR_Wasserpfeife.pdf)

**questions on reporting****problem definition**

Yes

**which option**

Establish a common compulsory reporting format; Introduce fees and sanctions

**regulation of ingredients****problem definition**

Yes

**which option**

Establish a common list of tobacco ingredients

**additional comments**

[http://www.dkfz.de/de/tabakkontrolle/download/Publikationen/Fakten/Factsheet\\_Strategy\\_for\\_Toxicity\\_Evaluation\\_.pdf](http://www.dkfz.de/de/tabakkontrolle/download/Publikationen/Fakten/Factsheet_Strategy_for_Toxicity_Evaluation_.pdf)

[http://www.dkfz.de/de/tabakkontrolle/download/Publikationen/Fakten/Factsheet\\_Zusatzstoffe](http://www.dkfz.de/de/tabakkontrolle/download/Publikationen/Fakten/Factsheet_Zusatzstoffe)

\_engl.pdf

[http://www.dkfz.de/de/tabakkontrolle/download/Publikationen/RoteReihe/Band\\_16\\_Tobacco\\_Product\\_Directive\\_en.pdf](http://www.dkfz.de/de/tabakkontrolle/download/Publikationen/RoteReihe/Band_16_Tobacco_Product_Directive_en.pdf)

[http://www.dkfz.de/de/tabakkontrolle/download/Publikationen/RoteReihe/Tabakindustriedokumente\\_I.pdf](http://www.dkfz.de/de/tabakkontrolle/download/Publikationen/RoteReihe/Tabakindustriedokumente_I.pdf)

[http://www.dkfz.de/de/tabakkontrolle/download/Publikationen/RoteReihe/Rauchlose\\_Tabakprodukte\\_Band6.pdf](http://www.dkfz.de/de/tabakkontrolle/download/Publikationen/RoteReihe/Rauchlose_Tabakprodukte_Band6.pdf)

**access to tobacco products**

**problem definition**

Yes

**which option**

Ban

**which one2**

Cross-border retail sales of tobacco to be banned over the Internet; Vending machines to be banned; Promotion and displays in retail stores to be banned

---

**NGO submission**

**identification**

**affiliation**

NGO

**name**

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**email**

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**country**

Poland

**age**

36

**gender**

male

**questions scope**

**problem definition**

Yes

**which option**

No change

**questions smokeless**

**problem definition**

Yes

**which option**

Lifting the ban on snus

**questions consumer****problem definition**

Yes

**which option**

No change

**questions on reporting****problem definition**

No

**explanations**

Bez komentarza

**which option**

Establish a common compulsory reporting format

**regulation of ingredients****problem definition**

No

**explanations**

Celem przepisów Unii Europejskiej i Polski powinno być zmniejszenie szkodliwych właściwości papierosów. Wskazany jest wyznczenie jasnych i czytelnych kryteriów bdań nad szkodliwością papierosów.

**which option**

No Change

**access to tobacco products****problem definition**

No

**explanations**

Szacuje się że w Polsce jest około 130 000 punktów sprzedaży papierosów. Właściciele tych punktów mają prawo pokazywania produktów, które mają w obrocie. Nie są znane żadne dowody na to że zakaz ekspozycji papierosów ograniczy palenie. Dostosowanie punktów wiązać się będzie z wprowadzeniem zmian co oznacza duże koszty.

**which option**

No change

---

## **NGO submission**

### **identification**

#### **affiliation**

NGO

#### **name**

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#### **country**

Belgium

### **questions scope**

#### **problem definition**

Yes

#### **which option**

Extend the scope of the Directive

### **additional comments**

All tobacco products are hazardous to health – there is no safe level of usage. Therefore we recommend that the scope of the Directive includes the regulation of any new smoked tobacco products (such as low emission or nicotine-free cigarettes), while the prohibition of any novel forms of oral tobacco, including snus, should be maintained. Herbal cigarettes are also harmful because it is the combustion and inhalation of smoke that causes most of the harm from smoking. Therefore, herbal cigarettes should be included in the scope Tobacco Products Directive and should also be subject to health warnings requirements. Finally, all forms of nicotine based products (that is, products containing nicotine but which are not tobacco products, such as electronic cigarettes, nicotine gel, drinks, and sweets) are often marketed as alternatives to cigarettes and in some cases as an aid to quitting smoking. Therefore, they should only be sold as quitting aids and comply with specific safety and quality requirements under the same regulatory framework as pharmaceutical products rather than under the scope of the Tobacco Products Directive.

### **questions smokeless**

#### **problem definition**

Yes

#### **which option**

No change

### **additional option**

The ban on snus should definitely be maintained. This is high priority. Indeed, there is no legitimate reason to introduce a dangerous product onto the market, particularly as, from an internal market point of view, we have no idea how snus would be perceived or used in other countries. A small study conducted by the University of Nottingham by Professor Ann

McNeil showed that, in the UK, people could not see the point of snus unless it was as a cessation aid (i.e. there is currently no demand). For internal market purposes, it really does not make sense to lift the ban. Furthermore, if the ban on snus were to be lifted, it could encourage dual use of cigarettes and smokeless tobacco and discourage total abstinence from tobacco, thus weakening any potential health gains. In this context, we stress that there are already available effective treatments for nicotine addiction, including medicinal or ‘clean’ nicotine (NRT), that do not carry the risks associated with the use of snus. These should be promoted first and foremost. It is clear that the public health interest can be served even more by encouraging a) greater use of these treatments and b) the development of more effective cessation aids, especially those that mimic more closely the nicotine ‘hit’ delivered by cigarettes. Regarding other forms of smokeless tobacco products, the SFP does not believe that they should be “marketed” in all Member States. We recognise that they are as addictive and dangerous as smoked tobacco. As stated in the Opinion of the Scientific Committee on Emerging and Newly Identified Health Risks (SCENIHR), many forms of smokeless tobacco increase the risk of mouth, esophageal, pancreatic and liver cancer, and other conditions including gum and heart disease. However, we also know that these products are mostly consumed in the UK and used by South Asian communities; introducing an EU-wide ban on these products now could lead to the creation of an unnecessary illegal market, pushing consumption underground. This is why we do not recommend an immediate ban on all types of smokeless tobacco products; we do recommend that they should be regulated in the same way as tobacco products.

**questions consumer  
problem definition**

No

**explanations**

The ban on snus should definitely be maintained. This is high priority. Indeed, there is no legitimate reason to introduce a dangerous product onto the market, particularly as, from an internal market point of view, we have no idea how snus would be perceived or used in other countries. A small study conducted by the University of Nottingham by Professor Ann McNeil showed that, in the UK, people could not see the point of snus unless it was as a cessation aid (i.e. there is currently no demand). For internal market purposes, it really does not make sense to lift the ban. Furthermore, if the ban on snus were to be lifted, it could encourage dual use of cigarettes and smokeless tobacco and discourage total abstinence from tobacco, thus weakening any potential health gains. In this context, we stress that there are already available effective treatments for nicotine addiction, including medicinal or ‘clean’ nicotine (NRT), that do not carry the risks associated with the use of snus. These should be promoted first and foremost. It is clear that the public health interest can be served even more by encouraging a) greater use of these treatments and b) the development of more effective cessation aids, especially those that mimic more closely the nicotine ‘hit’ delivered by cigarettes. Regarding other forms of smokeless tobacco products, the SFP does not believe that they should be “marketed” in all Member States. We recognise that they are as addictive and dangerous as smoked tobacco. As stated in the Opinion of the Scientific Committee on Emerging and Newly Identified Health Risks (SCENIHR), many forms of smokeless tobacco increase the risk of mouth, esophageal, pancreatic and liver cancer, and other conditions including gum and heart disease. However, we also know that these products are mostly consumed in the UK and used by South Asian communities; introducing an EU-wide ban on these products now could lead to the creation of an unnecessary illegal market, pushing consumption underground. This is why we do not recommend an immediate ban on all types

of smokeless tobacco products; we do recommend that they should be regulated in the same way as tobacco products.

### **which option**

Improve consumer information; Introduce generic or plain packaging

### **which improvement**

Picture warnings to become mandatory; Tar, nicotine and carbon monoxide levels to be replaced with general information on harmful substances in tobacco products; Information on harmful substances in tobacco products that cannot be placed on the package would be placed inside the package; Health warnings to be put on water pipes

### **additional option**

Crucial importance of Graphic health warnings: Evidence shows that text only warning messages are not as effective as graphic warnings. Pictures, especially fear inducing pictures, are proven to be effective in getting consumers more engaged with the warning message. Pictures are able to immediately provoke a reaction and prompt people to read the associated text message. The need for graphic health warnings on both sides of the pack: There is also evidence that pictures on both sides of the packaging have a greater impact. The need for LARGE pictorial health warnings (80%): Evidence clearly shows that increasing the size of warning messages (text only and combined text and picture) increases the effectiveness of the warning amongst both young and adult smokers / non smokers. Research carried out in Canada by Createc on behalf of Health Canada in 2007 showed that young and adult smokers/non smokers are sensitive to the size of health warning messages. Results showed that warning messages that cover 100% of the pack are significantly more effective across all measured effectiveness indicators compared with warning messages that cover only 50% of the pack. The importance of Rotation: Warning texts and pictures should be displayed on a rotating basis, so that each message is given equal display and can reach its target audience. The proved effectiveness of shocking health warnings & targeted messages: as specified in the Sambrook Research International report, fear inducing warnings (using strong “shocking” images related to health risks such as rotten teeth or throat cancer) and strong emotion inducing warnings (especially involving children and unborn babies) are the most effective way to educate consumers on the health risks of tobacco use and to achieve changes in attitudes and behaviour. These warnings’ effectiveness is enhanced if they are used in conjunction with a quit line. Generic or plain packaging: We strongly recommend the introduction of standardised/plain packaging. This should include not only the removal of all branding from the packaging but the size and shape of the packaging should also be standardised. Not only would this prevent the promotion of smoking through branding as occurs presently but it would reinforce the health warning messages. Tobacco packaging provides a direct link between consumers and manufacturers and is the main marketing channel, particularly in jurisdictions with tobacco advertising bans. Branding gives the misleading impression some cigarettes are safer than others. The tobacco industry claims that plain packaging would contravene intellectual property law. However, legal analysis concludes that this is incorrect and there are no international legal impediments to the implementation of generic packaging. Replace TNCO quantitative labelling with qualitative information on contents, emissions and quit-lines: The inclusion of machine-based tar, nicotine and carbon monoxide yields on cigarette packs promotes the mistaken belief that some cigarette brands are less harmful than others. We support the proposal to replace numerical measurements with descriptive information on the hazardous effects of tobacco constituents and emissions. We stress the importance of putting quit line numbers on the

package. As underlined in the Sambrook research (p46), providing a telephone number on the pack is more effective than telling smokers to seek advice from a doctor or pharmacist. P46 Health warnings on water pipes: There is a growing body of evidence to show that water pipes are at least as hazardous, if not more so, than other forms of tobacco use. Warnings should also be included on the packaging of tobacco used in water pipes.

### **additional comments**

The importance of Rotation: Warning texts and pictures should be displayed on a rotating basis, so that each message is given equal display and can reach its target audience. The proved effectiveness of shocking health warnings & targeted messages: as specified in the Sambrook Research International report, fear inducing warnings (using strong “shocking” images related to health risks such as rotten teeth or throat cancer) and strong emotion inducing warnings (especially involving children and unborn babies) are the most effective way to educate consumers on the health risks of tobacco use and to achieve changes in attitudes and behaviour. These warnings’ effectiveness is enhanced if they are used in conjunction with a quit line. Generic or plain packaging: We strongly recommend the introduction of standardised/plain packaging. This should include not only the removal of all branding from the packaging but the size and shape of the packaging should also be standardised. Not only would this prevent the promotion of smoking through branding as occurs presently but it would reinforce the health warning messages. Tobacco packaging provides a direct link between consumers and manufacturers and is the main marketing channel, particularly in jurisdictions with tobacco advertising bans. Branding gives the misleading impression some cigarettes are safer than others. The tobacco industry claims that plain packaging would contravene intellectual property law. However, legal analysis concludes that this is incorrect and there are no international legal impediments to the implementation of generic packaging. Replace TNCO quantitative labelling with qualitative information on contents, emissions and quit-lines: The inclusion of machine-based tar, nicotine and carbon monoxide yields on cigarette packs promotes the mistaken belief that some cigarette brands are less harmful than others. We support the proposal to replace numerical measurements with descriptive information on the hazardous effects of tobacco constituents and emissions. We stress the importance of putting quit line numbers on the package. As underlined in the Sambrook research (p46), providing a telephone number on the pack is more effective than telling smokers to seek advice from a doctor or pharmacist. P46 Health warnings on water pipes: There is a growing body of evidence to show that water pipes are at least as hazardous, if not more so, than other forms of tobacco use. Warnings should also be included on the packaging of tobacco used in water pipes.

### **questions on reporting**

#### **problem definition**

Yes

#### **which option**

Establish a common compulsory reporting format

### **additional comments**

The current situation which allows different formats and reporting mechanisms is unsatisfactory, making it difficult for authorities to compare and analyse the data. All tobacco manufacturers and importers should be subject to the same reporting requirements. The SFP believes that tobacco products, which are highly harmful, should be subject to an effective reporting system that allows the gathering and analysis of relevant data, including comparison

as appropriate, in order to ensure high levels of consumer safety and information. The format already exists (based on the voluntary reporting format developed by the Commission in May 2007) and it would therefore be very easy to adopt this measure and to implement it. We welcome the introduction of yearly registration fees in order to finance the data collection on ingredients by the national authorities and their analysis work on ingredients. The payment of penalties in case of non-compliance with the requirements of delivery of data on tobacco product ingredients also seems adequate and would contribute to fund the tests conducted on these products. It is crucial that the appropriate toxicological and addictiveness tests are properly conducted. Such tests would allow policy-makers to make more informed decisions in this field, as there would be more scientific evidence. It would enhance the scientific knowledge of the dangers of tobacco products and would contribute to a high protection of health, as stated in Article 95.3 TFEU. Besides, such measures would also have an indirect impact on illicit trade, since only registered products would be allowed on the market.

### **regulation of ingredients**

#### **problem definition**

Yes

#### **which option**

Establish a common list of tobacco ingredients

#### **which one**

Establish a positive common list of tobacco ingredients

#### **additional comments**

We support the adoption of a positive common list of tobacco ingredients. We believe that tobacco products are highly toxic and addictive, and that their content should therefore be closely regulated, in order to achieve high standards of health protection, as stated under article 114.3. There is a need for such a list at EU level since at the moment, consumers in the internal market are not subject to the same level of protection. Some citizens may be using substances that are banned in other Member States. Apart from creating unequal health protection across the EU, this may constitute an obstacle to free movement of goods within the internal market: some countries can refuse access to their markets of cigarettes from Member States that do not comply with the importing Member State's national requirements. Regulation of Flavours and Ingredients: Flavourings are an increasingly important part of tobacco industry marketing, particularly to young people. Flavourings enhance attractiveness, encourage youth initiation, and discourage cessation. The prohibition of ingredients that may be used to increase attractiveness, such as sugars and sweeteners, flavouring substances, and spices and herbs, in cigarettes and cigarette-like tobacco products should be introduced. The prohibition of ingredients that may create the impression of a health benefit (e.g. vitamins), ingredients associated with energy and vitality (e.g. caffeine), and ingredients with colouring properties (e.g. pink cigarette paper) should also be banned. Tobacco manufacturers and importers should report sales volume information by brand. This information is essential to help governments ensure that product regulation is effective. The above measures should be compliant with the Guidelines on Art. 9/10, adopted unanimously at the Fourth Conference of the Parties in Uruguay on the 20th November 2010.

### **access to tobacco products**

#### **problem definition**

Yes



**which option**

Ban

**which one2**

Cross-border retail sales of tobacco to be banned over the Internet; Vending machines to be banned; Promotion and displays in retail stores to be banned

**additional option**

We urge the Commission to call for a ban on the promotion of tobacco products at point of sale and a ban on vending machines as described in the Art 13 Guidelines of the FCTC.

**additional comments**

Internet. The principle of preventing cross-border promotion of tobacco products in order to protect public health was enshrined in the Tobacco Advertising directive (2001/0119). It is logical, therefore, to extend that principle to the sale of tobacco products between member states via the Internet. We support the prohibition of tobacco sales via the Internet. Vending machines. The majority of member states (22 out of 27) already prohibit the sale of tobacco products from vending machines in order to deter young people accessing cigarettes from this source. We support this measure. Point of Sale. Evidence shows that a coordinated cross border marketing strategy on the part of the tobacco companies is reflected at point of sale (i.e. point of sale marketing is similar in most EU countries (i.e.: a brand is advertised at point of sale in the same way in Germany and Belgium). There is a growing body of evidence to show that putting tobacco products out of sight in retail outlets can reduce youth smoking. To date, this measure has been adopted by Ireland and Finland (as well as Iceland and Norway). This measure is also official government policy in Scotland, Wales and Northern Ireland and a decision is awaited in England. We strongly support an EU-wide adoption of a ban on the display of tobacco products at the point of sale.

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**NGO submission****identification****affiliation**

NGO

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Fédération des Tabacs du Nord Pas de Calais

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sylvainhodicq@orange.fr

**country**

france

**questions scope****problem definition**

Yes

**which option**

No change

**questions smokeless****problem definition**

No

**comments**

Il n'y a pas d'études scientifiques efficaces prouvant les risques concernant les produits du tabac sans fumée

**which option**

Lifting the ban on snus

**questions consumer****problem definition**

No

**explanations**

Aucune étude ne prouve l'efficacité des paquets neutres aucune étude ne prouve l'efficacité des photos chocs

**which option**

No change

**questions on reporting****problem definition**

Yes

**which option**

Establish a common compulsory reporting format

**regulation of ingredients****problem definition**

No

**explanations**

Cela risque d'entraîner une standardisation de la production avec comme conséquence une diminution de l'offre au fumeur adulte et responsable, et cela risque de voir apparaître une augmentation des produits du tabac contrefait

**which option**

No Change

**access to tobacco products****problem definition**

Yes

**which option**

Controlled supply and access; Ban

**which supply and access**

Age verification of buyers and other legal conditions to be set for cross-border retail sale

**which one2**

Cross-border retail sales of tobacco to be banned over the Internet; Vending machines to be banned

---

**NGO submission**

**identification**

**affiliation**

NGO

**name**

Endres Christof

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**country**

Deutschland

**questions scope**

**problem definition**

Yes

**which option**

No change

**questions smokeless**

**problem definition**

Yes

**which option**

No change

**questions consumer**

**problem definition**

Yes

**which option**

No change

**questions on reporting**

**problem definition**

Yes

**which option**

No change

**regulation of ingredients**

**problem definition**

Yes

**which option**

No Change

**access to tobacco products**

**problem definition**

Yes

**which option**

No change

---

**NGO submission**

**identification**

**affiliation**

NGO

**name**

Witold Sosnówka

**email**

nho e-mail

**country**

Poland

**questions scope**

**problem definition**

Yes

**which option**

No change

**recommend option**

n.a

**additional comments**

n.a

**questions smokeless**

**problem definition**

No

**comments**

n.a

**which option**

No change

**additional option**

n.a

**additional comments**

n.a

**questions consumer**

**problem definition**

No

**explanations**

n.a

**which option**

No change

**additional option**

n.a

**additional comments**

n.a

**questions on reporting**

**problem definition**

Yes

**which option**

No change

**additional options**

n.a

**additional comments**

n.a

**regulation of ingredients**

**problem definition**

No

**explanations**

n.a

**which option**

No Change

**additional option**

n.a

**additional comments**

n.a

**access to tobacco products**

**problem definition**

No

**explanations**

n.a

**which option**

No change

**additional option**

n.a

**additional comments**

n.a

---

**NGO submission**

**identification**

**affiliation**

NGO

**name**

Fathi

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totti10200510@hotmail.com

**country**

deutschland

**age**

40

**gender**

male

**questions scope**

**problem definition**

Yes

**which option**

No change

**recommend option**

No change

**additional comments**

No change

**questions smokeless**

**problem definition**

Yes

**which option**

No change

**additional option**

No change

**additional comments**

No change

**questions consumer**

**problem definition**

Yes

**which option**

No change

**additional option**

No change

**additional comments**

No change

**questions on reporting**

**problem definition**

Yes

**which option**

No change

**additional options**

No change

**additional comments**

No change

**regulation of ingredients**

**problem definition**

Yes

**which option**

No Change

**additional option**

No Change

**additional comments**

No Change

**access to tobacco products**

**problem definition**

Yes

**which option**

No change

**additional option**

No change

**additional comments**

No change

---

**NGO submission**

**identification**

**affiliation**

NGO

**name**

Youth Association No Excuse Slovenia // Jan Peloza - president

**email**

info@noexcuse.si

**country**

Slovenia

**age**

25

**gender**

male

**questions scope**

**problem definition**



Yes

**which option**

Extend the scope of the Directive

**additional comments**

Nicotine drinks and nicotine sweets may rather be taken as "drugs" not as "Foods". Also, electronic cigarettes should not be advertised and should only be available on doctor's receipt. Only in this way it would be a pharmaceutical product that would not promote smoking! For some people smoking electronic cigarettes is really cool and fancy and some avoid the smoke-free public places law with it!

**questions smokeless**

**problem definition**

Yes

**which option**

Ban on all types of smokeless tobacco products

**additional comments**

We should strictly forbid smokeless tobacco advertising and to keep smokeless tobacco prohibited in the countries where it is already prohibited.

**questions consumer**

**problem definition**

Yes

**which option**

Introduce generic or plain packaging

**additional comments**

Uvede naj se standardizirana unificirana embalaža tobačnih izdelkov (bela škatlica, Arial 12 črna pisava, brez dodatkov na škatlici, razen zdravstvenih opozoril in vsebnosti toksičnih snovi) Ustrezna površina naj se določa na na podlagi vnaprej določene površine, ki ni pogojena z veličino škatlice (razlaga: S tem se zminimalizira napore tobačne industrije, da zmanjša prostornine tobačne škatlice zato, da je napis o vsebnosti snovi oz.zdravstvenih opozoril čimbolj neberljiv) Poleg omenjenih treh snovi, naj se v okvirčku omeni, da izdelek vsebuje še več kot 4 tisoč drugih snovi, od česar jih je preko 60 dokazano rakotvornih. Za ta namen naj se poveča tudi odstotek površine tobačnega izdelka Napis »Kajenje lahko ubija» ni spremenljiv. Izdelek, ki ubije več kot polovico svojih uporabnikov ne more biti kategoriziran kot izdelek, ki lahko ubija ampak mora biti kategoriziran kot smrtonosni izdelek. »Kajenje ubija« in pika, če ne celo »Tobačni izdelki ubijejo polovico svojih uporabnikov« Dodatno je potrebno prepovedati uporabo zavajajočih napisov kot je "light blue", "glamour", "silver" itd.

**questions on reporting**

**problem definition**

Yes

**which option**

Introduce fees and sanctions

**additional comments**

We should not forget that they are marketing a heavy drug that kills more people than any other product in the world. Also, no other thing to be consumed exists with NO available information about ingredients. At least not in Slovenia!

**regulation of ingredients****problem definition**

Yes

**which option**

Establish a common list of tobacco ingredients

**additional comments**

The common list is easiest and cheapest to achieve. The stress should be put on the addictive substances that are used in tobacco products

**access to tobacco products****problem definition**

Yes

**which option**

Ban

**which one2**

Cross-border retail sales of tobacco to be banned over the Internet; Vending machines to be banned; Promotion and displays in retail stores to be banned

**additional comments**

The tobacco should not be sold in the same shops as food or clothes. It should be sold in specialized shops to which only adults would have access. The specialized shops should acquire the license to sell the product just upon Government approval. The license should be given upon respecting certain rules (max availability of the product in a certain area, training of staff, no tobacco advertisement on the vending points etc.). The rules to acquire the license should be consulted with the public health institutions, NGOs and independent researching bodies. The tobacco industry must be taken out of the process of drafting the rules for the license acquire.

---

**NGO submission****identification****affiliation**

NGO

**name**

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**country**

Deutschland

**age**

51

**gender**

female

**questions scope**

**problem definition**

Yes

**which option**

No change

**questions smokeless**

**problem definition**

No

**comments**

we have enough warning on the smoking pack

**which option**

No change

**questions consumer**

**problem definition**

No

**explanations**

we are old enough to know what we do

**which option**

No change

**questions on reporting**

**problem definition**

No

**explanations**

know it is good for all

**which option**

No change

**regulation of ingredients**

**problem definition**

No

**explanations**

es gibt ein allgemeines Bewusstsein zum Rauchen, wir sind mündige Bürger und brauchen keine weiteren Richtlinien der EU. Es reicht allmählich mit den Reglementierungen

**which option**

No Change

**access to tobacco products**

**problem definition**

No

**explanations**

es existieren genug Warnhinweise auf den Zigarettenpackungen, wir sind mündige Bürger und brauchen keine weiteren Reglementierungen der EU

**which option**

No change

---

**NGO submission**

**identification**

**affiliation**

NGO

**name**

CYPRUS CHAMBER OF COMMERCE AND INDUSTRY

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**country**

CYPRUS

**questions scope**

**problem definition**

Yes

**which option**

No change

**recommend option**

THE SCOPE OF THE DIRECTIVE SHOULD COVER OTHER TOBACO PRODUCTS, BUT ANY BANS SHOULD BE SUPPORTED BY SCIENTIFIC EVIDENCE.

**questions smokeless**

**problem definition**

Yes

**which option**

No change

**questions consumer**

**problem definition**

No

**explanations**

TO DATE THERE IS NO SCIENTIFIC PROOF THAT SUGGESTS THAT BIGGER HEALTH WARNINGS ARE MORE EFFECTIVE. OPTIONS SUCH AS GENERIC PACKAGING WOULD MAKE IT EASIER TO CREATE COUNTERFEIT PRODUCTS AND WOULD ALSO VIOLATE INTELLECTUAL PROPERTY RIGHTS, A FUNDAMENTAL PRINCIPLE OF FREE TRADE.

**which option**

No change

**questions on reporting**

**problem definition**

Yes

**which option**

No change

**regulation of ingredients**

**problem definition**

Yes

**which option**

No Change

**access to tobacco products**

**problem definition**

No

**explanations**

WITH REGARDS TO THE PROHIBITION OF THE DISPLAY OF TOBACCO PRODUCTS THERE IS NO EVIDENCE THAT SUCH A MEASURE WOULD ACHIEVE HEALTH OBJECTIVES. ON THE OTHER HAND THE IMPLEMENTATION OF THE MEASURE IN OTHER COUNTRIES SUCH AS IRELAND HAS CREATED MANY PROBLEMS TO RETAILERS.

**which option**

No change

---

**NGO submission**

**identification****affiliation**

NGO

**name**

Chambre Syndicale des Buralistes des Deux-Sèvres 79

**email**

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**country**

FRANCE

**questions scope****problem definition**

Yes

**which option**

No change

**questions smokeless****problem definition**

No

**comments**

Il n'y a pas d'études scientifiques efficaces prouvant les risques concernant les produits du tabac sans fumée.

**which option**

Lifting the ban on snus

**questions consumer****problem definition**

No

**explanations**

Aucune étude ne prouve l'efficacité des paquets neutres. Aucune étude ne prouve l'efficacité des photos chocs, ni même de plus grands avertissements sanitaires sur les paquets. La mise en place de paquets neutres risque d'entraîner une guerre des prix du tabac (puisque cela restera le seul moyen pour les fabricants de se différencier). La mise en place de photos chocs sur les 2 faces des paquets ou de paquets génériques va pousser les consommateurs français à aller s'approvisionner sur les marchés parallèles du tabac (achats à l'étranger ou de contrebande, ou sur internet. De telles mesures risquent de déstabiliser et pénaliser économiquement le réseau des 28 000 buralistes français organisés dans un réseau réglementé et sous tutelle de l'Etat.

**which option**

No change

**questions on reporting****problem definition**

Yes

**which option**

Establish a common compulsory reporting format

**regulation of ingredients****problem definition**

No

**explanations**

Cela risque d'entraîner une standardisation de la production avec comme conséquence une diminution de l'offre au fumeur adulte et responsable, et le risque de voire apparaitre une augmentation des produits du tabac contrefaits.

**which option**

No Change

**access to tobacco products****problem definition**

Yes

**which option**

Controlled supply and access; Ban

**which supply and access**

Age verification of buyers and other legal conditions to be set for cross-border retail sale

**which one2**

Cross-border retail sales of tobacco to be banned over the Internet; Vending machines to be banned

**additional comments**

Il n'y a pas de corrélation prouvée entre la disparition des linéaires tabac et la lutte contre le tabagisme. La France dispose d'un réseau de 28 000 buralistes, préposés de l'administration responsables et professionnels, seuls habilités à vendre du tabac. Ce réseau est fortement réglementé par l'Etat ce qui permet déjà de contrôler efficacement l'accès au produit tabac.

---

**NGO submission****identification****affiliation**

NGO

**name**

Chambre Syndicale des Buralistes des Deux-Sèvres 79

**email**

daniel-billaud@wanadoo.fr

**country**

France

**questions scope****problem definition**

Yes

**which option**

No change

**questions smokeless****problem definition**

No

**comments**

Il n'y a pas d'études scientifiques efficaces prouvant les risques concernant les produits du tabac sans fumée.

**which option**

Lifting the ban on snus

**questions consumer****problem definition**

No

**explanations**

Aucune étude ne prouve l'efficacité des paquets neutres. Aucune étude ne prouve l'efficacité des photos chocs, ni même de plus grands avertissements sanitaires sur les paquets. La mise en place de paquets neutres risque d'entraîner une guerre des prix du tabac (puisque cela restera le seul moyen pour les fabricants de se différencier). La mise en place de photos chocs sur les 2 faces des paquets ou de paquets génériques va pousser les consommateurs français à aller s'approvisionner sur les marchés parallèles du tabac (achats à l'étranger ou de contrebande, ou sur internet. De telles mesures risquent de déstabiliser et pénaliser économiquement le réseau des 28 000 buralistes français organisés dans un réseau réglementé et sous tutelle de l'Etat.

**which option**

No change

**questions on reporting****problem definition**

Yes

**which option**

Establish a common compulsory reporting format

**regulation of ingredients**



**problem definition**

No

**explanations**

Cela risque d'entraîner une standardisation de la production avec comme conséquence une diminution de l'offre au fumeur adulte et responsable, et le risque de voire apparaitre une augmentation des produits du tabac contrefaits.

**which option**

No Change

**access to tobacco products****problem definition**

Yes

**which option**

Controlled supply and access; Ban

**which supply and access**

Age verification of buyers and other legal conditions to be set for cross-border retail sale

**which one2**

Cross-border retail sales of tobacco to be banned over the Internet; Vending machines to be banned

---

**NGO submission****identification****affiliation**

NGO

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**country**

Spain

**questions scope****problem definition**

Yes

**which option**

Extend the scope of the Directive

**questions smokeless**

**problem definition**

Yes

**which option**

No change

**questions consumer  
problem definition**

Yes

**which option**

Improve consumer information

**which improvement**

Information on harmful substances in tobacco products that cannot be placed on the package would be placed inside the package

**questions on reporting  
problem definition**

Yes

**which option**

Establish a common compulsory reporting format

**regulation of ingredients**

**problem definition**

Yes

**which option**

Establish a common list of tobacco ingredients

**access to tobacco products**

**problem definition**

Yes

**which option**

Ban

**which one2**

Cross-border retail sales of tobacco to be banned over the Internet; Vending machines to be banned

---

**NGO submission**

**identification**

**affiliation**

NGO

**name**

CHAMBRE SYNDICALE DES BURALISTES DE LA HAUTE-VIENNE

**email**

buralistes-hautevienne@orange.fr

**country**

FRANCE

**questions scope****problem definition**

Yes

**which option**

No change

**questions smokeless****problem definition**

No

**comments**

il n'y a pas d'études scientifiques efficaces prouvant les risques concernant les produits du tabac sans fumée

**which option**

Lifting the ban on snus

**questions consumer****problem definition**

No

**explanations**

aucune étude ne prouve l'efficacité des paquets neutres. Aucune étude ne prouve l'efficacité des photos chocs, ni même de plus grans avertissements sanitaires sur les paquets. La mise en place de paquets neutres risque d'entraîner une guerre des prix du tabac (puisque cela restera le seul moyen pour les fabricants de se différencier). La mise en place de photos chocs sur les 2 faces des paquets ou de paquets génériques va pousser les consommateurs français à aller s'approvisionner sur les marchés parallèles du tabac (achats à l'étranger ou de contrebande, ou sur internet; De telles mesures risquent de déstabiliser et pénaliser économiquement le réseau des 28 000 buralistes français organisés dans un réseau réglementé et sous tutelle de l'Etat.

**which option**

No change

**questions on reporting****problem definition**

Yes

**which option**

Establish a common compulsory reporting format

**regulation of ingredients****problem definition**

No

**explanations**

Cela risque d'entraîner une standardisation de la production avec comme conséquence une diminution de l'offre au fumeur adulte et responsable, et le risque de voire apparaitre une augmentation des produits du tabac contrefaits

**which option**

No Change

**access to tobacco products****problem definition**

Yes

**which option**

Controlled supply and access

**which supply and access**

Age verification of buyers and other legal conditions to be set for cross-border retail sale

**additional option**

Il n'y a pas de corrélation prouvée entre la disparition des linéaires tabac et la lutte contre le tabagiste. La France dsipose d'un réseau de 28 000 buralistes, préposés de l'administration responsables et professionnel, seuls habilités à vendre du tabac. Ce réseau esty fortement réglementé par l'Etat ce qui permet déjà de contrôler l'accès au produit tabac

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**NGO submission****identification****affiliation**

NGO

**name**

MARÍA JESÚS AMENABAR

**email**

aaguiamenabar@hotmail.com

**country**

Spain

**age**

65

**gender**

female

**questions scope**  
**problem definition**

No

**explanations**

This must be actual but the actualization must be made if it is sensefull. With these changes the Directive will be worse and it won't be better. Furhtermore, with this changes the illegal market will increase.

**which option**

No change

**recommend option**

In my opinion the biggest problem is the illegal market and I would like the efforts to be concentrated in reducing and disappearing the illegal market.

**questions smokeless**

**problem definition**

No

**comments**

The ban on snus has no sense. It is not bad for anybody's health.

**which option**

No change

**additional option**

No.

**questions consumer**

**problem definition**

No

**explanations**

Every tobacconist company like Philip Morris for example, gives information of the ingredients of their brands of tobacco. People can find this information if wanted and it is not necessary that it appears in each package.

**which option**

No change

**additional comments**

People can find this information if wanted and it is not necessary that it appears in each package.

**questions on reporting**

**problem definition**

No

**explanations**

Everybody can find this information if wanted. The health organisations and even the tobacco companies provide this information. I don't think that it is necessary at all that this information appears in every single package.

**which option**

No change

**additional options**

Governments of each country should be free to apply the regulation for each country.

**regulation of ingredients****problem definition**

No

**explanations**

The elimination of some ingredients and flavours would make an unification of flavours and there wouldn't be a variety of products. If we add this point to the fact that another proposal is the unification of the package format, in consequence customers won't be able to distinguish one brand from another and finally, the cheapest brand will be sold and the illegal market will increase.

**which option**

No Change

**additional option**

No change.

**additional comments**

The European Union published a document made by the Scientific Committee about the risks for health recently identified that depends on the European Commission. In this report is said that even though the tobacco is potentially addictive, it hasn't been able to evaluate the addiction of each ingredient.

**access to tobacco products****problem definition**

No

**explanations**

This revision will cause the opposite effect that it wants to have and the illegal market would be much more powerful. I mean this extended directive has no sense in my opinion. I think that it is totally wrong that the European Commission allows that something is sold but customers cannot watch it in the shop, that is, that the product must be cashed. No change is the best. So, will be permitted to sell it by the Internet? If the product cannot be seen before it is sold... If tobacco cannot be sold in the machines and other shops will sell it, the illegal market will increase and much lower control and regulation will be the consequences.

**which option**

No change

**additional option**

No change.

**additional comments**

The desire of every owner of a tobacconist is that the illegal market is decreased and big controls of the market are taken. This extended Directive, however, would cause the opposite effect. It seems that this extended directive is proposed by people who know nothing about the tobacco market and by people who don't understand this market.

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**NGO submission****identification****affiliation**

NGO

**name**

CHAMBRE SYNDICALE DES BURALISTES DU GERS

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**country**

france

**questions scope****problem definition**

Yes

**which option**

No change

**questions smokeless****problem definition**

No

**comments**

Il n'y a eu aucune étude de faite prouvant une éventuelle nocivité du tabac sans fumée

**which option**

Lifting the ban on snus

**questions consumer****problem definition**

No

**explanations**

Aucun étude sur les photos chocs et les avertissements sanitaires n'a prouvé leur efficacité

tout comme les paquets neutres. La mise en place de ces derniers entrainera une guerre des prix du tabac car celà restera le seul moyen pour les fabricants de se différencier. La mise en place des photos chocs sur deux faces en France va entraîner les fumeurs français à s'approvisionner à l'étranger ou sur les marchés parallèles et mafieux et sur le net. Le réseau des buralistes en France est bien encadré et réglementé sous tutelle de l'Etat et de telles mesures risquent de déstabiliser ce réseau de proximité.

**which option**

No change

**questions on reporting**

**problem definition**

Yes

**which option**

Establish a common compulsory reporting format

**regulation of ingredients**

**problem definition**

No

**explanations**

Il y a un gros risque de voir apparaître une augmentation de paquets contrefaits bien plus nocifs que le tabac "légal" et celà entraînera aussi une standardisation de la production avec une diminution de l'offre au fumeur adulte et responsable.

**which option**

No Change

**access to tobacco products**

**problem definition**

Yes

**which option**

Controlled supply and access; Ban

**which supply and access**

Age verification of buyers and other legal conditions to be set for cross-border retail sale

**which one2**

Cross-border retail sales of tobacco to be banned over the Internet; Vending machines to be banned

**additional comments**

Il n'y a aucune étude qui prouve un lien entre la disparition des linéaires tabac et la lutte contre le tabagisme La France dispose d'un réseau de 28 000 buralistes, préposés de l'administration, responsables et professionnels, seuls habilités à vendre du tabac. Ce réseau est fortement règlementé par l'Etat ce qui permet déjà de contrôler efficacement l'accès au produit tabac.



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## **NGO submission**

### **identification**

#### **affiliation**

NGO

#### **name**

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#### **country**

Lithuania

### **questions scope**

#### **problem definition**

Yes

#### **which option**

Extend the scope of the Directive

### **questions smokeless**

#### **problem definition**

Yes

#### **which option**

No change

### **questions consumer**

#### **problem definition**

No

### **explanations**

There is no scientific evidence connecting size of the Pictorial Health Warnings size with the effectiveness of the health message. Also, there is no evidence about the effect on the consumer behaviour of plain/generic packaging. In fact, making all cigarette packs to look the same way, would make it easier to counterfeit tobacco products.

#### **which option**

No change

### **additional comments**

We believe that informed consumers have a possibility to choose themselves to smoke or not to smoke. Member states must provide continuous educational programs against smoking and other harmful habits in schools, universities and other public platforms.

### **questions on reporting**

**problem definition**

Yes

**which option**

Establish a common compulsory reporting format

**regulation of ingredients****problem definition**

No

**explanations**

It should not be allowed to regulate ingredients on the basis of subjective criteria of "attractiveness", which cannot be proven by scientific evidence. Attractiveness is very subjective and different from one country to another.

**which option**

No Change

**access to tobacco products****problem definition**

No

**explanations**

No problem is defined in the problem definition section. However, retail trade is very local phenomenon and has no impact on the functioning of the internal market. Therefore, regulation of the retail trade should not be part of the Tobacco Products Directive.

**which option**

No change

**additional comments**

Banning display of tobacco products in retail shops is very likely to aggravate the issue of contraband and illegal sales of tobacco products.

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**NGO submission****identification****affiliation**

NGO

**name**

European Heart Network

**email**

mkestens@ehnheart.org

**country**

Belgium

**gender**  
female

**questions scope**  
**problem definition**  
Yes

**which option**  
Extend the scope of the Directive

**additional comments**  
All tobacco products are hazardous to health – there is no safe level of usage. Therefore we recommend that the scope of the Directive includes the regulation of any new smoked tobacco products (such as low emission or nicotine-free cigarettes), while the prohibition of any novel forms of oral tobacco, including snus, should be maintained. Herbal cigarettes are also harmful because it is the combustion and inhalation of smoke that causes most of the harm from smoking. Therefore, herbal cigarettes should be included in the scope Tobacco Products Directive and should also be subject to health warnings requirements. Finally, all forms of nicotine based products (that is, products containing nicotine but which are not tobacco products, such as electronic cigarettes, nicotine gel, drinks, and sweets) are often marketed as alternatives to cigarettes and in some cases as an aid to quitting smoking. Therefore, they should only be sold as quitting aids and comply with specific safety and quality requirements under the same regulatory framework as pharmaceutical products rather than under the scope of the Tobacco Products Directive.

**questions smokeless**  
**problem definition**  
Yes

**which option**  
No change

**additional option**  
The ban on snus should definitely be maintained. This is high priority. Indeed, there is no legitimate reason to introduce a dangerous product onto the market, particularly as, from an internal market point of view, we have no idea how snus would be perceived or used in other countries. A small study conducted by the University of Nottingham by Professor Ann McNeil showed that, in the UK, people could not see the point of snus unless it was as a cessation aid (i.e. there is currently no demand). For internal market purposes, it really does not make sense to lift the ban. Furthermore, if the ban on snus were to be lifted, it could encourage dual use of cigarettes and smokeless tobacco and discourage total abstinence from tobacco, thus weakening any potential health gains. In this context, we stress that there are already available effective treatments for nicotine addiction, including medicinal or ‘clean’ nicotine (NRT), that do not carry the risks associated with the use of snus. These should be promoted first and foremost. It is clear that the public health interest can be served even more by encouraging a) greater use of these treatments and b) the development of more effective cessation aids, especially those that mimic more closely the nicotine ‘hit’ delivered by cigarettes. Regarding other forms of smokeless tobacco products, the SFP does not believe that they should be “marketed” in all Member States. We recognise that they are as addictive

and dangerous as smoked tobacco. As stated in the Opinion of the Scientific Committee on Emerging and Newly Identified Health Risks (SCENIHR), many forms of smokeless tobacco increase the risk of mouth, esophageal, pancreatic and liver cancer, and other conditions including gum and heart disease. However, we also know that these products are mostly consumed in the UK and used by South Asian communities; introducing an EU-wide ban on these products now could lead to the creation of an unnecessary illegal market, pushing consumption underground. This is why we do not recommend an immediate ban on all types of smokeless tobacco products; we do recommend that they should be regulated in the same way as tobacco products.

### **questions consumer**

#### **problem definition**

No

#### **explanations**

The problem definition could be improved. We agree with the Commission that the current situation, whereby some Member States have made graphic warnings compulsory and others not, has led to a disparity in labelling throughout the EU. Consequently, this has an impact on the functioning of the internal market, on consumers' awareness and as a result, on their smoking behaviour. We also agree that packaging as an advertising tool is not covered by the current Directive. Finally, we welcome the acknowledgement that tobacco packaging and product features are increasingly used to attract consumers, to promote products and brand image. In this context, it would have been judicious to highlight the fact that, in the Eurobarometer survey released in 2010, the policy that received the most positive response is that of putting health warnings on all packages of tobacco products (on average, 75% of EU citizens are in favour of mandatory pictorial warnings, and over 54% support plain packaging measures).

#### **which option**

Improve consumer information; Introduce generic or plain packaging

#### **which improvement**

Picture warnings to become mandatory; Tar, nicotine and carbon monoxide levels to be replaced with general information on harmful substances in tobacco products; Information on harmful substances in tobacco products that cannot be placed on the package would be placed inside the package; Health warnings to be put on water pipes

#### **additional option**

Crucial importance of Graphic health warnings: Evidence shows that text only warning messages are not as effective as graphic warnings. Pictures, especially fear inducing pictures, are proven to be effective in getting consumers more engaged with the warning message. Pictures are able to immediately provoke a reaction and prompt people to read the associated text message. The need for graphic health warnings on both sides of the pack: There is also evidence that pictures on both sides of the packaging have a greater impact. The need for LARGE pictorial health warnings (80%): Evidence clearly shows that increasing the size of warning messages (text only and combined text and picture) increases the effectiveness of the warning amongst both young and adult smokers / non smokers. Research carried out in Canada by Createc on behalf of Health Canada in 2007 showed that young and adult smokers/non smokers are sensitive to the size of health warning messages. Results showed that warning messages that cover 100% of the pack are significantly more effective across all

measured effectiveness indicators compared with warning messages that cover only 50% of the pack. The importance of Rotation: Warning texts and pictures should be displayed on a rotating basis, so that each message is given equal display and can reach its target audience. The proved effectiveness of shocking health warnings & targeted messages: as specified in the Sambrook Research International report, fear inducing warnings (using strong “shocking” images related to health risks such as rotten teeth or throat cancer) and strong emotion inducing warnings (especially involving children and unborn babies) are the most effective way to educate consumers on the health risks of tobacco use and to achieve changes in attitudes and behaviour. These warnings’ effectiveness is enhanced if they are used in conjunction with a quit line. Generic or plain packaging: We strongly recommend the introduction of standardised/plain packaging. This should include not only the removal of all branding from the packaging but the size and shape of the packaging should also be standardised. Not only would this prevent the promotion of smoking through branding as occurs presently but it would reinforce the health warning messages. Tobacco packaging provides a direct link between consumers and manufacturers and is the main marketing channel, particularly in jurisdictions with tobacco advertising bans. Branding gives the misleading impression some cigarettes are safer than others. The tobacco industry claims that plain packaging would contravene intellectual property law. However, legal analysis concludes that this is incorrect and there are no international legal impediments to the implementation of generic packaging. Replace TNCO quantitative labelling with qualitative information on contents, emissions and quit-lines: The inclusion of machine-based tar, nicotine and carbon monoxide yields on cigarette packs promotes the mistaken belief that some cigarette brands are less harmful than others. We support the proposal to replace numerical measurements with descriptive information on the hazardous effects of tobacco constituents and emissions. We stress the importance of putting quit line numbers on the package. As underlined in the Sambrook research (p46), providing a telephone number on the pack is more effective than telling smokers to seek advice from a doctor or pharmacist. P46 Health warnings on water pipes: There is a growing body of evidence to show that water pipes are at least as hazardous, if not more so, than other forms of tobacco use. Warnings should also be included on the packaging of tobacco used in water pipes.

### **additional comments**

Under Article 5.3 of the TPD 2001, Member States have the option to adopt pictorial warnings. This situation emphasised the right of Member States to go further than the Directive to protect public health as set out in Article 30 of the Treaty of the Union (now article 36). Ten years after the entering into force of the TPD, four countries (the UK, Belgium, Romania and Malta) have adopted the option. More countries such as Spain and France are planning to adopt mandatory pictorial warnings. Such measures are in compliance with the current TPD and are welcomed by the tobacco control community. However, their adoption by some Member States necessarily creates growing discrepancies between Member States. As stated above, there is clear evidence that pictorial warnings are much more powerful than written health warnings. Extending the information and protection to all EU Member States would be in harmony with Article 168 of the TFEU and consistent with the objectives of the internal market stated in Article 114.3 of the TFEU and reiterated in Recital 19 of the Directive. A revision of the TPD should, therefore, aim at making pictorial health warnings of tobacco products subject to common rules. Note: Legislation on labelling, advertising and product regulation put forward by the Commission in the field of tobacco control, has been based on the internal market legislation (Articles 26 and 114 of the TFEU). Article 26 of the TFEU establishes the internal market. Article 114 gives EU institutions the competence to regulate and set rules for the functioning of the internal market. More

specifically, article 114.3 also states that when establishing rules for the functioning of the internal market in the context of health, safety, environmental protection and consumer protection, the Commission “will take as a base a high level of protection, taking account in particular of any new development based on scientific facts.” The European Court of Justice (the “ECJ”) made an extensive analysis of Article 95 EC (now Article 114) throughout the years. In *Spain v. Council*, the Court observed that “recourse to Article 100a (now Article 114) as a legal basis is possible if the aim is to prevent the emergence of future obstacles to trade resulting from multifarious development of national laws.” The TPD was adopted on the basis of Article 114 TFEU (ex Article 95). As a result, Recital 19 of the TPD states that “[t]he presentation of warning labels and yields has continued to remain variable in the different Member States. As a consequence, consumers in one Member State may be better informed as to the risks of tobacco products than in another. Such differences are unacceptable and are liable to constitute a barrier to trade and to impede the operation of the internal market in tobacco products, and should therefore be eliminated.”

### **questions on reporting**

#### **problem definition**

Yes

#### **which option**

Establish a common compulsory reporting format; Introduce fees and sanctions

#### **additional comments**

The current situation which allows different formats and reporting mechanisms is unsatisfactory, making it difficult for authorities to compare and analyse the data. All tobacco manufacturers and importers should be subject to the same reporting requirements. The SFP believes that tobacco products, which are highly harmful, should be subject to an effective reporting system that allows the gathering and analysis of relevant data, including comparison as appropriate, in order to ensure high levels of consumer safety and information. The format already exists (based on the voluntary reporting format developed by the Commission in May 2007) and it would therefore be very easy to adopt this measure and to implement it. We welcome the introduction of yearly registration fees in order to finance the data collection on ingredients by the national authorities and their analysis work on ingredients. The payment of penalties in case of non-compliance with the requirements of delivery of data on tobacco product ingredients also seems adequate and would contribute to fund the tests conducted on these products. It is crucial that the appropriate toxicological and addictiveness tests are properly conducted. Such tests would allow policy-makers to make more informed decisions in this field, as there would be more scientific evidence. It would enhance the scientific knowledge of the dangers of tobacco products and would contribute to a high protection of health, as stated in Article 95.3 TFEU. Besides, such measures would also have an indirect impact on illicit trade, since only registered products would be allowed on the market.

### **regulation of ingredients**

#### **problem definition**

Yes

#### **which option**

Establish a common list of tobacco ingredients

#### **which one**

Establish a positive common list of tobacco ingredients

**additional comments**

We support the adoption of a positive common list of tobacco ingredients. We believe that tobacco products are highly toxic and addictive, and that their content should therefore be closely regulated, in order to achieve high standards of health protection, as stated under article 114.3. There is a need for such a list at EU level since at the moment, consumers in the internal market are not subject to the same level of protection. Some citizens may be using substances that are banned in other Member States. Apart from creating unequal health protection across the EU, this may constitute an obstacle to free movement of goods within the internal market: some countries can refuse access to their markets of cigarettes from Member States that do not comply with the importing Member State's national requirements. Regulation of Flavours and Ingredients: Flavourings are an increasingly important part of tobacco industry marketing, particularly to young people. Flavourings enhance attractiveness, encourage youth initiation, and discourage cessation. The prohibition of ingredients that may be used to increase attractiveness, such as sugars and sweeteners, flavouring substances, and spices and herbs, in cigarettes and cigarette-like tobacco products should be introduced. The prohibition of ingredients that may create the impression of a health benefit (e.g. vitamins), ingredients associated with energy and vitality (e.g. caffeine), and ingredients with colouring properties (e.g. pink cigarette paper) should also be banned. Tobacco manufacturers and importers should report sales volume information by brand. This information is essential to help governments ensure that product regulation is effective. The above measures should be compliant with the Guidelines on Art. 9/10, adopted unanimously at the Fourth Conference of the Parties in Uruguay on the 20th November 2010.

**access to tobacco products**

**problem definition**

Yes

**which option**

Ban

**which one2**

Cross-border retail sales of tobacco to be banned over the Internet; Vending machines to be banned; Promotion and displays in retail stores to be banned

**additional option**

We urge the Commission to call for a ban on the promotion of tobacco products at point of sale and a ban on vending machines as described in the Art 13 Guidelines of the FCTC.

**additional comments**

Internet. The principle of preventing cross-border promotion of tobacco products in order to protect public health was enshrined in the Tobacco Advertising directive (2001/0119). It is logical, therefore, to extend that principle to the sale of tobacco products between member states via the Internet. We support the prohibition of tobacco sales via the Internet. Vending machines. The majority of member states (22 out of 27) already prohibit the sale of tobacco products from vending machines in order to deter young people accessing cigarettes from this source. We support this measure. Point of Sale. Evidence shows that a coordinated cross border marketing strategy on the part of the tobacco companies is reflected at point of sale (i.e. point of sale marketing is similar in most EU countries (i.e.: a brand is advertised at point

of sale in the same way in Germany and Belgium). There is a growing body of evidence to show that putting tobacco products out of sight in retail outlets can reduce youth smoking. To date, this measure has been adopted by Ireland and Finland (as well as Iceland and Norway). This measure is also official government policy in Scotland, Wales and Northern Ireland and a decision is awaited in England. We strongly support an EU-wide adoption of a ban on the display of tobacco products at the point of sale.

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## **NGO submission**

### **identification**

#### **affiliation**

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#### **questions scope**

#### **problem definition**

Yes

#### **which option**

Extend the scope of the Directive

#### **additional comments**

All tobacco products are hazardous to health – there is no safe level of usage. Therefore we recommend that the scope of the Directive includes the regulation of any new smoked tobacco products (such as low emission or nicotine-free cigarettes), while the prohibition of any novel forms of oral tobacco, including snus, should be maintained. Herbal cigarettes are also harmful because it is the combustion and inhalation of smoke that causes most of the harm from smoking. Therefore, herbal cigarettes should be included in the scope Tobacco Products Directive and should also be subject to health warnings requirements. Finally, all forms of nicotine based products (that is, products containing nicotine but which are not tobacco products, such as electronic cigarettes, nicotine gel, drinks, and sweets) are often marketed as alternatives to cigarettes and in some cases as an aid to quitting smoking. Therefore, they should only be sold as quitting aids and comply with specific safety and quality requirements under the same regulatory framework as pharmaceutical products rather than under the scope



of the Tobacco Products Directive.

**questions smokeless**

**problem definition**

Yes

**which option**

No change

**additional comments**

The ban on snus should definitely be maintained. This is high priority. Indeed, there is no legitimate reason to introduce a dangerous product onto the market, particularly as, from an internal market point of view, we have no idea how snus would be perceived or used in other countries. A small study conducted by the University of Nottingham by Professor Ann McNeil showed that, in the UK, people could not see the point of snus unless it was as a cessation aid (i.e. there is currently no demand). For internal market purposes, it really does not make sense to lift the ban. Furthermore, if the ban on snus were to be lifted, it could encourage dual use of cigarettes and smokeless tobacco and discourage total abstinence from tobacco, thus weakening any potential health gains. In this context, we stress that there are already available effective treatments for nicotine addiction, including medicinal or 'clean' nicotine (NRT), that do not carry the risks associated with the use of snus. These should be promoted first and foremost. It is clear that the public health interest can be served even more by encouraging a) greater use of these treatments and b) the development of more effective cessation aids, especially those that mimic more closely the nicotine 'hit' delivered by cigarettes. Regarding other forms of smokeless tobacco products, the SFP does not believe that they should be "marketed" in all Member States. We recognise that they are as addictive and dangerous as smoked tobacco. As stated in the Opinion of the Scientific Committee on Emerging and Newly Identified Health Risks (SCENIHR), many forms of smokeless tobacco increase the risk of mouth, esophageal, pancreatic and liver cancer, and other conditions including gum and heart disease. However, we also know that these products are mostly consumed in the UK and used by South Asian communities; introducing an EU-wide ban on these products now could lead to the creation of an unnecessary illegal market, pushing consumption underground. This is why we do not recommend an immediate ban on all types of smokeless tobacco products ; we do recommend that they should be regulated in the same way as tobacco products.

**questions consumer**

**problem definition**

No

**explanations**

We do not "disagree" with the problem definition but would like to state that it could be improved. We agree with the Commission that the current situation, whereby some Member States have made graphic warnings compulsory and others not, has led to a disparity in labelling throughout the EU. Consequently, this has an impact on the functioning of the internal market, on consumers' awareness and as a result, on their smoking behaviour. We also agree that packaging as an advertising tool is not covered by the current Directive. Finally, we welcome the acknowledgement that tobacco packaging and product features are increasingly used to attract consumers, to promote products and brand image. Improvement: In this context, it would have been judicious to highlight the fact that, in the Eurobarometer

survey released in 2010, the policy that received the most positive response is that of putting health warnings on all packages of tobacco products (on average, 75% of EU citizens are in favour of mandatory pictorial warnings, and over 54% support plain packaging measures).

### **which option**

Improve consumer information; Introduce generic or plain packaging

### **which improvement**

Picture warnings to become mandatory; Tar, nicotine and carbon monoxide levels to be replaced with general information on harmful substances in tobacco products; Information on harmful substances in tobacco products that cannot be placed on the package would be placed inside the package; Health warnings to be put on water pipes

### **additional option**

Crucial importance of Graphic health warnings: Evidence shows that text only warning messages are not as effective as graphic warnings. Pictures, especially fear inducing pictures, are proven to be effective in getting consumers more engaged with the warning message. Pictures are able to immediately provoke a reaction and prompt people to read the associated text message. The need for graphic health warnings on both sides of the pack: There is also evidence that pictures on both sides of the packaging have a greater impact. The need for LARGE pictorial health warnings (80%): Evidence clearly shows that increasing the size of warning messages (text only and combined text and picture) increases the effectiveness of the warning amongst both young and adult smokers / non smokers. Research carried out in Canada by Createc on behalf of Health Canada in 2007 showed that young and adult smokers/non smokers are sensitive to the size of health warning messages. Results showed that warning messages that cover 100% of the pack are significantly more effective across all measured effectiveness indicators compared with warning messages that cover only 50% of the pack. The importance of Rotation: Warning texts and pictures should be displayed on a rotating basis, so that each message is given equal display and can reach its target audience. The proved effectiveness of shocking health warnings & targeted messages: as specified in the Sambrook Research International report, fear inducing warnings (using strong “shocking” images related to health risks such as rotten teeth or throat cancer) and strong emotion inducing warnings (especially involving children and unborn babies) are the most effective way to educate consumers on the health risks of tobacco use and to achieve changes in attitudes and behaviour. These warnings’ effectiveness is enhanced if they are used in conjunction with a quit line. Generic or plain packaging: We strongly recommend the introduction of standardised/plain packaging. This should include not only the removal of all branding from the packaging but the size and shape of the packaging should also be standardised. Not only would this prevent the promotion of smoking through branding as occurs presently but it would reinforce the health warning messages. Tobacco packaging provides a direct link between consumers and manufacturers and is the main marketing channel, particularly in jurisdictions with tobacco advertising bans. Branding gives the misleading impression some cigarettes are safer than others. The tobacco industry claims that plain packaging would contravene intellectual property law. However, legal analysis concludes that this is incorrect and there are no international legal impediments to the implementation of generic packaging. Replace TNCO quantitative labelling with qualitative information on contents, emissions and quit-lines: The inclusion of machine-based tar, nicotine and carbon monoxide yields on cigarette packs promotes the mistaken belief that some cigarette brands are less harmful than others. We support the proposal to replace numerical measurements with descriptive information on the hazardous effects of tobacco

constituents and emissions. We stress the importance of putting quit line numbers on the package. As underlined in the Sambrook research (p46), providing a telephone number on the pack is more effective than telling smokers to seek advice from a doctor or pharmacist. P46 Health warnings on water pipes: There is a growing body of evidence to show that water pipes are at least as hazardous, if not more so, than other forms of tobacco use. Warnings should also be included on the packaging of tobacco used in water pipes.

### **additional comments**

Under Article 5.3 of the TPD 2001, Member States have the option to adopt pictorial warnings. This situation emphasised the right of Member States to go further than the Directive to protect public health as set out in Article 30 of the Treaty of the Union (now article 36). Ten years after the entering into force of the TPD, four countries (the UK, Belgium, Romania and Malta) have adopted the option. More countries such as Spain and France are planning to adopt mandatory pictorial warnings. Such measures are in compliance with the current TPD and are welcomed by the tobacco control community. However, their adoption by some Member States necessarily creates growing discrepancies between Member States. As stated above, there is clear evidence that pictorial warnings are much more powerful than written health warnings. Extending the information and protection to all EU Member States would be in harmony with Article 168 of the TFEU and consistent with the objectives of the internal market stated in Article 114.3 of the TFEU and reiterated in Recital 19 of the Directive. A revision of the TPD should, therefore, aim at making pictorial health warnings of tobacco products subject to common rules. Note: Legislation on labelling, advertising and product regulation put forward by the Commission in the field of tobacco control, has been based on the internal market legislation (Articles 26 and 114 of the TFEU). Article 26 of the TFEU establishes the internal market. Article 114 gives EU institutions the competence to regulate and set rules for the functioning of the internal market. More specifically, article 114.3 also states that when establishing rules for the functioning of the internal market in the context of health, safety, environmental protection and consumer protection, the Commission “will take as a base a high level of protection, taking account in particular of any new development based on scientific facts.” The European Court of Justice (the “ECJ”) made an extensive analysis of Article 95 EC (now Article 114) throughout the years. In *Spain v. Council*, the Court observed that “recourse to Article 100a (now Article 114) as a legal basis is possible if the aim is to prevent the emergence of future obstacles to trade resulting from multifarious development of national laws.” The TPD was adopted on the basis of Article 114 TFEU (ex Article 95). As a result, Recital 19 of the TPD states that “[t]he presentation of warning labels and yields has continued to remain variable in the different Member States. As a consequence, consumers in one Member State may be better informed as to the risks of tobacco products than in another. Such differences are unacceptable and are liable to constitute a barrier to trade and to impede the operation of the internal market in tobacco products, and should therefore be eliminated.”

### **questions on reporting**

#### **problem definition**

Yes

#### **which option**

Establish a common compulsory reporting format; Introduce fees and sanctions

### **additional comments**

The current situation which allows different formats and reporting mechanisms is

unsatisfactory, making it difficult for authorities to compare and analyse the data. All tobacco manufacturers and importers should be subject to the same reporting requirements. The SFP believes that tobacco products, which are highly harmful, should be subject to an effective reporting system that allows the gathering and analysis of relevant data, including comparison as appropriate, in order to ensure high levels of consumer safety and information. The format already exists (based on the voluntary reporting format developed by the Commission in May 2007) and it would therefore be very easy to adopt this measure and to implement it. We welcome the introduction of yearly registration fees in order to finance the data collection on ingredients by the national authorities and their analysis work on ingredients. The payment of penalties in case of non-compliance with the requirements of delivery of data on tobacco product ingredients also seems adequate and would contribute to fund the tests conducted on these products. It is crucial that the appropriate toxicological and addictiveness tests are properly conducted. Such tests would allow policy-makers to make more informed decisions in this field, as there would be more scientific evidence. It would enhance the scientific knowledge of the dangers of tobacco products and would contribute to a high protection of health, as stated in Article 95.3 TFEU. Besides, such measures would also have an indirect impact on illicit trade, since only registered products would be allowed on the market.

### **regulation of ingredients**

#### **problem definition**

Yes

#### **which option**

Establish a common list of tobacco ingredients

#### **which one**

Establish a positive common list of tobacco ingredients

#### **additional option**

The above measures should be compliant with the Guidelines on Art. 9/10, adopted unanimously at the Fourth Conference of the Parties in Uruguay on the 20th November 2010.

#### **additional comments**

We support the adoption of a positive common list of tobacco ingredients. We believe that tobacco products are highly toxic and addictive, and that their content should therefore be closely regulated, in order to achieve high standards of health protection, as stated under article 114.3. There is a need for such a list at EU level since at the moment, consumers in the internal market are not subject to the same level of protection. Some citizens may be using substances that are banned in other Member States. Apart from creating unequal health protection across the EU, this may constitute an obstacle to free movement of goods within the internal market: some countries can refuse access to their markets of cigarettes from Member States that do not comply with the importing Member State's national requirements. Regulation of Flavours and Ingredients: Flavourings are an increasingly important part of tobacco industry marketing, particularly to young people. Flavourings enhance attractiveness, encourage youth initiation, and discourage cessation. The prohibition of ingredients that may be used to increase attractiveness, such as sugars and sweeteners, flavouring substances, and spices and herbs, in cigarettes and cigarette-like tobacco products should be introduced. The prohibition of ingredients that may create the impression of a health benefit (e.g. vitamins), ingredients associated with energy and vitality (e.g. caffeine), and ingredients with colouring properties (e.g. pink cigarette paper) should also be banned. Tobacco manufacturers and

importers should report sales volume information by brand. This information is essential to help governments ensure that product regulation is effective.

**access to tobacco products**

**problem definition**

Yes

**which option**

Ban

**which one2**

Cross-border retail sales of tobacco to be banned over the Internet; Vending machines to be banned; Promotion and displays in retail stores to be banned

**additional option**

We urge the Commission to call for a ban on the promotion of tobacco products at point of sale and a ban on vending machines as described in the Art 13 Guidelines of the FCTC.

**additional comments**

Internet. The principle of preventing cross-border promotion of tobacco products in order to protect public health was enshrined in the Tobacco Advertising directive (2001/0119). It is logical, therefore, to extend that principle to the sale of tobacco products between member states via the Internet. We support the prohibition of tobacco sales via the Internet. Vending machines. The majority of member states (22 out of 27) already prohibit the sale of tobacco products from vending machines in order to deter young people accessing cigarettes from this source. We support this measure. Point of Sale. Evidence shows that a coordinated cross border marketing strategy on the part of the tobacco companies is reflected at point of sale (i.e. point of sale marketing is similar in most EU countries (i.e.: a brand is advertised at point of sale in the same way in Germany and Belgium). There is a growing body of evidence to show that putting tobacco products out of sight in retail outlets can reduce youth smoking. To date, this measure has been adopted by Ireland and Finland (as well as Iceland and Norway). This measure is also official government policy in Scotland, Wales and Northern Ireland and a decision is awaited in England. We strongly support an EU-wide adoption of a ban on the display of tobacco products at the point of sale.

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**NGO submission**

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NGO

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**questions scope**

**problem definition**

Yes

**which option**

Extend the scope of the Directive

**recommend option**

no

**additional comments**

I do not lead a health organisation but an organisation to protect non-smokers. So, Pro Rauchfrei, the biggest non-smoker organisation in Germany with about 2.000 members wants to ban all products which produce smoke. Our opinion is, that everybody can choose to kill himself but not any other. So non-smoke products (like snus) must not be forbidden.

**questions smokeless**

**problem definition**

Yes

**which option**

No change

**additional option**

there must be a ban for all smoke products without any exception: smokefree restaurants, smokefree pubs, smokefree outdoor sections in restaurants. Ban for advertising smoke products (tobacco and other products which emit smoke)

**additional comments**

no cigarette machine

**questions consumer**

**problem definition**

Yes

**which option**

Improve consumer information; Introduce generic or plain packaging

**which improvement**

Picture warnings to become mandatory; Tar, nicotine and carbon monoxide levels to be replaced with general information on harmful substances in tobacco products; Information on harmful substances in tobacco products that cannot be placed on the package would be placed

inside the package

**questions on reporting**

**problem definition**

Yes

**which option**

Introduce fees and sanctions

**regulation of ingredients**

**problem definition**

Yes

**which option**

Establish a common list of tobacco ingredients

**which one**

Establish a positive common list of tobacco ingredients; Establish a negative common list of tobacco ingredients

**access to tobacco products**

**problem definition**

Yes

**which option**

Controlled supply and access

**which supply and access**

Age verification of buyers and other legal conditions to be set for cross-border retail sale; Access to vending machines to be restricted to adults; Tobacco display and promotion at points of sales to be restricted

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**questions scope**

**problem definition**

No

**explanations**

no comments

**which option**

No change

**questions smokeless**

**problem definition**

Yes

**which option**

Ban on all types of smokeless tobacco products

**questions consumer**

**problem definition**

No

**explanations**

no comment

**which option**

No change

**questions on reporting**

**problem definition**

No

**explanations**

no comment

**which option**

Establish a common compulsory reporting format

**regulation of ingredients**

**problem definition**

No

**explanations**

no comment

**which option**



Introducing the basic criteria on the EU level without a common list

**access to tobacco products**

**problem definition**

No

**which option**

No change

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**questions scope**

**problem definition**

No

**explanations**

kein Komentar

**which option**

No change

**questions smokeless**

**problem definition**

No

**comments**

kein kommentar

**which option**

No change

**questions consumer  
problem definition**

No

**explanations**

kein kommentar

**which option**

No change

**questions on reporting  
problem definition**

No

**explanations**

kein kommentar

**which option**

No change

**regulation of ingredients  
problem definition**

No

**explanations**

kein Kommentar

**which option**

No Change

**access to tobacco products  
problem definition**

No

**explanations**

kein Kommentar

**which option**

No change

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**questions scope****problem definition**

Yes

**which option**

Extend the scope of the Directive

**questions smokeless****problem definition**

Yes

**which option**

No change

**additional comments**

Der Verkauf von Snus ist auch in der Schweiz verboten. Die Aufrechterhaltung des Verbots in der EU (mit Ausnahme von Schweden) ist deshalb für die Tabakprävention in der Schweiz ausgesprochen wichtig.

**questions consumer****problem definition**

Yes

**which option**

Improve consumer information; Introduce generic or plain packaging

**which improvement**

Picture warnings to become mandatory; Tar, nicotine and carbon monoxide levels to be replaced with general information on harmful substances in tobacco products; Information on harmful substances in tobacco products that cannot be placed on the package would be placed inside the package; Health warnings to be put on water pipes

**additional option**

Wir unterstützen den Vorschlag, auf jeder Zigarettenpackung die Telefonnummer einer Rauchstopplinie aufzudrucken. Zusätzlich schlagen wir vor, das Sortiment von Tabakerzeugnissen einzuschränken und für eine Marke nur ein einziges Produkt zuzulassen, wie bereits in Uruguay gesetzlich vorgeschrieben. Diese Massnahme trägt dazu bei, eine Falschinformation der Konsumentinnen und Konsumenten über die Gesundheitsschäden von

Tabakerzeugnissen zu verhindern.

**questions on reporting**

**problem definition**

Yes

**which option**

Establish a common compulsory reporting format; Introduce fees and sanctions

**additional options**

Wir begrüßen eine jährliche Registrierung.

**additional comments**

Die Abgabe der Daten in elektronischer Form ist unserer Ansicht nach unerlässlich.

**regulation of ingredients**

**problem definition**

Yes

**which option**

Establish a common list of tobacco ingredients

**which one**

Establish a positive common list of tobacco ingredients

**access to tobacco products**

**problem definition**

Yes

**which option**

Controlled supply and access; Ban

**which supply and access**

Age verification of buyers and other legal conditions to be set for cross-border retail sale;

Tobacco display and promotion at points of sales to be restricted

**which one2**

Cross-border retail sales of tobacco to be banned over the Internet; Promotion and displays in retail stores to be banned

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**NGO submission**

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NGO

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**questions scope****problem definition**

Yes

**which option**

Extend the scope of the Directive

**additional comments**

Alla tobaksprodukter är hälsofarliga. Vi menar därför att direktivet ska inkludera alla nya tobaksprodukter avsedda för rökning, samtidigt som förbud mot alla nya former av oral tobak, inkluderande snus, bibehålls. All inandning av förbränningsprodukter vid rökning är skadlig varför också örtcigaretter bör inkluderas i direktivet. Alla produkter som innehåller nikotin och som nu inte är klassade som tobaksprodukter, t ex elektroniska cigaretter, nikotingel, nikotindrinkar och nikotingodis, och marknadsförs som stöd vid rökavvänjning bör vara underställda samma säkerhets- och kvalitetskrav som gäller för farmaceutiska produkter.

**questions smokeless****problem definition**

Yes

**which option**

No change

**additional option**

Det är av högsta prioritet att behålla försäljningsförbudet för snus. Det finns ingen anledning att introducera ytterligare en hälsofarlig produkt. Erfarenheter från Sverige visar att snusbruk uppmuntrar till samtidig användning av cigaretter och snus och därigenom riskerar att minska benägenheten att komma ur nikotinberoendet. Fyra av tio dagligbrukare av snus är också rökare. Snus attraherar ungdomar till tobaksbruk. Fyra av tio dagligbrukare av snus har aldrig rökt. Det finns på marknaden i dag effektiva produkter inkluderande rena nikotinläkemedel som stöd för att sluta röka. Dessa ska i första hand användas som stöd och forskning intensifieras för att få fram ännu bättre läkemedel. Rökproblemet kan inte lösas genom att en ny tobaksprodukt introduceras av tobaksindustrin. Det är också värt att notera att andra rökfria produkter än snus marknadsförs i unionen. Eftersom användningen av dessa är marginell – mest framträdande i Storbritannien av invandrargrupper – kan man, å ena sidan, anse att ett försäljningsförbud för alla orala produkter inte är särskilt relevant. Å andra sidan kan man hävda att också dessa mindre befolkningsgrupper har rätt till det skydd för hälsan som ett försäljningsförbud avser att ge. I vilket fall bör dessa produkter regleras som tobaksprodukter.

**questions consumer**

**problem definition**

No

**explanations**

Olikheten i märkning av tobaksprodukter på den inre marknaden är otillfredsställande – några länder har infört obligatoriska varningsbilder men de flesta har det inte. I dessa senare länder saknas den konsumentmedvetenhet och påverkan på konsumtionen som varningsbilder visat sig medföra. I Sverige är enligt Eurobarometern 2010 69 procent av befolkningen positiva till införande av bildvarningar. Vi välkomnar också insikten att tobaksförpackningar i sig alltmer utnyttjas som reklampelare för att öka konsumtionen. Fyrtioen procent av befolkningen i Sverige välkomnar införande av neutrala tobaksförpackningar enligt Eurobarometern 2010.

**which option**

Improve consumer information; Introduce generic or plain packaging

**which improvement**

Picture warnings to become mandatory; Tar, nicotine and carbon monoxide levels to be replaced with general information on harmful substances in tobacco products; Information on harmful substances in tobacco products that cannot be placed on the package would be placed inside the package; Health warnings to be put on water pipes

**additional option**

Bildvarningar är överlägsna textvarningar Det finns evidens för att bildvarningar är mer effektiva än textvarningar. Bilder ger en mer omedelbar reaktion och leder till att textvarningen uppmärksammas bättre. Bildvarningar ska finnas på förpackningens två största sidor Varningsbudskapets (text + bild) storlek har betydelse – ju större desto mer effektiva Varningsbudskapen ska även växlas på förpackningarna i ett roterande system Bilder av hälsoskador orsakade av rökning har, tillsammans med ”känslösamma” bilder på barn och foster, visat sig vara mest effektiva. Effektiviteten ökar ytterligare om bilderna kombineras med telefonnummer till Sluta Röka-linje och om de i större utsträckning genderanpassas i enlighet med Tobakskonventionens artikel 4.2.d. Det är av högsta prioritet att neutrala tobaksförpackningar införs! Detta innebär en standardisering av storlek och form och frånvaro av märkesspecifika kännetecken. Juridisk analys i samband med pågående införande i Australien visar att det inte finns några internationella juridiska hinder för införande av neutrala paket så som tobaksindustrin hävdar. Det är av högsta prioritet att numeriska uppgifter om nivå på nikotin och kolmonoxid ersätts med kvalitativ beskrivning av skadlig inverkan av innehållet i tobak och tobaksrök. De nu förekommande numeriska värdena har erhållits vid maskinrökta tester och är vilseledande. Hälsovarningar ska också finnas på vattenpipor och tobak som röks i dessa.

**questions on reporting****problem definition**

Yes

**which option**

Establish a common compulsory reporting format; Introduce fees and sanctions

**additional comments**

Den nuvarande situationen med olika format och rapporteringssystem är helt otillfredsställande för alla parter. Ett nytt system – baserat på det Kommissionen utarbetat

2007 – är det minsta man kan kräva för tobaksprodukter som ju dödar i förtid varannan av sina långtidsanvändare. Årliga avgifter bör också tas ut för att bekosta hantering, analys, och bedömning av detta material samt kommunikering av resultatet till medborgarna.

### **regulation of ingredients**

#### **problem definition**

Yes

#### **which option**

Establish a common list of tobacco ingredients

#### **which one**

Establish a positive common list of tobacco ingredients

#### **additional comments**

En gemensam lista som tillåter ett antal ingredienser bör skapas med avsikt att konsumenter i alla medlemsländer ska ha tillgång till samma nivå av hälsoskydd. Reglering av smaktillsatser är högt prioriterad eftersom sådana har ökat markant i produktionen för att öka attraktionen, särskilt hos unga, och minska benägenheten att sluta. Även ingredienser som ger sken av att ha hälsoeffekt, t ex vitamin, ge energi, t ex koffein, eller färgämnen bör regleras. Riktlinjerna till Tobakskonventionens artiklar 9/10, nyligen antagna vid COP 4, ska beaktas.

### **access to tobacco products**

#### **problem definition**

Yes

#### **which option**

Ban

#### **which one2**

Cross-border retail sales of tobacco to be banned over the Internet; Vending machines to be banned; Promotion and displays in retail stores to be banned

#### **additional option**

Riktlinjerna till Tobakskonventionens artikel 13 innehåller krav på dolda tobaksprodukter på säljstället och förbud mot försäljning genom tobaksautomater. Dessa riktlinjer måste respekteras.

#### **additional comments**

Principen att förbjuda gränsöverskridande reklam för tobaksprodukter för att skydda folkhälsan slås fast i Tobacco Advertising Directive (2001/01 19). Det är därför logiskt att också förbjuda försäljningen av tobaksvaror mellan länder via Internet. Tobaksautomater är redan förbjudna i 22 av 27 medlemsländer för att försvåra tillgängligheten för unga. Det är konsekvent att införa samma reglering i alla medlemsländer. Det finns en ökande grad av evidens för att dolda tobaksförpackningar på säljställen kan minska ungas rökning. Denna ordning bör därför införas i alla medlemsländer.

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NGO

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**questions scope****problem definition**

Yes

**which option**

Extend the scope of the Directive

**recommend option**

The Standing Committee of European Doctors (CPME) is pleased to be given the possibility to contribute to this process and welcomes the Commission's current evaluation of Directive 2001/37/EC as a valuable opportunity to highlight a number of areas that need clarification and revision in the interest of public health. First of all, European Doctors want to point out that, in the area of tobacco control, the priority should be to get all Member States fully implement the provisions of the Directive as well as adopt and implement the WHO Framework Convention on Tobacco Control (FCTC). CPME advocates for comprehensive tobacco control strategies at EU and Member State level including high taxation, bans on direct and indirect advertising, smoking bans in public places and workplaces including bars, clubs and restaurants, prevention and cessation programs. CPME is particularly concerned about the recruitment of young people to smoking and believes that more efforts should be made in view to prevent the youngest ones to start smoking. Moreover, CPME believes that regulatory authorities should lower the allowed concentration levels of carcinogens present in all smokeless tobacco products available on the market, as they do for other consumer products. In the long term, the European doctors advocate that all tobacco and nicotine delivery products are classified as dangerous drugs and controlled accordingly .

**additional comments**

CPME very much agree with the problem definition and strongly support Option number 2, to extend the scope of the directive in order to include novel forms of oral tobacco, herbal cigarettes and electronic nicotine delivery systems (ENDS). All tobacco and nicotine products, which have not been scientifically proven to be Nicotine Replacement Therapy (NRT) products should be subjected, under tobacco control laws, to regulation of contents and labeling, age restriction, prohibitions against public use and restrictions on advertising, promotion and sponsorship. CPME is indeed highly concerned about the recent trends in smokeless tobacco and nicotine products, some of which fall into dangerous regulatory gaps. They should be clearly differentiated from NRT products and claims imputing health benefits,



reduced harm or use in smoking cessation should be prohibited until (if ever) they are scientifically proven. European doctors urge regulators to act rapidly and apply age restrictions to these products. Independent scientific research should be conducted concerning their toxicology and addictive effects of, as well as on the effects on those who do not consume it but are exposed, for example to the smoke of herbal cigarettes or the steam of ENDS. CPME strongly recommends that the use of ENDS, all kinds of tobacco products and cigarette-like products are banned in public places by the same smoke free regulations which restrict the places in which smoking is allowed. CPME stresses four reasons: - First, there is no evidence that the use of ENDS or cigarette-like products will not expose non-users to toxic emissions. - Second, if smokers start using ENDS or other smokeless tobacco products in public places where smoking is prohibited, their nicotine dependence will clearly be sustained and this will make it even more difficult for them to quit. - Third, there is no evidence that smokeless tobacco products will help to quit smoking. Instead, evidence-based counseling and treatment, including pharmacotherapy, should be available to help consumers succeed at quitting. - Fourth, cigarette-like products have similar harmful effects as regular cigarettes.

**questions smokeless**

**problem definition**

Yes

**which option**

Ban on all types of smokeless tobacco products

**additional comments**

CPME very much agree with the problem definition and strongly support Option number 3, to extend the current ban on “snus” to all types of smokeless tobacco products. See CPME response to the question on the scope of the directive. CPME emphasizes the need for more robust independent and scientific research is on the physical and psychological addictive effects of these products. They should be clearly differentiated from NRT products and claims imputing health benefits, reduced harm or use in smoking cessation should be prohibited until (if ever) they are scientifically proven. CPME believes that it is very likely that if smokers start using smokeless tobacco products in public places where smoking is prohibited, their nicotine dependence will clearly be sustained and this will make it even more difficult for them to quit.

**questions consumer**

**problem definition**

Yes

**which option**

Improve consumer information

**which improvement**

Picture warnings to become mandatory; Information on harmful substances in tobacco products that cannot be placed on the package would be placed inside the package; Health warnings to be put on water pipes

**additional comments**

CPME emphasizes that there are no “less harmful cigarettes”, irrespective of the nicotine or carbon monoxide yields. Any type of cigarette, tobacco product or cigarette-like should be

addressed as a very harmful substance with high risks for consumer's health. Tobacco products packaging and labelling should not mislead the consumer, create erroneous impression about their health hazards or create the false impression that a particular tobacco product is less harmful than another, as in the use of terms such as "light", "mild", "low tar", etc. (Ref. FCTC Art. 11) Water pipes should be included in this directive and regulated accordingly with the same smoke free regulations concerning their use, advertisement, packages and health warnings. CPME is in favor of improving consumer information and believes that option 2a) and 2c) would address the problem effectively. Concerning option 2b) : CPME does not think that information on the levels of tar, nicotine and carbon monoxide (TNCO) should be removed, but completed with qualitative information about hazardous content and "stop smoking" help lines. It should be ensured that the data on the quantities of TNCO is accurate.

**questions on reporting  
problem definition**

No

**explanations**

CPME agrees with the problem definition. Health concerns regarding the mis-reporting of industry should however be added to the problem definition.

**which option**

Establish a common compulsory reporting format; Introduce fees and sanctions

**additional comments**

CPME supports Arts. 9 and 10 of the FCTC highlighting that comprehensive disclosure of the physical, chemical and design characteristics of all tobacco products should be required and made public.

**regulation of ingredients**

**problem definition**

Yes

**which option**

Establish a common list of tobacco ingredients

**additional comments**

Ingredients used in the manufacturing of tobacco products should be regulated and listed in a transparent and unified way.

**access to tobacco products**

**problem definition**

Yes

**which option**

Ban

**which one2**

Cross-border retail sales of tobacco to be banned over the Internet; Vending machines to be banned; Promotion and displays in retail stores to be banned

**additional comments**

CPME is very concerned about cross-border sale of tobacco products via the internet that definitely undermines tobacco control efforts as well as the fight against tobacco smuggling. Cross-border retail sales of tobacco products should be banned over the internet, including a ban on postal delivery of tobacco to consumers. Tobacco products vending machines jeopardize authorities control efforts and provide an easy mean for youngsters to bypass legal age restrictions. The fight against the use of tobacco products by young people should be the first priority. Therefore and because restricting the use of vending machines to adults is unrealistic, CPME strongly advocates banning them in all Member States. The display of tobacco products can constitute a stimulus for consumers but also for non-smokers to buy these products. Therefore, CPME believes it should be restricted.

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**NGO submission****identification****affiliation**

NGO

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Dr. R. Goebel

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**country**

Germany

**gender**

male

**questions scope****problem definition**

Yes

**which option**

Extend the scope of the Directive

**recommend option**

Der Geltungsbereich der Richtlinie sollte auf alle nikotinhaltigen Erzeugnisse ausgeweitet werden, die nicht durch andere EU-Bestimmungen geregelt werden.

**questions smokeless****problem definition**

Yes

**which option**

Ban on all types of smokeless tobacco products

**additional option**

Das Verbot sollte auf alle nicht rauchbaren Tabakerzeugnisse in der EU ausgeweitet werden.

**questions consumer****problem definition**

Yes

**which option**

Improve consumer information; Introduce generic or plain packaging

**which improvement**

Picture warnings to become mandatory; Tar, nicotine and carbon monoxide levels to be replaced with general information on harmful substances in tobacco products; Information on harmful substances in tobacco products that cannot be placed on the package would be placed inside the package; Health warnings to be put on water pipes

**additional option**

Wir plädieren für eine deutlich verbesserte verpflichtende Verbraucherinformation, einschließlich Bildwarnungen und Textinformationen (außen und in der Verpackung - gut lesbar).

**questions on reporting****problem definition**

Yes

**which option**

Introduce fees and sanctions

**additional options**

Wir unterstützen die gebührenpflichtige Meldung und Zulassung von Inhaltsstoffen von Tabakprodukten.

**regulation of ingredients****problem definition**

Yes

**which option**

Introducing the basic criteria on the EU level without a common list

**additional option**

Eine gemeinsame Liste von Tabakinhaltsstoffen auf der Grundlage von Einzelkriterien wird für zielführend erachtet.

**access to tobacco products****problem definition**

Yes

**which option**

Ban

**which one2**

Promotion and displays in retail stores to be banned

**additional option**

Verbot des Internet-Handels von Zigarettensautomaten/Produkten, Werbung

---

**NGO submission****identification****affiliation**

NGO

**name**

syndicat des buuralistes du var // madame malomert

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mariep83@hotmail.fr

**country**

france

**questions scope****problem definition**

Yes

**which option**

No change

**questions smokeless****problem definition**

No

**comments**

Il n'y a pas d'études scientifiques efficaces prouvant les risques concernant les produits du tabac sans fumée

**which option**

Lifting the ban on snus

**questions consumer****problem definition**

No

**explanations**

L'efficacité des paquets neutres n'a pas été prouvée scientifiquement. Pas d'étude également sur l'efficacité des photos chocs, ni même de plus grands avertissements sanitaires sur les paquets. Les paquets neutres vont entraîner la guerre des prix, puisque cela restera le seul

moyen de se différencier pour le fabricant. La mise en place des photos chocs sur les deux faces des paquets ou de paquets génériques va pousser les consommateurs français à aller s'approvisionner sur les marchés parallèles du tabac (achats à l'étranger ou de contrebande, ou sur internet). De telles mesures risquent de déstabiliser et pénaliser économiquement le réseau des 28000 buralistes français organisés dans un réseau réglementé et sous tutelle de l'Etat.

**which option**

No change

**questions on reporting**

**problem definition**

Yes

**which option**

Establish a common compulsory reporting format

**regulation of ingredients**

**problem definition**

No

**explanations**

Une production standardisée va entraîner une diminution de l'offre au fumeur adulte et responsable. Les produits du tabac contrefaits vont apparaître de manière encore plus importante.

**which option**

No Change

**access to tobacco products**

**problem definition**

Yes

**which option**

Controlled supply and access

**which supply and access**

Age verification of buyers and other legal conditions to be set for cross-border retail sale

**additional option**

Interdiction des ventes transfrontalières de tabac par internet. Interdiction des distributeurs de tabac.

**additional comments**

Rien n'est prouvé concernant le lien entre la disparition des linéaires tabac et la lutte contre le tabagisme. La France dispose d'un réseau de 28000 buralistes, préposés de l'administration responsables et professionnels, seuls habilités à vendre du tabac. Ce réseau est fortement réglementé par l'Etat ce qui permet déjà de contrôler efficacement l'accès au produit tabac.

---

## **NGO submission**

### **identification**

#### **affiliation**

NGO

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#### **country**

FRANCE

### **questions scope**

#### **problem definition**

Yes

#### **which option**

No change

### **questions smokeless**

#### **problem definition**

No

#### **comments**

il n y a pas d etude scientifique efficace prouvant les risques concernant les produits tabac sans fumees

#### **which option**

Lifting the ban on snus

### **questions consumer**

#### **problem definition**

No

### **explanations**

Aucune etude ne prouve l'efficacité des photos chocs ni meme de plus grands avertissements sanitaires sur les paquets. La mise en place de paquets neutres risque d entrainer une guerre des prix du tabac, puisque cela restera le seul moyen pour les fabricants de se differencier. La mise en place de photos chocs sur les 2 faces des paquets ou de paquets generiques va pousser les consommateurs francais a s'approvisionner sur les marches paralleles du tabac (achat a l 'etranger, contrebande, internet). De telles mesures risquent de destabiliser et penaliser economiquement le reseau des 28000 buralistes francais organises dans un reseau reglemente sous tutelle de l'Etat.

#### **which option**

No change

**questions on reporting****problem definition**

Yes

**which option**

Establish a common compulsory reporting format

**regulation of ingredients****problem definition**

No

**explanations**

cela risque d entrainer une standardisation de la production avec comme consequence une diminution de l offre au fumeur adulte et responsable, et le risque de voir apparaître une augmentation des produits du tabac contrefaits.

**which option**

No Change

**access to tobacco products****problem definition**

Yes

**which option**

Controlled supply and access; Ban

**which supply and access**

Age verification of buyers and other legal conditions to be set for cross-border retail sale

**which one2**

Cross-border retail sales of tobacco to be banned over the Internet; Vending machines to be banned

**additional comments**

Il n'y a pas de corrélation prouvée entre la disparition des linéaires tabac et la lutte contre le tabagisme. La France dispose d'un reseau de 28000 buralistes preposes de l'administration, responsables et professionnels, seuls habilités à vendre du tabac. Ce reseau est fortement règlementé par l'Etat ce qui permet déjà de controler efficacement l'accès au produit tabac.

---

**NGO submission****identification****affiliation**

NGO

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cyprus

**age**

50

**gender**

female

**questions scope****problem definition**

Yes

**which option**

No change

**questions smokeless****problem definition**

Yes

**which option**

No change

**questions consumer****problem definition**

Yes

**which option**

No change

**questions on reporting****problem definition**

No

**explanations**

nc

**which option**

No change

**regulation of ingredients****problem definition**

No

**explanations**

no comment

**which option**

No Change

**access to tobacco products**

**problem definition**

Yes

**which option**

No change

---

**NGO submission**

**identification**

**affiliation**

NGO

**name**

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**email**

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**country**

Spain

**questions scope**

**problem definition**

Yes

**which option**

Extend the scope of the Directive

**questions smokeless**

**problem definition**

Yes

**which option**

Ban on all types of smokeless tobacco products

**questions consumer**

**problem definition**

Yes

**which option**

Improve consumer information; Introduce generic or plain packaging

**which improvement**

Picture warnings to become mandatory; Tar, nicotine and carbon monoxide levels to be replaced with general information on harmful substances in tobacco products; Information on harmful substances in tobacco products that cannot be placed on the package would be placed inside the package; Health warnings to be put on water pipes

**questions on reporting**

**problem definition**

Yes

**which option**

Establish a common compulsory reporting format; Introduce fees and sanctions

**regulation of ingredients**

**problem definition**

Yes

**which option**

Establish a common list of tobacco ingredients

**which one**

Establish a positive common list of tobacco ingredients

**access to tobacco products**

**problem definition**

Yes

**which option**

Ban

**which one2**

Cross-border retail sales of tobacco to be banned over the Internet; Vending machines to be banned; Promotion and displays in retail stores to be banned

---

**NGO submission**

**identification**

**affiliation**

NGO

**name**

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**email**

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**country**

Germany

**age**  
41

**gender**  
male

**questions scope**  
**problem definition**  
No

**explanations**  
Es kann nicht sein, daß nicht nur von unserem Staat sondern jetzt auch von der EU in unsere unternehmerische Tätigkeit in diesem Maße eingegriffen wird. Das was hier versucht wird, ist für uns als Tankstelle existenzgefährdend.

**which option**  
Extend the scope of the Directive

**recommend option**  
Jeder der über 18 Jahre alt ist kann das für sich selbst entscheiden.

**questions smokeless**  
**problem definition**  
No

**which option**  
No change

**questions consumer**  
**problem definition**  
No

**explanations**  
Ist nicht ausgereift, es gibt mit Sicherheit andere Möglichkeiten dieses Problem anzugehen.

**which option**  
Improve consumer information

**which improvement**  
Information on harmful substances in tobacco products that cannot be placed on the package would be placed inside the package

**questions on reporting**  
**problem definition**  
No

**explanations**  
Nein

**which option**

No change

**regulation of ingredients**

**problem definition**

No

**explanations**

Wenn man dieses Formular verstehen könnte, würde hier auch eine Antwort stehen

**which option**

No Change

**access to tobacco products**

**problem definition**

No

**explanations**

Wenn man dieses Formular verstehen könnte, würde hier auch eine Antwort stehen

**which option**

No change

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**NGO submission**

**identification**

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NGO

**name**

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**country**

Hungary

**gender**

male

**questions scope**

**problem definition**

Yes

**which option**

Extend the scope of the Directive

**questions smokeless**

**problem definition**

Yes

**which option**

Ban on all types of smokeless tobacco products

**questions consumer  
problem definition**

Yes

**which option**

Improve consumer information; Introduce generic or plain packaging

**which improvement**

Picture warnings to become mandatory; Tar, nicotine and carbon monoxide levels to be replaced with general information on harmful substances in tobacco products; Information on harmful substances in tobacco products that cannot be placed on the package would be placed inside the package; Health warnings to be put on water pipes

**questions on reporting  
problem definition**

Yes

**which option**

Establish a common compulsory reporting format; Introduce fees and sanctions

**regulation of ingredients  
problem definition**

Yes

**which option**

Establish a common list of tobacco ingredients

**which one**

Establish a negative common list of tobacco ingredients

**access to tobacco products  
problem definition**

Yes

**which option**

Ban

**which one2**

Cross-border retail sales of tobacco to be banned over the Internet; Vending machines to be banned; Promotion and displays in retail stores to be banned

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**NGO submission**

**identification**  
**affiliation**  
NGO

**name**  
hjh

**email**  
kjj

**country**  
kjj

**age**  
54

**gender**  
male

**questions scope**  
**problem definition**  
Yes

**which option**  
Extend the scope of the Directive

**questions smokeless**  
**problem definition**  
Yes

**which option**  
Ban on all types of smokeless tobacco products

**questions consumer**  
**problem definition**  
Yes

**which option**  
Improve consumer information; Introduce generic or plain packaging

**which improvement**  
Picture warnings to become mandatory; Tar, nicotine and carbon monoxide levels to be replaced with general information on harmful substances in tobacco products; Information on harmful substances in tobacco products that cannot be placed on the package would be placed inside the package; Health warnings to be put on water pipes

**questions on reporting**  
**problem definition**  
Yes

**which option**

Establish a common compulsory reporting format; Introduce fees and sanctions

**regulation of ingredients****problem definition**

Yes

**which option**

Establish a common list of tobacco ingredients

**which one**

Establish a negative common list of tobacco ingredients

**access to tobacco products****problem definition**

Yes

**which option**

Ban

**which one2**

Cross-border retail sales of tobacco to be banned over the Internet; Vending machines to be banned; Promotion and displays in retail stores to be banned

---

**NGO submission****identification****affiliation**

NGO

**name**

chambre syndicale des buralistes du Nord - Pas-de-Calais

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**country**

france

**questions scope****problem definition**

Yes

**which option**

No change

**questions smokeless**



**problem definition**

No

**comments**

il n'y a aucune études scientifiques efficaces prouvant les risques concernant les produits de tabac sans fumée

**which option**

Lifting the ban on snus

**questions consumer****problem definition**

No

**explanations**

Aucune étude ne prouve l'efficacité des paquets neutres, aucune étude ne prouve l'efficacité des photos chocs, ni même sur de plus grand avertissements sanitaires sur les paquets. La mise en place de paquets neutres risque d'entraîner une guerre des prix, car cela restera l'unique moyen pour les fabricants de se différencier. La mise en place de photos chocs sur les deux faces des paquets ou de paquets neutres va pousser les consommateurs à aller s'approvisionner sur des marchés parallèles du tabac : achat à l'étranger, contrebande, internet. De telles mesures risquent de destabiliser et pénaliser économiquement le réseau des 28000 buralistes français organisés dans un réseau réglementé et sous tutelle de l'état

**which option**

No change

**questions on reporting****problem definition**

Yes

**which option**

Establish a common compulsory reporting format

**regulation of ingredients****problem definition**

No

**explanations**

cela risque d'entraîner une standardisation de la production avec comme conséquence une diminution de l'offre au fumeur adulte et responsable et le risque de voir apparaître une augmentation des produits du tabac contrefaits

**which option**

No Change

**access to tobacco products****problem definition**

Yes

**which option**

Controlled supply and access

**which supply and access**

Age verification of buyers and other legal conditions to be set for cross-border retail sale

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**NGO submission**

**identification**

**affiliation**

NGO

**name**

CCA

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**country**

cyprus

**questions scope**

**problem definition**

Yes

**which option**

Extend the scope of the Directive

**questions smokeless**

**problem definition**

Yes

**which option**

Ban on all types of smokeless tobacco products

**questions consumer**

**problem definition**

Yes

**which option**

Improve consumer information

**which improvement**

Picture warnings to become mandatory

**questions on reporting**

**problem definition**

Yes

**which option**

Introduce fees and sanctions

**regulation of ingredients****problem definition**

Yes

**which option**

Establish a common list of tobacco ingredients

**which one**

Establish a negative common list of tobacco ingredients

**access to tobacco products****problem definition**

Yes

**which option**

Ban

**which one2**

Cross-border retail sales of tobacco to be banned over the Internet; Vending machines to be banned; Promotion and displays in retail stores to be banned

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**NGO submission****identification****affiliation**

NGO

**name**

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**country**

Turkey

**questions scope****problem definition**

Yes

**which option**

Extend the scope of the Directive

**recommend option**

Topics of Suggestions for the New Legislation: 1 All the European Union member and candidate member countries have to fully adapt all the articles of the 2003 Law accepted by the WHO Framework Convention on Tobacco Control. 2 All the countries should collect social claims fund aside from the tobacco taxes. 3 Smoking is a disease spreading with visuals. In order to prevent this, the use of smoking as a part of the role on television and in movies has to be banned. 4 All the brand names, logos, colors have to be removed from the cigarette packages and the packages should be identified with numbers.

#### **additional comments**

1 - All the European Union member and candidate member countries has to fully adapt all the articles of the 2003 Law accepted by the WHO Framework Convention on Tobacco Control. The new legislation has to include all the articles on the agreement accepted by the EU member countries on 16 June 2003 at the 2003 World Health Organization meeting. 2- All the countries should collect social claims fund aside from the tobacco taxes. Every tobacco consumer has a social obligation to the society. The money paid by the tobacco addicts empowers the tobacco industry enabling them to spread the use of tobacco. In order to break this cycle, the tobacco users should pay what can be called 'social claims fund' aside from the existing tobacco taxes. This payment will also be a claim paid by the smokers in return of the damage they create for the society. This fund will be an independent fund and will only be used to fight against smoking. It should be managed by a non-governmental organization. The fund should be at a considerable price compared to the prices of cigarettes, in order to create an economic power for the organizations to fight effectively against the international tobacco industry. 3- Smoking is a disease spreading with visuals. In order to prevent this, the use of smoking as a part of the role on television and in movies has to be banned. The most important aspect of fight against smoking is banning the use of smoking in televisions and movies. Turkey has accepted the below law in 2008. "Tobacco products cannot be featured in television programs, movies, series, video clips, advertisement and promotional movies." We suggest adaptation of such law in European Union as well. 4- All the brand names, logos, colors have to be removed from the cigarette packages and the packages should be identified with numbers. The cigarette brands pay a great role on the psychological aspects of the tobacco addiction. All the packaging, brand names, logos, and colors of the tobacco products are designed to send hidden positive messages to people. All the brand names, logos and colorings on the packages should be removed from the boxes in 5-7 years and replaced with numbers only. The numbers can be 6-digit combinations such as 327842. If the number is designed as 444444 or 123456 they can also become brand names in time. The cigarette packages designed as this should also have no attracting colors. The warning writings and pictures should cover the whole box. This way the brand name addiction can be eliminated. Although this may face some resistance in the beginning, it can be achieved when we understand that this will positively affect the 5.5 million EU member population and 600,000 smokers of this population. This will also show the value of human life in the 21st century. In 2012, Australia will be the first to apply this program. Our association made the proposal of such application in 2000 Geneva World Health Organization meeting. We are delighted to see this program come to life after 12 years in Australia.

#### **questions smokeless**

##### **problem definition**

No

##### **which option**

No change

**questions consumer  
problem definition**

Yes

**which option**

Improve consumer information

**which improvement**

Picture warnings to become mandatory; Tar, nicotine and carbon monoxide levels to be replaced with general information on harmful substances in tobacco products; Information on harmful substances in tobacco products that cannot be placed on the package would be placed inside the package; Health warnings to be put on water pipes

**additional option**

Every tobacco consumer has a social obligation to the society. The money paid by the tobacco addicts empowers the tobacco industry enabling them to spread the use of tobacco. In order to break this cycle, the tobacco users should pay what can be called 'social claims fund' aside from the existing tobacco taxes. This payment will also be a claim paid by the smokers in return of the damage they create for the society. This fund will be an independent fund and will only be used to fight against smoking. It should be managed by a non-governmental organization. The fund should be at a considerable price compared to the prices of cigarettes, in order to create an economic power for the organizations to fight effectively against the international tobacco industry.

**questions on reporting**

**problem definition**

Yes

**which option**

Establish a common compulsory reporting format

**regulation of ingredients**

**problem definition**

Yes

**which option**

Establish a common list of tobacco ingredients

**which one**

Establish a negative common list of tobacco ingredients

**access to tobacco products**

**problem definition**

Yes

**which option**

Controlled supply and access

**which supply and access**

Age verification of buyers and other legal conditions to be set for cross-border retail sale;  
Access to vending machines to be restricted to adults; Tobacco display and promotion at  
points of sales to be restricted

---

## **NGO submission**

### **identification**

#### **affiliation**

NGO

#### **name**

CONFAGRICOLTURA - CONFEDERAZIONE GENERALE DELL'AGRICOLTURA  
ITALIANA (Responsabile Settore Tabacco - Dott.ssa Giuseppina Romano)

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#### **country**

Italia

### **questions scope**

#### **problem definition**

Yes

#### **which option**

No change

### **additional comments**

Non reputiamo necessario un allargamento dell'ambito della Direttiva ad altre categorie di prodotti. Seppure riteniamo interessante controllare il mercato delle sigarette senza tabacco, non si può accettare il divieto proposto per tutte le forme di tabacco senza fumo tra cui lo "snus" che rappresenta sbocchi interessanti per alcuni Paesi, non essendo stata dimostrata scientificamente una nocività di questi prodotti analoga a quella degli altri prodotti del tabacco.

### **questions smokeless**

#### **problem definition**

No

#### **comments**

La spiegazione dettagliata è nello spazio relativo alla scelta dell'opzione.

#### **which option**

Lifting the ban on snus

### **additional comments**

Riteniamo ingiusto che la commercializzazione del tabacco umido in polvere per uso orale (c.d. "snus") sia consentita in un solo Stato dell'UE, ovvero la Svezia, e vietata in tutti gli altri

Stati. Il divieto di vendita non è basato su prove scientifiche ed andrebbe rimosso. La nostra posizione è sostenuta anche dal fatto che, in Svezia, diverse ricerche scientifiche dimostrano la riduzione dell'incidenza delle patologie correlate al fumo rispetto alla media UE proprio grazie all'utilizzo dello "snus". Inoltre, anche la percentuale dei fumatori sul totale della popolazione è inferiore alla media UE. Tale dato dimostrerebbe l'efficacia dello "snus" come potenziale strumento di supporto per smettere di consumare prodotti da fumo. Ci auguriamo, quindi, che lo "snus" venga liberamente commercializzato in tutti gli Stati Membri del mercato unico europeo.

**questions consumer  
problem definition**

No

**explanations**

La spiegazione dettagliata è nello spazio relativo alla scelta dell'opzione.

**which option**

No change

**additional comments**

Non esistono più fumatori che ignorano i pericoli del consumo. Le foto non hanno dato la prova della loro efficienza. La consapevolezza dei rischi sanitari connessi al prodotto, come sostenuto da più ricerche scientifiche, non aumenta con l'utilizzo di ulteriori avvertenze speciali. A nostro avviso, quindi, la possibilità di inserire avvertenze sotto forma di fotografie a colori o altre illustrazioni dovrebbe essere lasciata alla libera iniziativa degli Stati Membri, come previsto dalla Direttiva attuale. Inoltre, l'introduzione di restrizioni sul pacchetto (es. il c.d. pacchetto generico che riteniamo un'aberrazione per un prodotto da banco e il rischio di mascherare il prodotto a discapito della qualità del tabacco), come suggerito dall'opzione 3, a nostro avviso, mina seriamente la sopravvivenza stessa dell'industria legale a causa del rischio di incremento della contraffazione dei prodotti che va a tutto vantaggio del commercio illecito e delle organizzazioni criminali, rendendo il prodotto più accessibile ai giovani.

**questions on reporting  
problem definition**

Yes

**which option**

Establish a common compulsory reporting format

**regulation of ingredients**

**problem definition**

No

**explanations**

La spiegazione dettagliata è nello spazio relativo alla scelta dell'opzione.

**which option**

No Change

**additional comments**

Il rischio che alcuni o anche tutti gli ingredienti, vengano vietati, senza fondamento scientifico, è troppo grande. A nostro avviso, la regolamentazione degli ingredienti inseriti nei prodotti del tabacco dovrebbe rimanere competenza degli Stati Membri, come già previsto dall'attuale Direttiva. Questo anche in virtù dei risultati del rapporto del Comitato SCENIHR, incaricato dalla Commissione Europea/DG SANCO di valutare il ruolo degli ingredienti utilizzati in riferimento all'attrattività e all'assuefazione degli stessi. Il rapporto conferma che l'attrattività è un concetto assolutamente soggettivo. L'eventuale divieto di uso degli ingredienti avrebbe gravissime ripercussioni economiche ed occupazionali per il settore del tabacco greggio in Italia. Queste misure, infatti, renderebbero non più economicamente conveniente la coltivazione di alcune varietà di tabacco utilizzato per la produzione di sigarette di tipo American blend e la sopravvivenza dell'intero settore della coltivazione e della prima trasformazione del tabacco in Italia, che occupano circa 60.000 addetti, verrebbe seriamente minata.

**access to tobacco products**  
**problem definition**

Yes

**which option**

Controlled supply and access

**which supply and access**

Age verification of buyers and other legal conditions to be set for cross-border retail sale;  
Access to vending machines to be restricted to adults

**additional comments**

Riteniamo opportuno una discussione sull'accesso controllato, ma non attraverso un approccio di restrizioni globali globale all'interno delle tabaccherie e di internet, che è difficilmente controllabile. A nostro avviso, la determinazione delle misure che stabiliscono i limiti all'accesso ai prodotti a base di tabacco dovrebbe rimanere competenza degli Stati Membri. In particolare, siamo contrari ad ulteriori ed ingiustificate restrizioni, come il divieto totale di esposizione dei prodotti, in quanto determinano una sorta di criminalizzazione del consumo di un prodotto legale, con gravi ripercussioni su tutta la filiera produttiva. Peraltro, auspichiamo che la Direttiva adotti la regolamentazione già presente in Italia, in particolare per quanto riguarda la verifica dell'età dell'acquirente e l'installazione di distributori automatici provvisti di sistema di verifica anagrafica. Infine, supportiamo le restrizioni prospettate per le vendite via internet poiché tali misure, a nostro avviso, preservano il livello qualitativo del prodotto garantito, in Italia, dal sistema di concessione delle licenze ai prodotti del tabacco tutelando, quindi, anche la salute del consumatore.

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**NGO submission**

**identification**

**affiliation**

NGO

**name**

chambre syndicale du var



**email**

delpech.tabac@orange.fr

**country**

france

**questions scope****problem definition**

Yes

**which option**

No change

**questions smokeless****problem definition**

No

**comments**

il n'y a pas d'études efficaces prouvant les risques concernant les produits du tabac sans fumée

**which option**

Lifting the ban on snus

**questions consumer****problem definition**

No

**explanations**

aucune étude ne prouve l'efficacité des paquets neutres. aucune étude ne prouve l'efficacité des photos chocs, ni même de plus grands avertissements sanitaires sur les paquets. la mise en place des paquets neutres risque d'entraîner une guerre des prix du tabac. la mise en place de photos chocs sur les 2 faces des paquets ou des génériques va pousser les consommateurs français à aller s'approvisionner sur les marchés parallèles du tabac. de telles mesures risquent de déstabiliser et pénaliser économiquement le réseau des 28000 buralistes français organisés dans un réseau réglementé et sous tutelle de l'état.

**which option**

No change

**questions on reporting****problem definition**

Yes

**which option**

Establish a common compulsory reporting format

**regulation of ingredients****problem definition**

No

**explanations**

cela risque d'entraîner une standardisation de la production avec comme conséquence une diminution de l'offre au fumeur adulte et responsable, et le risque de voir apparaître une augmentation des produits du tabac cotrefaits.

**which option**

No Change

**access to tobacco products****problem definition**

Yes

**which option**

Controlled supply and access; Ban

**which supply and access**

Age verification of buyers and other legal conditions to be set for cross-border retail sale

**which one2**

Cross-border retail sales of tobacco to be banned over the Internet

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**NGO submission****identification****affiliation**

NGO

**name**

Cheshire and Merseyside Public Health Network (ChaMPs) Suzanne Sweeney, [Sent on behalf of Jo McCullagh, Tobacco Control Programme Lead and Dawn Leicester, Cheshire and Merseyside Public Health Network Lead]

**email**

suzanne.sweeney@heartofmersey.org.uk About ChaMPs The ChaMPs network can be defined as groups of public health professionals and wider practitioners, working together across organisations and structural boundaries, that have a common agenda to promote health and well-being and reduce health inequalities. The following is a response to the EU Consultation on Possible Revision of the Tobacco Products Directive 2001/37/EC submitted by ChaMPs:

**country**

England

**gender**

female

**questions scope**

**problem definition**

Yes

**which option**

Extend the scope of the Directive

**recommend option**

ChaMPs recommend the following: • Extend the scope of the Directive to include all smoked products including herbal cigarettes. • Do NOT extend the Directive to include electronic nicotine delivery systems (ENDS or E-cigarettes). It is the combustion process and inhalation of smoke that causes most of the harm from smoking. Herbal cigarettes, which are used in a similar way as nicotine cigarettes, should be regulated in the same way as smoked tobacco products, and should be included in the scope of the Directive. All tobacco products are hazardous to health – there is no safe level of usage. ChaMPs recommend that the scope of the Directive includes the regulation of any new smoked tobacco products (such as low emission or nicotine-free cigarettes). Nicotine based products that contain nicotine but not tobacco, have the potential to offer a less hazardous alternative to cigarettes. Currently these include e-cigarettes and nicotine gel. However, as such products are generally marketed as alternatives to cigarettes and in some cases as an aid to quitting smoking, it is appropriate for them to be brought under the same regulatory framework as pharmaceutical products rather than under the scope of the tobacco products directive. The question of how nicotine containing products should be controlled is currently under consideration by the UK's Medicines and Healthcare Regulatory Authority (MHRA) following a recent public consultation on whether to extend its remit on the regulation of nicotine replacement therapies to other nicotine containing products (1). The outcome of this consultation may assist the Commission in developing its policy on these products. ChaMPs believes that the scope of the Directive should be extended to include smoking paraphernalia such as filters, cigarette paper, pipes, water pipes as well as the tobacco leaf. ChaMPs agrees with the impact assessment study conducted by RAND Europe(2) stating that the primary benefit of extending the scope of the directive to paraphernalia and other non-tobacco nicotine products would be to increase consumers' awareness of the risks of these products. Smokers of roll-your-own cigarettes (RYO), pipes and water pipes often believe that these products are less harmful than manufactured cigarettes when in fact there is evidence to the contrary.(3,4).

**additional comments**

(1) Medicines and Healthcare Regulatory Authority. Public consultation (MLX 364): The regulation of nicotine containing products (NCPs). June 2010  
<http://www.mhra.gov.uk/Publications/Consultations/Medicinesconsultations/MLXs/CON065617> (2) RAND Europe (2010): Assessing the Impacts of Revising the Tobacco Products Directive Study to support a DG SANCO Impact Assessment. At:  
[http://ec.europa.eu/health/tobacco/docs/tobacco\\_ia\\_rand\\_en.pdf](http://ec.europa.eu/health/tobacco/docs/tobacco_ia_rand_en.pdf) (3) Young, D., R. Borland, D. Hammond, K. M. Cummings, E. Devlin, H. H. Yong and R. J. O'Connnor, 'Prevalence and Attributes of Roll-your-own Smokers in the International Tobacco Control (ITC) Four Country Survey,' Tobacco Control, Vol. 15, Suppl., 3 Jun 2006, pp. iii76–82.3 (4) Richter, P. A., L. L. Pederson and M. M. O'Hegarty, 'Young Adult Smoker Risk Perceptions of Traditional Cigarettes and Nontraditional Tobacco Products', American Journal of Health Behaviour, Vol. 30, No. 3, May–Jun 2006, pp. 302–312.

**questions smokeless****problem definition**

Yes

**which option**

No change

**additional option**

ChaMPs advise that it is a high priority that the current ban on snus is definitely maintained. Indeed, there is no legitimate reason to introduce a dangerous product on the market, particularly as, from an internal market point of view, we have no idea how snus would be perceived or used in other countries. ChaMPs believes that there is inadequate evidence on the impacts on smoking uptake and quit rates and no evidence to show the effect of introducing snus to a new market. The SCENIHR report(5) notes the difficulties of extrapolating to new markets from experience in existing markets, pointing out different patterns for smoking prevalence and snus use in Sweden and Norway for example. The switching behaviour reported in Swedish men is not reflected in Norway where smoking cessation rates have been similar in Norwegian men and women during the last decade, but increased use of smokeless tobacco is observed only in young men. There is little evidence that smokers in EU countries other than Sweden would find snus to be an acceptable alternative to cigarettes, were it to be legalised. If the ban on snus were to be lifted, it could encourage dual use of cigarettes and smokeless tobacco and discourage total abstinence from tobacco, thus weakening any potential health gains.(6) Therefore, there is no legitimate reason to justify bringing a new hazardous product onto the market. With regard to other smokeless tobacco products, particularly those used by ethnic minority populations, does not believe that they should be “marketed” in all Member States. ChaMPs therefore recommends that they are more tightly regulated (in the same way as tobacco products) but we do not support a total ban on such products. ChaMPs fears that a total ban would likely be counter-productive by facilitating the use of smokeless tobacco products underground and creating an unnecessary illegal market. This would make it more difficult to engage with users and to offer help in quitting.

**additional comments**

(5)Borland R, Wilson N, Fong GT. et al. Impact of graphic and text warnings on cigarette packs: findings from four countries over five years. *Tob Control* 2009;18:358–64. doi:10.1136/ tc.2008.028043 PMID:19561362 (6)Borland R, Yong HH, Wilson N. et al. How reactions to cigarette packet health warnings influence quitting: findings from the ITC Four-Country survey. *Addiction* 2009;104:669–75. doi:10.1111/j.1360-0443.2009.02508.x PMID:19215595

**questions consumer**

**problem definition**

Yes

**which option**

Improve consumer information; Introduce generic or plain packaging

**which improvement**

Picture warnings to become mandatory; Tar, nicotine and carbon monoxide levels to be replaced with general information on harmful substances in tobacco products; Information on harmful substances in tobacco products that cannot be placed on the package would be placed inside the package; Health warnings to be put on water pipes

### **additional option**

ChaMPs strongly recommend that picture warnings should be mandatory in all Member States and that they should occupy a minimum of 80% of the front and back surfaces of all tobacco packaging, not just cigarettes. The warnings should be placed on the upper portion of the packs for maximum visibility. The current situation with some Member States adopting picture warnings whilst others have not done so has created a discrepancy and uneven health protection across the EU. From an internal market perspective, the differences in rules are contrary to the operation of the single market and may constitute a barrier to trade. These obstacles should therefore be removed and pictorial health warnings should be mandatory to ensure optimum health protection for all EU citizens. There is good evidence to show that health warnings are effective in conveying the dangers of smoking and helping smokers to quit (5), (6). They also help deter young people from starting to smoke. Picture warnings are more effective than written warnings (5). Research carried out in Canada by Createc(7) on behalf of Health Canada in 2007 showed that young and adult smokers/non smokers are sensitive to the size of health warning messages. Results showed that warning messages that cover 100% of the pack are significantly more effective across all measured effectiveness indicators compared with warning messages that cover only 50% of the pack. ChaMPs also advocates that all warnings should be displayed in rotation so that each message is given equal display to reach its target audience. There is widespread consumer support for pictorial health warnings. A Eurobarometer survey conducted in October 2009 showed that 78% of respondents supported health warnings. Information on Tar, nicotine & carbon monoxide (TNCO) Currently the Directive requires the inclusion of machine-based tar, nicotine and carbon monoxide yields on cigarette packs. This promotes the mistaken belief that some cigarette brands are less harmful than others (8). The EU should not only remove this requirement from the Directive but should prohibit ISO or any other emissions numbers on the pack. ChaMPs support the proposal to replace numerical measurements with descriptive information on the hazardous effects of tobacco constituents and emissions. The addition of a quitline telephone service should be included on the packaging.

### **additional comments**

Additional information on harmful substances in tobacco products ChaMPs support the proposal to include additional information on the health effects of tobacco consumption on inserts inside the packaging. We advocate that this should include advice on quitting smoking. Health warnings on water pipes There is a growing body of evidence to show that water pipes are at least as hazardous, if not more so, than other forms of tobacco use. However, there is a common perception that tobacco smoke is 'cleansed' by the water and therefore not as dangerous and some users believe flavoured shisha is not in fact tobacco. It is important that these myths are countered by the inclusion of a health warning on water pipes. Warnings should also be included on the packaging of tobacco used in water pipes. Generic or plain packaging ChaMPs strongly recommend the introduction of plain or generic packaging. This should include not only the removal of all branding from the packaging but the size and shape of the packaging should also be standardised. Not only would this prevent the promotion of smoking through branding as occurs presently but it would reinforce the health warning messages. The Australian federal government has recently announced its intention to introduce plain packaging in 2012, setting a standard that the EU should follow (9). Tobacco packaging provides a direct link between consumers and manufacturers and is the main marketing channel, particularly in jurisdictions with tobacco advertising bans (10). Branding gives the misleading impression some cigarettes are safer than others (11). The tobacco industry claims that plain packaging would contravene intellectual property law. However, legal analysis concludes that this is incorrect and there are no international legal impediments

to the implementation of generic packaging in the EU (12). (7) Createc report prepared for Health Canada (2008). Effects of modified packaging through increasing the size of warnings on cigarette packs. Quantitative study of Canadian adult smokers. (8) Koslowski LT, Goldberg ME, Yost BA, et al. Smokers' misperceptions of light and ultra-light cigarettes may keep them smoking. *Am J Prev Med* 1998; 15: 9-16. (9) Government to demand no frills cigarette packs. ABC News 29 April 2010 <http://www.abc.net.au/news/stories/2010/04/28/2885166.htm> (10) Wakefield M, Germain D, Durkin S. How does increasingly plainer cigarette packaging influence adult smokers' perceptions about brand image? An experimental study. *Tobacco Control* 2008; 17: 416-421 (11) Hammond D. et al Cigarette pack design and perceptions of risk among UK adults and youth *Eur J Public Health*. 2009 Dec;19(6):631-7. (12) The lawfulness of requiring plain packaging for tobacco products. Opinion of Sir Richard Buxton. Nov 2008

### **questions on reporting**

#### **problem definition**

Yes

#### **which option**

Establish a common compulsory reporting format; Introduce fees and sanctions

#### **additional options**

ChaMPs advises that the current situation which allows different formats and reporting mechanisms is unsatisfactory, making it difficult for authorities to compare and analyse the data. Tobacco companies should be required to use a standardised reporting format. Additionally the companies should be required to pay a yearly registration fee to cover the costs of administering this data collection. The above measures should be compliant with Articles 9 & 10 of the Framework Convention on Tobacco Control (FCTC).

### **regulation of ingredients**

#### **problem definition**

Yes

#### **which option**

Establish a common list of tobacco ingredients

#### **additional option**

ChaMPs support the adoption of a positive common list of tobacco ingredients. Tobacco products are highly toxic and addictive; their contents should therefore be regulated in order to achieve high standards of health protection. A positive common list would ensure that only registered products, with ingredients, flavourings and additives that appear on the positive list would be permitted on the EU market. Currently, EU citizens are not subject to the same level of health protection and a common list of permitted ingredients would go some way towards addressing this anomaly. The tobacco industry uses a range of additives to alter the composition of tobacco products. These can make the product more palatable to children or increase the addictiveness of the product. Therefore any flavourings that may be used to enhance the addictiveness or attractiveness of tobacco products should be banned. The revised Product Directive should be fully compliant with the guidelines on Articles 9 & 10 adopted at the fourth Conference of the Parties of the FCTC on 20th November 2010.

### **access to tobacco products**

**problem definition**

Yes

**which option**

Ban

**which one2**

Cross-border retail sales of tobacco to be banned over the Internet; Vending machines to be banned; Promotion and displays in retail stores to be banned

**additional option**

Whilst ChaMPs would urge the Commission to call for a ban on the promotion of tobacco products at point of sale and a ban on vending machines, we are aware that these issues do not have cross-border effects. The legal basis for such measures at an EU level is weak. However, these measures are important for health protection and we call on the Commission to include them as non-mandatory measures as part of the Tobacco Products Directive. ChaMPs believes that the Directive should also remind national governments that they should adopt a comprehensive ban on all forms of tobacco advertising, promotion and sponsorship in accordance with Article 13 of the FCTC which calls on Parties to. The EU Directive should follow the lead set by Finland which, as part of its recently passed Tobacco Act, has set limits on the amount of tobacco that can be imported into Finland where the labelling differs from that of tobacco products sold in Finland. ChaMPs recommend that similar limits should be set at EU level, that is, that for each Member State the amount of tobacco that may be imported for personal use which does not conform to domestic labelling requirements, should be limited to a maximum of 200 cigarettes, 50 cigars, 100 cigarillos and 250 grams of pipe or cigarette tobacco.

**additional comments**

Internet. The principle of preventing cross-border promotion of tobacco products in order to protect public health was enshrined in the Tobacco Advertising directive (2001/0119). It is logical, therefore, to extend that principle to the sale of tobacco products between member states via the Internet. ChaMPs support the prohibition of tobacco sales via the Internet.

Vending machines. The majority of member states (22 out of 27) already prohibit the sale of tobacco products from vending machines in order to deter young people accessing cigarettes from this source. ChaMPs support this measure. However, as this does not have cross-border effects, we urge the Commission to make the prohibition of tobacco vending machines a non-mandatory measure as part of the product directive. Point of Sale ChaMPs support an EU-wide adoption of a ban on the display of tobacco products at the point of sale. Across the EU, most forms of tobacco advertising are now prohibited but the tobacco industry continues to market its products by the use of attractive packaging. Research shows that point of sale displays of tobacco have a direct impact on young people's intention to smoke (13).

Furthermore, there is a growing body of evidence to show that putting tobacco products out of sight in retail outlets can reduce youth smoking (14). To date, this measure has been adopted by Ireland and Finland (as well as Iceland and Norway) and is going through the parliamentary process in the UK. (13)Point of Sale Display of Tobacco Products. The Centre for Tobacco Control Research. University of Stirling, 2008. (14)Tobacco displays at the point of sale. ASH Briefing, Nov. 2010

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## **NGO submission**

### **identification**

#### **affiliation**

NGO

#### **name**

Heart of Mersey Suzanne Sweeney, [Sent on behalf of Robin Ireland, Chief Executive and Jo McCullagh, Tobacco Control Programme Lead]

#### **email**

suzanne.sweeney@heartofmersey.org.uk About Heart of Mersey Heart of Mersey (HoM) is a cardiovascular health charity covering Cheshire and Merseyside. HoM aims to co-ordinate a strategic approach to preventing the high rates of cardiovascular disease and associated inequalities in our region. HoM focuses on improving nutrition and controlling tobacco as two of the key modifiable risk factors in CVD prevention.

#### **country**

England

#### **gender**

female

### **questions scope**

#### **problem definition**

Yes

#### **which option**

Extend the scope of the Directive

### **recommend option**

HoM recommend the following: • Extend the scope of the Directive to include all smoked products including herbal cigarettes. • Do NOT extend the Directive to include electronic nicotine delivery systems (ENDS or E-cigarettes). It is the combustion process and inhalation of smoke that causes most of the harm from smoking. Herbal cigarettes, which are used in a similar way as nicotine cigarettes, should be regulated in the same way as smoked tobacco products, and should be included in the scope of the Directive. All tobacco products are hazardous to health – there is no safe level of usage. HoM recommend that the scope of the Directive includes the regulation of any new smoked tobacco products (such as low emission or nicotine-free cigarettes). Nicotine based products that contain nicotine but not tobacco, have the potential to offer a less hazardous alternative to cigarettes. Currently these include e-cigarettes and nicotine gel. However, as such products are generally marketed as alternatives to cigarettes and in some cases as an aid to quitting smoking, it is appropriate for them to be brought under the same regulatory framework as pharmaceutical products rather than under the scope of the tobacco products directive. The question of how nicotine containing products should be controlled is currently under consideration by the UK's Medicines and Healthcare Regulatory Authority (MHRA) following a recent public consultation on whether to extend its remit on the regulation of nicotine replacement therapies to other nicotine containing products (1). The outcome of this consultation may assist the Commission in developing its policy on



these products. The HoM believes that the scope of the Directive should be extended to include smoking paraphernalia such as filters, cigarette paper, pipes, water pipes as well as the tobacco leaf. HoM agrees with the impact assessment study conducted by RAND Europe(2) stating that the primary benefit of extending the scope of the directive to paraphernalia and other non-tobacco nicotine products would be to increase consumers' awareness of the risks of these products. Smokers of roll-your-own cigarettes (RYO), pipes and water pipes often believe that these products are less harmful than manufactured cigarettes when in fact there is evidence to the contrary.(3,4).

### **additional comments**

(1) Medicines and Healthcare Regulatory Authority. Public consultation (MLX 364): The regulation of nicotine containing products (NCPs). June 2010  
<http://www.mhra.gov.uk/Publications/Consultations/Medicinesconsultations/MLXs/CON065617> (2) RAND Europe (2010): Assessing the Impacts of Revising the Tobacco Products Directive Study to support a DG SANCO Impact Assessment. At:  
[http://ec.europa.eu/health/tobacco/docs/tobacco\\_ia\\_rand\\_en.pdf](http://ec.europa.eu/health/tobacco/docs/tobacco_ia_rand_en.pdf) (3) Young, D., R. Borland, D. Hammond, K. M. Cummings, E. Devlin, H. H. Yong and R. J. O'Connnor, 'Prevalence and Attributes of Roll-your-own Smokers in the International Tobacco Control (ITC) Four Country Survey,' Tobacco Control, Vol. 15, Suppl., 3 Jun 2006, pp. iii76–82.3 (4) Richter, P. A., L. L. Pederson and M. M. O'Hegarty, 'Young Adult Smoker Risk Perceptions of Traditional Cigarettes and Nontraditional Tobacco Products', American Journal of Health Behaviour, Vol. 30, No. 3, May–Jun 2006, pp. 302–312.

### **questions smokeless**

#### **problem definition**

Yes

#### **which option**

No change

### **additional option**

HoM advise that it is a high priority that the current ban on snus is definitely maintained. Indeed, there is no legitimate reason to introduce a dangerous product on the market, particularly as, from an internal market point of view, we have no idea how snus would be perceived or used in other countries. HoM believes that there is inadequate evidence on the impacts on smoking uptake and quit rates and no evidence to show the effect of introducing snus to a new market. The SCENIHR report(5) notes the difficulties of extrapolating to new markets from experience in existing markets, pointing out different patterns for smoking prevalence and snus use in Sweden and Norway for example. The switching behaviour reported in Swedish men is not reflected in Norway where smoking cessation rates have been similar in Norwegian men and women during the last decade, but increased use of smokeless tobacco is observed only in young men. There is little evidence that smokers in EU countries other than Sweden would find snus to be an acceptable alternative to cigarettes, were it to be legalised. If the ban on snus were to be lifted, it could encourage dual use of cigarettes and smokeless tobacco and discourage total abstinence from tobacco, thus weakening any potential health gains.(6) Therefore, there is no legitimate reason to justify bringing a new hazardous product onto the market. With regard to other smokeless tobacco products, particularly those used by ethnic minority populations, HoM does not believe that they should be "marketed" in all Member States. HoM therefore recommends that they are more tightly regulated (in the same way as tobacco products) but we do not support a total ban on such

products. HoM fears that a total ban would likely be counter-productive by facilitating the use of smokeless tobacco products underground and creating an unnecessary illegal market. This would make it more difficult to engage with users and to offer help in quitting.

### **additional comments**

(5) Borland R, Wilson N, Fong GT. et al. Impact of graphic and text warnings on cigarette packs: findings from four countries over five years. *Tob Control* 2009;18:358–64. doi:10.1136/tc.2008.028043 PMID:19561362 (6) Borland R, Yong HH, Wilson N. et al. How reactions to cigarette packet health warnings influence quitting: findings from the ITC Four-Country survey. *Addiction* 2009;104:669–75. doi:10.1111/j.1360-0443.2009.02508.x PMID:19215595

### **questions consumer problem definition**

Yes

### **which option**

Improve consumer information; Introduce generic or plain packaging

### **which improvement**

Picture warnings to become mandatory; Tar, nicotine and carbon monoxide levels to be replaced with general information on harmful substances in tobacco products; Information on harmful substances in tobacco products that cannot be placed on the package would be placed inside the package; Health warnings to be put on water pipes

### **additional option**

Picture Warnings HoM strongly recommend that picture warnings should be mandatory in all Member States and that they should occupy a minimum of 80% of the front and back surfaces of all tobacco packaging, not just cigarettes. The warnings should be placed on the upper portion of the packs for maximum visibility. The current situation with some Member States adopting picture warnings whilst others have not done so has created a discrepancy and uneven health protection across the EU. From an internal market perspective, the differences in rules are contrary to the operation of the single market and may constitute a barrier to trade. These obstacles should therefore be removed and pictorial health warnings should be mandatory to ensure optimum health protection for all EU citizens. There is good evidence to show that health warnings are effective in conveying the dangers of smoking and helping smokers to quit (5), (6). They also help deter young people from starting to smoke. Picture warnings are more effective than written warnings (5). Research carried out in Canada by Createc(7) on behalf of Health Canada in 2007 showed that young and adult smokers/non smokers are sensitive to the size of health warning messages. Results showed that warning messages that cover 100% of the pack are significantly more effective across all measured effectiveness indicators compared with warning messages that cover only 50% of the pack. The CMTA also advocates that all warnings should be displayed in rotation so that each message is given equal display to reach its target audience. There is widespread consumer support for pictorial health warnings. A Eurobarometer survey conducted in October 2009 showed that 78% of respondents supported health warnings. Information on Tar, nicotine & carbon monoxide (TNCO) Currently the Directive requires the inclusion of machine-based tar, nicotine and carbon monoxide yields on cigarette packs. This promotes the mistaken belief that some cigarette brands are less harmful than others (8). The EU should not only remove this requirement from the Directive but should prohibit ISO or any other emissions

numbers on the pack. HoM support the proposal to replace numerical measurements with descriptive information on the hazardous effects of tobacco constituents and emissions. The addition of a quitline telephone service should be included on the packaging.

### **additional comments**

Additional information on harmful substances in tobacco products HoM support the proposal to include additional information on the health effects of tobacco consumption on inserts inside the packaging. We advocate that this should include advice on quitting smoking. Health warnings on water pipes There is a growing body of evidence to show that water pipes are at least as hazardous, if not more so, than other forms of tobacco use. However, there is a common perception that tobacco smoke is 'cleansed' by the water and therefore not as dangerous and some users believe flavoured shisha is not in fact tobacco. It is important that these myths are countered by the inclusion of a health warning on water pipes. Warnings should also be included on the packaging of tobacco used in water pipes. Generic or plain packaging HoM strongly recommend the introduction of plain or generic packaging. This should include not only the removal of all branding from the packaging but the size and shape of the packaging should also be standardised. Not only would this prevent the promotion of smoking through branding as occurs presently but it would reinforce the health warning messages. The Australian federal government has recently announced its intention to introduce plain packaging in 2012, setting a standard that the EU should follow (9). Tobacco packaging provides a direct link between consumers and manufacturers and is the main marketing channel, particularly in jurisdictions with tobacco advertising bans (10). Branding gives the misleading impression some cigarettes are safer than others (11). The tobacco industry claims that plain packaging would contravene intellectual property law. However, legal analysis concludes that this is incorrect and there are no international legal impediments to the implementation of generic packaging in the EU (12). (7)Createc report prepared for Health Canada (2008). Effects of modified packaging through increasing the size of warnings on cigarette packs. Quantitative study of Canadian adult smokers. (8)Koslowski LT, Goldberg ME, Yost BA, et al. Smokers' misperceptions of light and ultra-light cigarettes may keep them smoking. *Am J Prev Med* 1998; 15: 9-16. (9)Government to demand no frills cigarette packs. ABC News 29 April 2010 <http://www.abc.net.au/news/stories/2010/04/28/2885166.htm> (10)Wakefield M, Germain D, Durkin S. How does increasingly plainer cigarette packaging influence adult smokers' perceptions about brand image? An experimental study. *Tobacco Control* 2008; 17: 416-421 (11)Hammond D. et al Cigarette pack design and perceptions of risk among UK adults and youth *Eur J Public Health*. 2009 Dec;19(6):631-7. (12)The lawfulness of requiring plain packaging for tobacco products. Opinion of Sir Richard Buxton. Nov 2008

### **questions on reporting**

#### **problem definition**

Yes

#### **which option**

Establish a common compulsory reporting format; Introduce fees and sanctions

#### **additional options**

HoM advises that the current situation which allows different formats and reporting mechanisms is unsatisfactory, making it difficult for authorities to compare and analyse the data. Tobacco companies should be required to use a standardised reporting format. Additionally the companies should be required to pay a yearly registration fee to cover the

costs of administering this data collection. The above measures should be compliant with Articles 9 & 10 of the Framework Convention on Tobacco Control (FCTC).

### **regulation of ingredients**

#### **problem definition**

Yes

#### **which option**

Establish a common list of tobacco ingredients

#### **additional option**

HoM support the adoption of a positive common list of tobacco ingredients. Tobacco products are highly toxic and addictive; their contents should therefore be regulated in order to achieve high standards of health protection. A positive common list would ensure that only registered products, with ingredients, flavourings and additives that appear on the positive list would be permitted on the EU market. Currently, EU citizens are not subject to the same level of health protection and a common list of permitted ingredients would go some way towards addressing this anomaly. The tobacco industry uses a range of additives to alter the composition of tobacco products. These can make the product more palatable to children or increase the addictiveness of the product. Therefore any flavourings that may be used to enhance the addictiveness or attractiveness of tobacco products should be banned. The revised Product Directive should be fully compliant with the guidelines on Articles 9 & 10 adopted at the fourth Conference of the Parties of the FCTC on 20th November 2010.

#### **additional comments**

(13)Point of Sale Display of Tobacco Products. The Centre for Tobacco Control Research. University of Stirling, 2008. (14)Tobacco displays at the point of sale. ASH Briefing, Nov. 2010

### **access to tobacco products**

#### **problem definition**

Yes

#### **which option**

Ban

#### **which one2**

Cross-border retail sales of tobacco to be banned over the Internet; Vending machines to be banned; Promotion and displays in retail stores to be banned

#### **additional option**

Whilst HoM would urge the Commission to call for a ban on the promotion of tobacco products at point of sale and a ban on vending machines, we are aware that these issues do not have cross-border effects. The legal basis for such measures at an EU level is weak. However, these measures are important for health protection and we call on the Commission to include them as non-mandatory measures as part of the Tobacco Products Directive. HoM believes that the Directive should also remind national governments that they should adopt a comprehensive ban on all forms of tobacco advertising, promotion and sponsorship in accordance with Article 13 of the FCTC which calls on Parties to. The EU Directive should follow the lead set by Finland which, as part of its recently passed Tobacco Act, has set limits

on the amount of tobacco that can be imported into Finland where the labelling differs from that of tobacco products sold in Finland. HoM recommend that similar limits should be set at EU level, that is, that for each Member State the amount of tobacco that may be imported for personal use which does not conform to domestic labelling requirements, should be limited to a maximum of 200 cigarettes, 50 cigars, 100 cigarillos and 250 grams of pipe or cigarette tobacco.

### **additional comments**

Internet. The principle of preventing cross-border promotion of tobacco products in order to protect public health was enshrined in the Tobacco Advertising directive (2001/0119). It is logical, therefore, to extend that principle to the sale of tobacco products between member states via the Internet. HoM support the prohibition of tobacco sales via the Internet. Vending machines. The majority of member states (22 out of 27) already prohibit the sale of tobacco products from vending machines in order to deter young people accessing cigarettes from this source. HoM support this measure. However, as this does not have cross-border effects, we urge the Commission to make the prohibition of tobacco vending machines a non-mandatory measure as part of the product directive. Point of Sale HoM support an EU-wide adoption of a ban on the display of tobacco products at the point of sale. Across the EU, most forms of tobacco advertising are now prohibited but the tobacco industry continues to market its products by the use of attractive packaging. Research shows that point of sale displays of tobacco have a direct impact on young people's intention to smoke (13). Furthermore, there is a growing body of evidence to show that putting tobacco products out of sight in retail outlets can reduce youth smoking (14). To date, this measure has been adopted by Ireland and Finland (as well as Iceland and Norway) and is going through the parliamentary process in the UK.

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### **NGO submission**

#### **identification**

##### **affiliation**

NGO

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##### **country**

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##### **gender**

female

##### **questions scope**

##### **problem definition**

Yes

**which option**

Extend the scope of the Directive

**recommend option**

(1) Medicines and Healthcare Regulatory Authority. Public consultation (MLX 364): The regulation of nicotine containing products (NCPs). June 2010  
<http://www.mhra.gov.uk/Publications/Consultations/Medicinesconsultations/MLXs/CON065617> (2) RAND Europe (2010): Assessing the Impacts of Revising the Tobacco Products Directive Study to support a DG SANCO Impact Assessment. At:  
[http://ec.europa.eu/health/tobacco/docs/tobacco\\_ia\\_rand\\_en.pdf](http://ec.europa.eu/health/tobacco/docs/tobacco_ia_rand_en.pdf) (3) Young, D., R. Borland, D. Hammond, K. M. Cummings, E. Devlin, H. H. Yong and R. J. O'Connnor, 'Prevalence and Attributes of Roll-your-own Smokers in the International Tobacco Control (ITC) Four Country Survey,' Tobacco Control, Vol. 15, Suppl., 3 Jun 2006, pp. iii76–82.3 (4) Richter, P. A., L. L. Pederson and M. M. O'Hegarty, 'Young Adult Smoker Risk Perceptions of Traditional Cigarettes and Nontraditional Tobacco Products', American Journal of Health Behaviour, Vol. 30, No. 3, May–Jun 2006, pp. 302–312.

**additional comments**

The CMTA recommend the following: • Extend the scope of the Directive to include all smoked products including herbal cigarettes. • Do NOT extend the Directive to include electronic nicotine delivery systems (ENDS or E-cigarettes). It is the combustion process and inhalation of smoke that causes most of the harm from smoking. Herbal cigarettes, which are used in a similar way as nicotine cigarettes, should be regulated in the same way as smoked tobacco products, and should be included in the scope of the Directive. All tobacco products are hazardous to health – there is no safe level of usage. The CMTA recommend that the scope of the Directive includes the regulation of any new smoked tobacco products (such as low emission or nicotine-free cigarettes). Nicotine based products that contain nicotine but not tobacco, have the potential to offer a less hazardous alternative to cigarettes. Currently these include e-cigarettes and nicotine gel. However, as such products are generally marketed as alternatives to cigarettes and in some cases as an aid to quitting smoking, it is appropriate for them to be brought under the same regulatory framework as pharmaceutical products rather than under the scope of the tobacco products directive. The question of how nicotine containing products should be controlled is currently under consideration by the UK's Medicines and Healthcare Regulatory Authority (MHRA) following a recent public consultation on whether to extend its remit on the regulation of nicotine replacement therapies to other nicotine containing products (1). The outcome of this consultation may assist the Commission in developing its policy on these products. The CMTA believes that the scope of the Directive should be extended to include smoking paraphernalia such as filters, cigarette paper, pipes, water pipes as well as the tobacco leaf. The CMTA agrees with the impact assessment study conducted by RAND Europe(2) stating that the primary benefit of extending the scope of the directive to paraphernalia and other non-tobacco nicotine products would be to increase consumers' awareness of the risks of these products. Smokers of roll-your-own cigarettes (RYO), pipes and water pipes often believe that these products are less harmful than manufactured cigarettes when in fact there is evidence to the contrary.(3,4).

**questions smokeless****problem definition**

Yes

**which option**

No change

**additional option**

(5) Borland R, Wilson N, Fong GT. et al. Impact of graphic and text warnings on cigarette packs: findings from four countries over five years. *Tob Control* 2009;18:358–64.

doi:10.1136/tc.2008.028043 PMID:19561362 (6) Borland R, Yong HH, Wilson N. et al. How reactions to cigarette packet health warnings influence quitting: findings from the ITC Four-Country survey. *Addiction* 2009;104:669–75. doi:10.1111/j.1360-0443.2009.02508.x PMID:19215595

**additional comments**

The CMTA advise that it is a high priority that the current ban on snus is definitely maintained. Indeed, there is no legitimate reason to introduce a dangerous product on the market, particularly as, from an internal market point of view, we have no idea how snus would be perceived or used in other countries. The CMTA believes that there is inadequate evidence on the impacts on smoking uptake and quit rates and no evidence to show the effect of introducing snus to a new market. The SCENIHR report(5) notes the difficulties of extrapolating to new markets from experience in existing markets, pointing out different patterns for smoking prevalence and snus use in Sweden and Norway for example. The switching behaviour reported in Swedish men is not reflected in Norway where smoking cessation rates have been similar in Norwegian men and women during the last decade, but increased use of smokeless tobacco is observed only in young men. There is little evidence that smokers in EU countries other than Sweden would find snus to be an acceptable alternative to cigarettes, were it to be legalised. If the ban on snus were to be lifted, it could encourage dual use of cigarettes and smokeless tobacco and discourage total abstinence from tobacco, thus weakening any potential health gains.(6) Therefore, there is no legitimate reason to justify bringing a new hazardous product onto the market. With regard to other smokeless tobacco products, particularly those used by ethnic minority populations, the CMTA does not believe that they should be “marketed” in all Member States. The CMTA therefore recommends that they are more tightly regulated (in the same way as tobacco products) but we do not support a total ban on such products. The CMTA fears that a total ban would likely be counter-productive by facilitating the use of smokeless tobacco products underground and creating an unnecessary illegal market. This would make it more difficult to engage with users and to offer help in quitting.

**questions consumer  
problem definition**

Yes

**which option**

Improve consumer information; Introduce generic or plain packaging

**which improvement**

Picture warnings to become mandatory; Tar, nicotine and carbon monoxide levels to be replaced with general information on harmful substances in tobacco products; Information on harmful substances in tobacco products that cannot be placed on the package would be placed inside the package; Health warnings to be put on water pipes

**additional option**

Picture Warnings The CMTA strongly recommend that picture warnings should be mandatory

in all Member States and that they should occupy a minimum of 80% of the front and back surfaces of all tobacco packaging, not just cigarettes. The warnings should be placed on the upper portion of the packs for maximum visibility. The current situation with some Member States adopting picture warnings whilst others have not done so has created a discrepancy and uneven health protection across the EU. From an internal market perspective, the differences in rules are contrary to the operation of the single market and may constitute a barrier to trade. These obstacles should therefore be removed and pictorial health warnings should be mandatory to ensure optimum health protection for all EU citizens. There is good evidence to show that health warnings are effective in conveying the dangers of smoking and helping smokers to quit (5), (6). They also help deter young people from starting to smoke. Picture warnings are more effective than written warnings (5). Research carried out in Canada by Createc (7) on behalf of Health Canada in 2007 showed that young and adult smokers/non smokers are sensitive to the size of health warning messages. Results showed that warning messages that cover 100% of the pack are significantly more effective across all measured effectiveness indicators compared with warning messages that cover only 50% of the pack. The CMTA also advocates that all warnings should be displayed in rotation so that each message is given equal display to reach its target audience. There is widespread consumer support for pictorial health warnings. A Eurobarometer survey conducted in October 2009 showed that 78% of respondents supported health warnings. Information on Tar, nicotine & carbon monoxide (TNCO) Currently the Directive requires the inclusion of machine-based tar, nicotine and carbon monoxide yields on cigarette packs. This promotes the mistaken belief that some cigarette brands are less harmful than others (8). The EU should not only remove this requirement from the Directive but should prohibit ISO or any other emissions numbers on the pack. The CMTA support the proposal to replace numerical measurements with descriptive information on the hazardous effects of tobacco constituents and emissions. The addition of a quitline telephone service should be included on the packaging.

### **additional comments**

Additional information on harmful substances in tobacco products The CMTA support the proposal to include additional information on the health effects of tobacco consumption on inserts inside the packaging. We advocate that this should include advice on quitting smoking. Health warnings on water pipes There is a growing body of evidence to show that water pipes are at least as hazardous, if not more so, than other forms of tobacco use. However, there is a common perception that tobacco smoke is 'cleansed' by the water and therefore not as dangerous and some users believe flavoured shisha is not in fact tobacco. It is important that these myths are countered by the inclusion of a health warning on water pipes. Warnings should also be included on the packaging of tobacco used in water pipes. Generic or plain packaging The CMTA strongly recommend the introduction of plain or generic packaging. This should include not only the removal of all branding from the packaging but the size and shape of the packaging should also be standardised. Not only would this prevent the promotion of smoking through branding as occurs presently but it would reinforce the health warning messages. The Australian federal government has recently announced its intention to introduce plain packaging in 2012, setting a standard that the EU should follow (9). Tobacco packaging provides a direct link between consumers and manufacturers and is the main marketing channel, particularly in jurisdictions with tobacco advertising bans (10). Branding gives the misleading impression some cigarettes are safer than others (11). The tobacco industry claims that plain packaging would contravene intellectual property law. However, legal analysis concludes that this is incorrect and there are no international legal impediments to the implementation of generic packaging in the EU (12). (7)Createc report prepared for Health Canada (2008). Effects of modified packaging through increasing the size of warnings



on cigarette packs. Quantitative study of Canadian adult smokers. (8)Koslowski LT, Goldberg ME, Yost BA, et al. Smokers' misperceptions of light and ultra-light cigarettes may keep them smoking. Am J Prev Med 1998; 15: 9-16. (9)Government to demand no frills cigarette packs. ABC News 29 April 2010 <http://www.abc.net.au/news/stories/2010/04/28/2885166.htm> (10)Wakefield M, Germain D, Durkin S. How does increasingly plainer cigarette packaging influence adult smokers' perceptions about brand image? An experimental study. Tobacco Control 2008; 17: 416-421 (11)Hammond D. et al Cigarette pack design and perceptions of risk among UK adults and youth Eur J Public Health. 2009 Dec;19(6):631-7. (12)The lawfulness of requiring plain packaging for tobacco products. Opinion of Sir Richard Buxton. Nov 2008

### **questions on reporting**

#### **problem definition**

Yes

#### **which option**

Establish a common compulsory reporting format; Introduce fees and sanctions

#### **additional comments**

The CMTA advises that the current situation which allows different formats and reporting mechanisms is unsatisfactory, making it difficult for authorities to compare and analyse the data. Tobacco companies should be required to use a standardised reporting format.

Additionally the companies should be required to pay a yearly registration fee to cover the costs of administering this data collection. The above measures should be compliant with Articles 9 & 10 of the Framework Convention on Tobacco Control (FCTC).

### **regulation of ingredients**

#### **problem definition**

Yes

#### **which option**

Establish a common list of tobacco ingredients

#### **additional comments**

The CMTA support the adoption of a positive common list of tobacco ingredients. Tobacco products are highly toxic and addictive; their contents should therefore be regulated in order to achieve high standards of health protection. A positive common list would ensure that only registered products, with ingredients, flavourings and additives that appear on the positive list would be permitted on the EU market. Currently, EU citizens are not subject to the same level of health protection and a common list of permitted ingredients would go some way towards addressing this anomaly. The tobacco industry uses a range of additives to alter the composition of tobacco products. These can make the product more palatable to children or increase the addictiveness of the product. Therefore any flavourings that may be used to enhance the addictiveness or attractiveness of tobacco products should be banned. The revised Product Directive should be fully compliant with the guidelines on Articles 9 & 10 adopted at the fourth Conference of the Parties of the FCTC on 20th November 2010.

### **access to tobacco products**

#### **problem definition**

Yes

**which option**

Ban

**which one2**

Cross-border retail sales of tobacco to be banned over the Internet; Vending machines to be banned; Promotion and displays in retail stores to be banned

**additional option**

Whilst the CMTA would urge the Commission to call for a ban on the promotion of tobacco products at point of sale and a ban on vending machines, we are aware that these issues do not have cross-border effects. The legal basis for such measures at an EU level is weak. However, these measures are important for health protection and we call on the Commission to include them as non-mandatory measures as part of the Tobacco Products Directive. The CMTA believes that the Directive should also remind national governments that they should adopt a comprehensive ban on all forms of tobacco advertising, promotion and sponsorship in accordance with Article 13 of the FCTC which calls on Parties to. The EU Directive should follow the lead set by Finland which, as part of its recently passed Tobacco Act, has set limits on the amount of tobacco that can be imported into Finland where the labelling differs from that of tobacco products sold in Finland. The CMTA recommend that similar limits should be set at EU level, that is, that for each Member State the amount of tobacco that may be imported for personal use which does not conform to domestic labelling requirements, should be limited to a maximum of 200 cigarettes, 50 cigars, 100 cigarillos and 250 grams of pipe or cigarette tobacco.

**additional comments**

Internet. The principle of preventing cross-border promotion of tobacco products in order to protect public health was enshrined in the Tobacco Advertising directive (2001/0119). It is logical, therefore, to extend that principle to the sale of tobacco products between member states via the Internet. The CMTA support the prohibition of tobacco sales via the Internet. Vending machines. The majority of member states (22 out of 27) already prohibit the sale of tobacco products from vending machines in order to deter young people accessing cigarettes from this source. The CMTA support this measure. However, as this does not have cross-border effects, we urge the Commission to make the prohibition of tobacco vending machines a non-mandatory measure as part of the product directive. Point of Sale The CMTA support an EU-wide adoption of a ban on the display of tobacco products at the point of sale. Across the EU, most forms of tobacco advertising are now prohibited but the tobacco industry continues to market its products by the use of attractive packaging. Research shows that point of sale displays of tobacco have a direct impact on young people's intention to smoke (13). Furthermore, there is a growing body of evidence to show that putting tobacco products out of sight in retail outlets can reduce youth smoking (14). To date, this measure has been adopted by Ireland and Finland (as well as Iceland and Norway) and is going through the parliamentary process in the UK. (13)Point of Sale Display of Tobacco Products. The Centre for Tobacco Control Research. University of Stirling, 2008. (14)Tobacco displays at the point of sale. ASH Briefing, Nov. 2010

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**NGO submission**

**identification**  
**affiliation**  
NGO

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**country**  
Spain

**questions scope**  
**problem definition**  
Yes

**which option**  
Extend the scope of the Directive

**questions smokeless**  
**problem definition**  
Yes

**which option**  
Ban on all types of smokeless tobacco products

**questions consumer**  
**problem definition**  
Yes

**which option**  
Improve consumer information; Introduce generic or plain packaging

**which improvement**  
Picture warnings to become mandatory; Tar, nicotine and carbon monoxide levels to be replaced with general information on harmful substances in tobacco products; Information on harmful substances in tobacco products that cannot be placed on the package would be placed inside the package; Health warnings to be put on water pipes

**additional comments**  
Plain packaging should be mandatory also for secondary and tertiary packaging.

**questions on reporting**  
**problem definition**  
Yes

**which option**  
Establish a common compulsory reporting format; Introduce fees and sanctions

**regulation of ingredients****problem definition**

Yes

**which option**

Establish a common list of tobacco ingredients

**which one**

Establish a positive common list of tobacco ingredients

**access to tobacco products****problem definition**

Yes

**which option**

Ban

**which one2**

Cross-border retail sales of tobacco to be banned over the Internet; Vending machines to be banned; Promotion and displays in retail stores to be banned

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**NGO submission****identification****affiliation**

NGO

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**country**

Costa Rica

**questions scope****problem definition**

Yes

**which option**

No change

**recommend option**

Nos parece que el alcance de la directiva se puede ampliar para cubrir a otros productos, sin embargo, no debe incluir una prohibición automática sobre una categoría de productos (por ejemplo, formas novedosas de tabaco de uso oral). Es nuestro criterio que cualquier prohibición debería basarse en valoraciones científicas.

**questions smokeless****problem definition**

Yes

**which option**

Lifting the ban on snus

**additional option**

La prohibición del snus no cuenta con una justificación de base científica y se debería levantar. Dado que millones de personas adultas en la Unión Europea utilizan muchas formas de productos de tabaco, lo que debería propiciarse es que tengan una opción informada para comprar snus, un producto de tabaco alternativo que, tal y como reconocen los defensores de la salud pública, es sustancialmente menos dañino que los cigarrillo convencionales

**questions consumer****problem definition**

No

**explanations**

No hay evidencia de que las advertencias de mayor tamaño sean más efectivas al momento de disuadir a una persona a utilizar tabaco. No hay evidencia de que los empaques sencillos mejoren el funcionamiento del mercado interno o que tengan algún beneficio en la salud pública. Esta medida le facilitaría a los delincuentes copiar marcas legítimas y conduciría a un aumento en las ventas ilegales de cigarrillos

**which option**

No change

**questions on reporting****problem definition**

No

**explanations**

Los estados miembros de la UE ya pueden introducir tarifas y sanciones. La aplicación de las disposiciones de la directiva debería ser responsabilidad de los Estados Miembros.

**which option**

Establish a common compulsory reporting format

**regulation of ingredients****problem definition**

No

**explanations**

Creemos que el enfoque de las pruebas de los ingredientes debería estar en si éstos dan como resultado un aumento en la toxicidad del humo del tabaco

**which option**

No Change

**access to tobacco products****problem definition**

No

**explanations**

No se plantea un problema claro en cuanto a las máquinas expendedoras o la exhibición en puntos de venta. No se ha aportado evidencia de por qué advertencias mejorarían el funcionamiento del mercado interno o lograrían algún progreso en la consecución de los objetivos de salud pública

**which option**

No change

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**NGO submission****identification****affiliation**

NGO

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**country**

FRANCE

**questions scope****problem definition**

Yes

**which option**

No change

**questions smokeless****problem definition**

No

**comments**

Il n'y a pas d'études scientifiques efficaces prouvant les risques concernant les produits du tabac sans fumée.

**which option**

Lifting the ban on snus

**questions consumer**

**problem definition**

No

**explanations**

Aucune études scientifique ne prouve l'efficacité des paquets neutres, aucune étude ne prouve l'efficacité des photos chocs, ni même de plus grands avertissements sanitaires sur les paquets. la mise en place des paquets neutres risque d'entraîner une guerre des prix du tabac ( seule difference ) la mise en place de photos chocs sur les 2 faces des paquets ou de paquets génériques va pousser les consommateurs français à aller s'approvisionner sur les marchés parallèles. De telles mesures risquent de déstabiliser et pénaliser économiquement le réseau des 28 000 buralistes français organisés dans un réseau réglementé et sous tutelle de l'Etat.

**which option**

No change

**questions on reporting****problem definition**

Yes

**which option**

Establish a common compulsory reporting format

**regulation of ingredients****problem definition**

No

**explanations**

cela risque d'entraîner une standardisation de la production avec comme conséquence une diminution de l'offre au fumeur adulte et responsable, et le risque de voire apparaitre une augmentation des produits du tabac contrefait.

**which option**

No Change

**access to tobacco products****problem definition**

Yes

**which option**

Controlled supply and access; Ban

**which supply and access**

Age verification of buyers and other legal conditions to be set for cross-border retail sale

**which one2**

Cross-border retail sales of tobacco to be banned over the Internet; Vending machines to be banned

**additional comments**

Il n'y a pas de corrélation prouvée entre la disparition des linéaires tabac et la lutte contre le

tabagisme. La France dispose d'un réseau de 28000 buralistes, préposé de l'administration responsables et professionnels, seuls habilités à vendre du tabac. Ce réseau est fortement réglementé par l'Etat ce qui permet déjà de contrôler efficacement l'accès au produit tabac.

---

## **NGO submission**

### **identification**

#### **affiliation**

NGO

#### **name**

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kvanderhorst@adoexpo.org

#### **country**

Republica Dominicana

### **questions scope**

#### **problem definition**

Yes

#### **which option**

No change

### **recommend option**

No estamos de acuerdo con la prohibicion de una categoria de producto específico, cuya prohibición no este basada en evidencia científica.

### **questions smokeless**

#### **problem definition**

Yes

#### **which option**

Lifting the ban on snus

### **questions consumer**

#### **problem definition**

No

### **explanations**

no existe evidencia de que el empaque generico ofrezca beneficios a la salud publica, si impide sin embargo a los fabricantes hacer uso de su propiedad intelectual y sus marcas.

#### **which option**

No change



**questions on reporting****problem definition**

No

**explanations**

la aplicacion del Directivo debe seguir siendo responsabilidad de cada pais miembro.

**which option**

Establish a common compulsory reporting format

**regulation of ingredients****problem definition**

No

**explanations**

el enfoque sobre ingredientes deberia ser si los ingredientes aumentan el nivel de toxicidad del humo del tabaco.

**which option**

No Change

**access to tobacco products****problem definition**

No

**which option**

No change

---

**NGO submission****identification****affiliation**

NGO

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Germany

**age**

49

**gender**

male

**questions scope  
problem definition**

No

**explanations**

kein kommentar

**which option**

No change

**recommend option**

kein kommentar

**additional comments**

kein kommentar

**questions smokeless**

**problem definition**

No

**comments**

kein kommentar

**which option**

No change

**additional option**

kein kommentar

**questions consumer**

**problem definition**

No

**explanations**

kein kommentar

**which option**

No change

**additional option**

kein kommentar

**additional comments**

kein kommentar

**questions on reporting**

**problem definition**

No

**explanations**  
kein kommentar

**which option**  
No change

**additional options**  
kein kommentar

**additional comments**  
kein kommentar

**regulation of ingredients**  
**problem definition**  
No

**explanations**  
kein kommentar

**which option**  
No Change

**access to tobacco products**  
**problem definition**  
No

**explanations**  
kein kommentar

**which option**  
No change

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**NGO submission**

**identification**  
**affiliation**  
NGO

**name**  
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**country**  
Sweden

**questions scope**

**problem definition**

No

**explanations**

We do not wish to provide any comment hereon. Please ignore any answer provided in this section as it was needed in order to continue answering the questionnaire.

**which option**

No change

**recommend option**

We do not wish to provide any comment hereon. Please ignore any answer provided in this section as it was needed in order to continue answering the questionnaire.

**questions smokeless****problem definition**

No

**comments**

We do not wish to provide any comment hereon. Please ignore any answer provided in this section as it was needed in order to continue answering the questionnaire.

**which option**

No change

**additional option**

We do not wish to provide any comment hereon. Please ignore any answer provided in this section as it was needed in order to continue answering the questionnaire.

**questions consumer****problem definition**

Yes

**which option**

No change

**additional comments**

We see a great risk that the implementation of plain packaging would lead to an increase in the illegal trade as it would be much easier to copy standardized tobacco products and packages, and also harder for the consumers to recognize illegal products. There is a risk that such regulation will result in an increase of illegal trade with tobacco products and therefore seriously harm many of our members.

**questions on reporting****problem definition**

No

**explanations**

We do not wish to provide any comment hereon. Please ignore any answer provided in this section as it was needed in order to continue answering the questionnaire.

**which option**

No change

**additional options**

We do not wish to provide any comment hereon. Please ignore any answer provided in this section as it was needed in order to continue answering the questionnaire.

**additional comments**

We do not wish to provide any comment hereon. Please ignore any answer provided in this section as it was needed in order to continue answering the questionnaire.

**regulation of ingredients****problem definition**

No

**explanations**

We do not wish to provide any comment hereon. Please ignore any answer provided in this section as it was needed in order to continue answering the questionnaire.

**which option**

No Change

**additional option**

We do not wish to provide any comment hereon. Please ignore any answer provided in this section as it was needed in order to continue answering the questionnaire.

**additional comments**

We do not wish to provide any comment hereon. Please ignore any answer provided in this section as it was needed in order to continue answering the questionnaire.

**access to tobacco products****problem definition**

Yes

**which option**

No change

**additional comments**

We would like to present the following main reasons in regards to and against a possible introduction of a so called display ban. - In countries where such a ban has been tested, retailers have been impacted negatively due to lost revenues and significant costs related to implementing the ban. In e.g. Canada many retailers have been forced to shut down following the implementation of a display ban. - The illegal trade with tobacco products has increased in countries that have tested such a ban which has resulted in both lost revenues for retailers, and in increasing levels of crime which affects small retailers and society as a whole. - Selling tobacco from under the counter will make it harder for consumers to differentiate illegal products from legal ones, as the legal products would then be sold in a manner similar to that of illegal products.

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## **NGO submission**

### **identification**

#### **affiliation**

NGO

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SWEDEN

### **questions scope**

#### **problem definition**

Yes

#### **which option**

Extend the scope of the Directive

### **questions smokeless**

#### **problem definition**

Yes

#### **which option**

No change

### **additional option**

Vi koncentrerar vårt svar på åtgärder som syftar till minskad rökning och som också innebär minskad passiv rökning.

### **questions consumer**

#### **problem definition**

Yes

#### **which option**

Introduce generic or plain packaging

### **questions on reporting**

#### **problem definition**

Yes

#### **which option**

No change

### **additional options**

Vi koncentrerar vårt svar på åtgärder/restriktioner som minskar rökning och därmed även passiv rökning.

**regulation of ingredients**

**problem definition**

Yes

**which option**

No Change

**additional option**

Vi koncentrerar vårt svar på åtgärder/restriktioner som syftar till minskad rökning och därmed även passiv rökning.

**access to tobacco products**

**problem definition**

Yes

**which option**

Ban

**which one2**

Cross-border retail sales of tobacco to be banned over the Internet; Vending machines to be banned; Promotion and displays in retail stores to be banned

---

**NGO submission**

**identification**

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NGO

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**questions scope**

**problem definition**

No

**explanations**

kein Kommentar

**which option**

No change

**questions smokeless  
problem definition**

No

**comments**

kein kommentar

**which option**

No change

**questions consumer  
problem definition**

No

**explanations**

kein kommentar

**which option**

No change

**questions on reporting  
problem definition**

No

**explanations**

kein kommentar

**which option**

Establish a common compulsory reporting format

**regulation of ingredients  
problem definition**

No

**explanations**

kein kommentar

**which option**

No Change

**access to tobacco products  
problem definition**

No

**which option**

No change

---



## **NGO submission**

### **identification**

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NGO

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#### **age**

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#### **gender**

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#### **questions scope**

#### **problem definition**

No

#### **explanations**

The problem definition could be improved. It should be clearly stated that the tobacco product directive sets the minimum limits to regulate the tobacco products. To ensure the high-level health protection of their citizens the member states would be allowed impose further regulations as long as those do not restrict the free movements of goods. Finland, as well as the European Commission, has ratified Framework Convention on Tobacco Control. It reaffirms the right of all people to the highest standard of health. Furthermore, article 114.3 of the Treaty states that when establishing rules for the functioning of the internal market in the context of health, safety, environmental protection and consumer protection, the Commission "will take as a base a high level of protection, taking account in particular of any new development based on scientific facts."

#### **which option**

Extend the scope of the Directive

#### **recommend option**

Tobacco products are no ordinary commodities. Many compounds of the tobacco products contain and the smoke they produce is pharmacologically active, toxic, mutagenic and carcinogenic. There is no safe level of usage. Therefore we recommend that the scope of the Directive includes the regulation of any new smoked tobacco products (such as low emission or nicotine-free cigarettes). The prohibition of snus, should be maintained. Herbal cigarettes are also dangerous, and therefore they should be included in the scope Tobacco Products Directive and have health warnings. Some forms of nicotine based products (such as electronic cigarettes, nicotine gel, drinks, and sweets) are often marketed as alternatives to

cigarettes and as quitting aid. In our opinion they should in no circumstances to be considered as an aid to quitting smoking. There are strictly regulated pharmaceutical products to help smokers in quitting.

**questions smokeless**

**problem definition**

Yes

**which option**

Ban on all types of smokeless tobacco products

**additional comments**

The International Agency for Research on Cancer (IARC) in their Monographs Vol 6 (IARC Monographs on the Evaluation of Carcinogenic Risks to Humans Volume 89 (2007), Smokeless Tobacco and Some Tobacco-specific N-Nitrosamine) represent as a scientific conclusion that “there is sufficient evidence in humans for the carcinogenicity of smokeless tobacco. Smokeless tobacco causes cancers of the oral cavity and pancreas. There is sufficient evidence in experimental animals for the carcinogenicity of moist snuff.” As an overall evaluation they declare that smokeless tobacco is carcinogenic to humans (Group 1). Now that the use of smokeless tobacco products is not widely spread we recommend a ban on all types of smokeless tobacco products. We do not support lifting the ban of snus as there is no legitimate reason to introduce any new dangerous product onto the market. Finland is Sweden's neighbouring country, and was a part of Sweden for about 600 years. However, we have not get used to use snus. In Finland, due to our comprehensive tobacco control policy daily smoking has been declining constantly. Nowadays, the prevalence of daily smoking is among the lowest in the EU: 22 % men and 16 % women were daily smokers in 2009. The use of snus is minimal. Snus is not an alternative to treat nicotine addiction. There are already available effective treatments for nicotine addiction, including medicinal or ‘clean’ nicotine (NRT), that do not carry the risks associated with the use of snus.

**questions consumer**

**problem definition**

No

**explanations**

The problem definition could be clarified. The current situation, where some Member States have mandatory graphic warnings and others have not, has led to a disparity in labelling. In addition some consumers do not get enough information on the devastating effects of smoking on their health. Indeed, tobacco packaging and product features are increasingly used to attract consumers, to promote products and brand image. The importance of packaging as a marketing channel has increased when other kind of tobacco advertising has been banned or restricted. Packaging as an advertising measure is not covered by the current Directive.

**which option**

Improve consumer information; Introduce generic or plain packaging

**which improvement**

Picture warnings to become mandatory; Health warnings to be put on water pipes

**additional option**

There should be mandatory pictorial health warnings on all tobacco products (including oral and water pipe tobacco) covering 80% of the front and the back of the packs towards the top, in combination with standardized packaging. Pictures are able to create interest and make people to read the associated text message. We find it important to introduce standardised/plain packaging. Tobacco packaging and product features are used to attract consumers, especially young people. All branding from the packaging should be removed and the size and shape of the packaging should be standardised. In addition, tobacco companies should only be allowed to have one standardized package size per cigarette brand. There should be information on Quit line, preferably the number, on all packs of tobacco products.

#### **additional comments**

The article 114.3 of the Treaty states that when establishing rules for the functioning of the internal market in the context of health, safety, environmental protection and consumer protection, the Commission “will take as a base a high level of protection, taking account in particular of any new development based on scientific facts.”

#### **questions on reporting**

##### **problem definition**

Yes

##### **which option**

Establish a common compulsory reporting format; Introduce fees and sanctions

#### **additional comments**

The current system makes it difficult for authorities to compare and analyse the data. All tobacco manufacturers and importers should have the same reporting requirements. We welcome a yearly registration fee paid by the tobacco companies to national competent authorities in order to finance their data collection and analysis work on ingredients. To control smuggling it is extremely important that only registered products would be allowed on the market.

#### **regulation of ingredients**

##### **problem definition**

Yes

##### **which option**

Establish a common list of tobacco ingredients

##### **which one**

Establish a positive common list of tobacco ingredients

#### **additional comments**

Cigarettes and some other products containing tobacco are highly engineered to create and maintain dependence. Many of the compounds they contain and the smoke they produce are pharmacologically active, toxic, mutagenic and carcinogenic. Flavourings are an increasingly important element of tobacco marketing, particularly to young people. Flavourings, such as sugars and sweeteners, flavouring substances, and spices and herbs enhance attractiveness, encourage youth initiation, and discourage cessation. The prohibition of these kinds of ingredients in cigarettes and cigarette-like tobacco products should be introduced. The ingredients that may create the impression of a health benefit, ingredients associated with

energy and vitality (e.g. caffeine), and ingredients with colouring properties (e.g. coloured cigarette paper) should also be banned. The above measures should be compliant with Articles 9 & 10 of the Framework Convention on Tobacco Control (FCTC).

**access to tobacco products**

**problem definition**

Yes

**which option**

Ban

**which one2**

Cross-border retail sales of tobacco to be banned over the Internet; Vending machines to be banned; Promotion and displays in retail stores to be banned

**additional option**

We urge the Commission to call for a ban on the promotion of tobacco products at point of sale and a ban on vending machines. These measures are important for health protection. The Directive should also remind national governments that they should adopt a comprehensive ban on all forms of tobacco advertising, promotion and sponsorship in accordance with Article 13 of the FCTC which calls on Parties to.

**additional comments**

Internet. The principle of preventing cross-border promotion of tobacco products in order to protect public health was highlighted in the Tobacco Advertising directive (2001/0119). Buying tobacco through Internet has become easier and more common. The problem includes the sale of tobacco products to minors, tax evasion and uncontrolled sales promotion of tobacco products. Therefore, we support the prohibition of tobacco sales via the Internet. Vending machines. In Finland vending machines will be banned in 2015. Point of Sale. In the EU member states the tobacco companies' marketing strategy is to advertise their products by making them very visible at point of sale. In Finland tobacco displays are banned on 1st January 2012. The measure has also been adopted by Ireland, and there are some other member states planning to do so. There is a growing body of evidence to show that putting tobacco products out of sight in retail outlets can reduce youth smoking. We support an EU-wide adoption of a ban on the display of tobacco products at the point of sale.

---

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NGO

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Wales

**gender**

female

**questions scope****problem definition**

Yes

**which option**

Extend the scope of the Directive

**additional comments**

We recommend the following: Extend the scope of the Directive to include all smoked products including herbal cigarettes. Do NOT extend the Directive to include electronic nicotine delivery systems (ENDS or E-cigarettes). It is the combustion process and inhalation of smoke that causes most of the harm from smoking. Given this well-established observation, and emerging evidence that some types of herbal, non-tobacco or non-nicotine cigarettes are likely to be injurious to health in a similar manner to conventional tobacco cigarettes it is appropriate that herbal cigarettes, which are used in a similar way to nicotine cigarettes, are regulated in the same way as smoked tobacco products, and should be included in the scope of the Directive. Therefore we recommend that the scope of the Directive includes the regulation of any new smoked tobacco products (such as low emission or nicotine-free cigarettes). Novel nicotine based products (that is, products containing nicotine but not tobacco products) have the potential to offer a less hazardous alternative to cigarettes. Currently these include e-cigarettes and nicotine gel. However, as such products are generally marketed as alternatives to cigarettes and in some cases as an aid to quitting smoking, it is appropriate for them to be brought under the same regulatory framework as pharmaceutical products rather than under the scope of the tobacco products directive. The question of how nicotine containing products should be controlled is currently under consideration by the UK's Medicines and Healthcare Regulatory Authority (MHRA) following a recent public consultation on whether to extend its remit on the regulation of nicotine replacement therapies to other nicotine containing products. The outcome of this consultation may assist the Commission in developing its policy on these products.

**questions smokeless****problem definition**

Yes

**which option**

No change

**additional comments**

We recommend that the existing ban on the snus in all Member States (except Sweden) should be maintained. Smokeless tobacco products, particularly modified low-nitrosamine products like Swedish snus, although significantly less hazardous than smoking, do not appear to be completely without risk. A systematic review concluded that an increased risk of cardiovascular mortality cannot be ruled out. This conclusion was based mainly on findings from a large study of construction workers in Sweden. More recent, smaller scale studies have

found no significant increase in risk, but they may not have sufficient statistical power to detect modest increases in CVD risk or mortality due to smaller sample sizes. The European Commission's Scientific Committee on Emerging and Newly Identified Health Risks (SCENIHR, 2008) has recently published similar conclusions regarding increased risk of cardiovascular mortality. ASH Wales recommends that other smokeless tobacco products that are currently marketed within the UK, such as those more commonly used by black and minority ethnic communities (e.g. gutka), should be subject to tighter regulation to ensure accurate communication of the health risks of use. Smoking cessation professionals should also be trained to effectively help individuals who use these products to quit.

### **questions consumer**

#### **problem definition**

Yes

#### **which option**

Improve consumer information; Introduce generic or plain packaging

#### **which improvement**

Picture warnings to become mandatory; Tar, nicotine and carbon monoxide levels to be replaced with general information on harmful substances in tobacco products; Information on harmful substances in tobacco products that cannot be placed on the package would be placed inside the package; Health warnings to be put on water pipes

#### **additional option**

The minimum size of health warnings should be increased to 80% of the front and back surfaces of all tobacco packaging.

#### **additional comments**

Picture Warnings We strongly recommend that picture warnings should be mandatory and that they should occupy a minimum of 80% of the front and back surfaces of all tobacco packaging (i.e. not just cigarettes). The warnings should be placed on the upper portion of the packs for maximum visibility. The current situation with some Member States adopting picture warnings whilst others have not done so has created a discrepancy and uneven health protection across the EU. From an internal market perspective, the differences in rules are contrary to the operation of the single market and may constitute a barrier to trade. These obstacles should therefore be removed and pictorial health warnings should be mandatory to ensure optimum health protection for all EU citizens. There is good evidence to show that health warnings are effective in conveying the dangers of smoking and helping smokers to quit . They also help deter young people from starting to smoke. Picture warnings are more effective than written warnings<sup>5</sup>. All warnings should be displayed in rotation so that each message is given equal display to reach its target audience. There is widespread consumer support for pictorial health warnings. An ASH Wales survey of Welsh adults conducted in October 2009 showed that 68% of respondents supported health warnings . Information on tar, nicotine & carbon monoxide (TNCO) Currently the Directive requires the inclusion of machine-based tar, nicotine and carbon monoxide yields on cigarette packs. This promotes the mistaken beliefs that some cigarette brands are less harmful than others and that nicotine causes disease . The EU should not only remove this requirement from the Directive but should prohibit ISO or any other emissions numbers on the pack. We support the proposal to replace numerical measurements with descriptive information on the hazardous effects of tobacco constituents and emissions. The addition of a quitline telephone service should be

included on the packaging. Additional information on harmful substances in tobacco products We support the proposal to include additional information on the health effects of tobacco consumption on inserts inside the packaging. This should include advice on quitting smoking. Health warnings on water pipes There is a growing body of evidence to show that water pipes are at least as hazardous , if not more so, than other forms of tobacco use. However, there is a common perception that tobacco smoke is ‘cleansed’ by the water and therefore not as dangerous and some users believe flavoured shisha is not in fact tobacco. Given this, and the fact there are typically very few warnings on waterpipes or their accessories , it is important that these myths are countered by requiring the inclusion of a health warning on all water pipes. Warnings should also be included on the packaging of tobacco used in water pipes. Generic or plain packaging We strongly recommend the introduction of plain or generic packaging. This should include not only the removal of all branding from the packaging but the size and shape of the packaging should also be standardised. Not only would this prevent the promotion of smoking through branding as occurs presently but it would reinforce the health warning messages.

### **questions on reporting**

#### **problem definition**

Yes

#### **which option**

Establish a common compulsory reporting format; Introduce fees and sanctions

#### **additional options**

No

#### **additional comments**

The current situation which allows different formats and reporting mechanisms is unsatisfactory, making it difficult for authorities to compare and analyse the data. Tobacco companies should be required to use a standardised reporting format. Additionally the companies should be required to pay a yearly registration fee to cover the costs of administering this data collection. In this context, a harmonised reporting format for use across the Member States would be clearly beneficial. This reporting scheme should be compulsory. It should ideally utilise electronic submission and compilation of data to facilitate good data management and access. Doing this at EU level would free up resources for the relevant national authorities and improve the capacity for analysis of tobacco product ingredients. The costs for administering this process could be borne by tobacco manufacturers through registration fees, and appropriate sanctions should apply in the event of non-compliance with this scheme. The above measures should be compliant with Articles 9 & 10 of the Framework Convention on Tobacco Control (FCTC).

### **regulation of ingredients**

#### **problem definition**

Yes

#### **which option**

Establish a common list of tobacco ingredients

#### **which one**

Establish a positive common list of tobacco ingredients

**additional comments**

We support the adoption of a positive common list of tobacco ingredients. Tobacco products are highly toxic and addictive; their contents should therefore be regulated in order to achieve high standards of health protection. A positive common list would ensure that only registered products, with ingredients, flavourings and additives that appear on the positive list would be permitted on the EU market. Currently, EU citizens are not subject to the same level of health protection and a common list of permitted ingredients would go some way towards addressing this anomaly. The tobacco industry uses a range of additives to alter the composition of tobacco products. These may make the product more palatable to children or increase the addictiveness of the product. Therefore any flavourings that may be used to enhance the addictiveness or attractiveness of tobacco products should be banned. The revised Product Directive should be fully compliant with the guidelines on Articles 9 & 10 adopted at the fourth Conference of the Parties of the FCTC on 20th November 2010.

**access to tobacco products****problem definition**

Yes

**which option**

Ban

**which one2**

Cross-border retail sales of tobacco to be banned over the Internet; Vending machines to be banned; Promotion and displays in retail stores to be banned

**additional option**

The EU Directive should follow the lead set by Finland which, as part of its recently passed Tobacco Act, has set limits on the amount of tobacco that can be imported into Finland where the labelling differs from that of tobacco products sold in Finland. We recommend that similar limits should be set at EU level, that is, that for each Member State the amount of tobacco that may be imported for personal use which does not conform to domestic labelling requirements, should be limited to a maximum of 200 cigarettes, 50 cigars, 100 cigarillos and 250 grams of pipe or cigarette tobacco.

**additional comments**

Internet. The principle of preventing cross-border promotion of tobacco products in order to protect public health was enshrined in the Tobacco Advertising directive (2001/0119). It is logical, therefore, to extend that principle to the sale of tobacco products between member states via the Internet. We support the prohibition of tobacco sales via the Internet. Vending machines. The majority of member states (22 out of 27) already prohibit the sale of tobacco products from vending machines in order to deter young people accessing cigarettes from this source. We support this measure. Point of Sale. We support an EU-wide adoption of a ban on the display of tobacco products at the point of sale. Across the EU, most forms of tobacco advertising are now prohibited but the tobacco industry continues to market its products by the use of attractive packaging. Research shows that point of sale displays of tobacco have a direct impact on young people's intention to smoke. Furthermore, there is a growing body of evidence to show that putting tobacco products out of sight in retail outlets can reduce youth smoking. To date, this measure has been adopted by Ireland and Finland (as well as Iceland and Norway) and is going through the parliamentary process in the UK.



---

**NGO submission**

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NGO

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**gender**

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**questions scope**

**problem definition**

Yes

**which option**

No change

**questions smokeless**

**problem definition**

Yes

**which option**

No change

**questions consumer**

**problem definition**

Yes

**which option**

No change

**questions on reporting**

**problem definition**

Yes

**which option**

No change

**regulation of ingredients**

**problem definition**

Yes

**which option**

No Change

**access to tobacco products**

**problem definition**

Yes

**which option**

No change

---

**NGO submission**

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NGO

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**questions scope**

**problem definition**

Yes

**which option**

No change

**recommend option**

There should not be an automatic ban of products without scientific assessments, only because the scope of the Directive could be enlarged

**questions smokeless**

**problem definition**

Yes

**which option**

Lifting the ban on snus

**additional option**

There is no scientific justification of why the snus is ban, there should be the option of buying this kind of products in an informed manner

**questions consumer****problem definition**

No

**explanations**

By doing plain packaging this will facilitate the copy of the brands, in this way affecting the companies without any gain for the public health. Also there are not proof that this measure is effective

**which option**

No change

**questions on reporting****problem definition**

No

**explanations**

Only the members states should be responsables of the enforcement of the directive.

**which option**

Establish a common compulsory reporting format

**regulation of ingredients****problem definition**

No

**explanations**

The testing of the ingredients have to be only with the intention of verifying whether this increase the toxicity of the tobacco.

**which option**

No Change

**access to tobacco products****problem definition**

No

**explanations**

The problem regarding the vending machines still is not even clear, and also there is not even a research that show how banning this machines will improve the public health policies

**which option**

No change

---

## **NGO submission**

### **identification**

#### **affiliation**

NGO

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### **questions scope**

#### **problem definition**

Yes

#### **which option**

Extend the scope of the Directive

### **questions smokeless**

#### **problem definition**

Yes

#### **which option**

Ban on all types of smokeless tobacco products

### **questions consumer**

#### **problem definition**

Yes

#### **which option**

Introduce generic or plain packaging

### **questions on reporting**

#### **problem definition**

Yes

#### **which option**

Introduce fees and sanctions

### **regulation of ingredients**

#### **problem definition**

Yes

#### **which option**

Establish a common list of tobacco ingredients

**which one**

Establish a positive common list of tobacco ingredients

**access to tobacco products**

**problem definition**

Yes

**which option**

Ban

**which one2**

Vending machines to be banned; Promotion and displays in retail stores to be banned

---

**NGO submission**

**identification**

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NGO

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41

**gender**

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**questions scope**

**problem definition**

Yes

**which option**

Extend the scope of the Directive

**questions smokeless**

**problem definition**

Yes

**which option**

Ban on all types of smokeless tobacco products

**questions consumer**

**problem definition**

Yes

**which option**

Introduce generic or plain packaging

**questions on reporting**

**problem definition**

Yes

**which option**

Introduce fees and sanctions

**regulation of ingredients**

**problem definition**

Yes

**which option**

Establish a common list of tobacco ingredients

**which one**

Establish a negative common list of tobacco ingredients

**access to tobacco products**

**problem definition**

Yes

**which option**

Ban

**which one2**

Cross-border retail sales of tobacco to be banned over the Internet; Vending machines to be banned; Promotion and displays in retail stores to be banned

---

**NGO submission**

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NGO

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38

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**questions scope**  
**problem definition**  
Yes

**which option**  
No change

**questions smokeless**  
**problem definition**  
Yes

**which option**  
Lifting the ban on snus

**questions consumer**  
**problem definition**  
No

**explanations**  
sin comentarios

**which option**  
No change

**questions on reporting**  
**problem definition**  
No

**explanations**  
sin comentarios

**which option**  
Establish a common compulsory reporting format

**regulation of ingredients**  
**problem definition**  
No

**explanations**  
sin comentarios

**which option**

No Change

**access to tobacco products****problem definition**

No

**explanations**

sin comentarios

**which option**

No change

---

**NGO submission****identification****affiliation**

NGO

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Greece

**gender**

male

**questions scope****problem definition**

No

**explanations**

Διαφωνούμε με κάθε μέτρο που πλήττει την επιχειρηματικότητα και την επικοινωνία ενός νόμιμου καταναλωτικού προϊόντος με τους καταναλωτές.

**which option**

No change

**questions smokeless****problem definition**

No

**comments**



no comments

**which option**

No change

**questions consumer**

**problem definition**

No

**explanations**

no comments

**which option**

No change

**questions on reporting**

**problem definition**

No

**explanations**

no comments

**which option**

No change

**regulation of ingredients**

**problem definition**

No

**explanations**

no comments

**which option**

No Change

**access to tobacco products**

**problem definition**

No

**explanations**

no comments

**which option**

No change

---

**NGO submission**

**identification**

**affiliation**

NGO

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**age**

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**gender**

female

**questions scope****problem definition**

Yes

**which option**

No change

**questions smokeless****problem definition**

No

**comments**

il n'y a pas d'études scientifiques efficaces prouvant les risques concernant les produits du tabac sans fumée

**which option**

Lifting the ban on snus

**questions consumer****problem definition**

No

**explanations**

Aucune étude ne prouve l'efficacité des produits neutres Aucune étude ne prouve l'efficacité des photos chocs ,ni même les grands avertissements sanitaires sur les paquets La mise en place des produits neutres risquent d'entraîner une guerre des prix du tabac La mise en place de photos chocs sur les 2 faces des paquets ou de paquets génériques va pousser les consommateurs français à aller s'approvisionner sur les marchés parallèles du tabac De telles mesures risquent de déstabiliser et pénaliser économiquement le réseau des 28000 buralistes français organisés dans un réseau réglementé et sous tutelle de l'Etat

**which option**

No change

**questions on reporting  
problem definition**

Yes

**which option**

Establish a common compulsory reporting format

**regulation of ingredients  
problem definition**

No

**explanations**

Cela risque d'entraîner une standardisation de la production avec comme conséquence une diminution de l'offre au fumeur adulte et responsable, et le risque de voire apparaître une augmentation des produits du tabac contrefaits

**which option**

No Change

**access to tobacco products  
problem definition**

Yes

**which option**

Controlled supply and access; Ban

**which supply and access**

Age verification of buyers and other legal conditions to be set for cross-border retail sale

**which one2**

Cross-border retail sales of tobacco to be banned over the Internet; Vending machines to be banned

**additional comments**

Il n'a pas de corrélation prouvée entre la disparition des linéaires tabac et la lutte contre le tabagisme la France dispose d'un réseau de 28000 buralistes, préposés de l'administration responsables et professionnels, seuls habilités à vendre du tabac. Ce réseau est fortement réglementé par l'Etat ce qui permet déjà de contrôler efficacement l'accès au produit tabac

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**NGO submission**

**identification**

**affiliation**

NGO

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**country**

france

**questions scope**

**problem definition**

Yes

**which option**

No change

**questions smokeless**

**problem definition**

No

**comments**

il n'y a pas d'étude scientifiques efficaces prouvant les risques concernant les produits du tabac sans fumée

**which option**

Lifting the ban on snus

**questions consumer**

**problem definition**

No

**explanations**

Aucune étude ne prouve l'efficacité des paquets neutres. Aucune étude ne prouve l'efficacité des photos chocs, ni même de plus grands avertissements sanitaires sur les paquets. La mise en place de photos neutres risque d'entraîner une guerre des prix du tabac ( puisque cela reste le seul moyen pour les fabricants de se différencier). La mise en place de photos chocs sur les 2 faces des paquets ou de paquets génériques va pousser les consommateurs français à aller s'approvisionner sur les marchés parallèles du tabac (achats à l'étranger ou de contrebande, ou sur internet). De telles mesures risquent de déstabiliser et pénaliser économiquement le réseau des 28 000 buralistes français organisés dans un réseau règlementé et sous tutelle de l'état.

**which option**

No change

**questions on reporting**

**problem definition**

Yes

**which option**

Establish a common compulsory reporting format

**regulation of ingredients****problem definition**

No

**explanations**

Cela risque d'entraîner une standardisation de la production avec comme conséquence une diminution de l'offre au fumeur adulte et responsable, et le risque de voir apparaître une augmentation des produits du tabac contrefaits.

**which option**

No Change

**access to tobacco products****problem definition**

Yes

**which option**

Controlled supply and access; Ban

**which supply and access**

Age verification of buyers and other legal conditions to be set for cross-border retail sale

**which one2**

Cross-border retail sales of tobacco to be banned over the Internet; Vending machines to be banned

**additional option**

Il n'y a pas de corrélation prouvée entre la disparition des linéaires tabac et la lutte contre le tabagisme. La France dispose d'un réseau de 28 000 buralistes, préposés de l'administration responsables et professionnels, seuls habilités à vendre du tabac. Ce réseau est fortement règlementé par l'Etat ce qui permet déjà de contrôler efficacement l'accès du produit tabac.

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**NGO submission****identification****affiliation**

NGO

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**country**

Luxembourg

**age**

**gender**

female

**questions scope****problem definition**

Yes

**which option**

Extend the scope of the Directive

**additional comments**

All tobacco products are hazardous to health – there is no safe level of usage. Therefore we recommend that the scope of the Directive includes the regulation of any new smoked tobacco products (such as low emission or nicotine-free cigarettes), while the prohibition of any novel forms of oral tobacco, including snus, should be maintained. Herbal cigarettes are also harmful because it is the combustion and inhalation of smoke that causes most of the harm from smoking. Therefore, herbal cigarettes should be included in the scope Tobacco Products Directive and should also be subject to health warnings requirements. Finally, all forms of nicotine based products (that is, products containing nicotine but which are not tobacco products, such as electronic cigarettes, nicotine gel, drinks, and sweets) are often marketed as alternatives to cigarettes and in some cases as an aid to quitting smoking. Therefore, they should only be sold as quitting aids and comply with specific safety and quality requirements under the same regulatory framework as pharmaceutical products rather than under the scope of the Tobacco Products Directive.

**questions smokeless****problem definition**

Yes

**which option**

No change

**additional option**

The ban on snus should definitely be maintained. This is high priority. Indeed, there is no legitimate reason to reintroduce a carcinogenic and addictive product onto the EU market. Furthermore, if the ban on snus were to be lifted, it could encourage dual use of cigarettes and smokeless tobacco and discourage total abstinence from tobacco, thus weakening any potential health gains. In this context, we stress that there are already available effective treatments for nicotine addiction, including medicinal or ‘clean’ nicotine (NRT), that do not carry the risks associated with the use of snus. These should be promoted first and foremost. It is clear that the public health interest can be served even more by encouraging a) greater use of these treatments and b) the development of more effective cessation aids, especially those that mimic more closely the nicotine ‘hit’ delivered by cigarettes. Regarding other forms of smokeless tobacco products, the Union does not believe that they should be “marketed” in all Member States. We recognise that they are as addictive and dangerous as smoked tobacco. As stated in the Opinion of the Scientific Committee on Emerging and Newly Identified Health Risks (SCENIHR), many forms of smokeless tobacco increase the risk of mouth, esophageal, pancreatic and liver cancer, and other conditions including gum and heart disease. However,

we also know that these products are mostly consumed in the UK and used by South Asian communities; introducing an EU-wide ban on these products now could lead to the creation of an unnecessary illegal market, pushing consumption underground. This is why we do not recommend an immediate ban on all types of smokeless tobacco products; we do recommend that they should be regulated in the same way as tobacco products.

**questions consumer  
problem definition**

No

**explanations**

The problem definition could be improved. We agree with the Commission that the current situation, whereby some Member States have made graphic warnings compulsory and others not, has led to a disparity in labelling throughout the EU. Consequently, this has an impact on the functioning of the internal market, on consumers' awareness and as a result, on their smoking behaviour. We also agree that packaging as an advertising tool is not covered by the current Directive. Finally, we welcome the acknowledgement that tobacco packaging and product features are increasingly used to attract consumers, to promote products and brand image. In this context, it would have been judicious to highlight the fact that, in the Eurobarometer survey released in 2010, the policy that received the most positive response is that of putting health warnings on all packages of tobacco products (on average, 75% of EU citizens are in favour of mandatory pictorial warnings, and 54% support plain packaging measures).

**which option**

Improve consumer information; Introduce generic or plain packaging

**which improvement**

Picture warnings to become mandatory; Tar, nicotine and carbon monoxide levels to be replaced with general information on harmful substances in tobacco products; Information on harmful substances in tobacco products that cannot be placed on the package would be placed inside the package; Health warnings to be put on water pipes

**additional option**

Crucial importance of Graphic health warnings: Evidence shows that text only warning messages are not as effective as graphic warnings. Pictures, especially fear inducing pictures, are proven to be effective in getting consumers more engaged with the warning message. Pictures are able to immediately provoke a reaction and prompt people to read the associated text message. The need for graphic health warnings on both sides of the pack: There is also evidence that pictures on both sides of the packaging have a greater impact. The need for LARGE pictorial health warnings (80%): The global trend is towards larger health warnings. Uruguay, for instance, has implemented legislation to make pictorial health warnings obligatory, covering 80% of the front and the back of cigarette packs. Evidence clearly shows that increasing the size of warning messages (text only and combined text and picture) increases the effectiveness of the warning amongst both young and adult smokers / non smokers. Research carried out in Canada by Createc on behalf of Health Canada in 2007 showed that young and adult smokers/non smokers are sensitive to the size of health warning messages. Results showed that warning messages that cover 100% of the pack are significantly more effective across all measured effectiveness indicators compared with warning messages that cover only 50% of the pack. The importance of Rotation: Warning

texts and pictures should be displayed on a rotating basis, so that each message is given equal display and can reach its target audience. The proved effectiveness of shocking health warnings & targeted messages: as specified in the Sambrook Research International report, fear inducing warnings (using strong “shocking” images related to health risks such as rotten teeth or throat cancer) and strong emotion inducing warnings (especially involving children and unborn babies) are the most effective way to educate consumers on the health risks of tobacco use and to achieve changes in attitudes and behaviour. These warnings’ effectiveness is enhanced if they are used in conjunction with a quit line. Generic or plain packaging: We strongly recommend the introduction of standardised/plain packaging. This should include not only the removal of all branding from the packaging but the size and shape of the packaging should also be standardised. Not only would this prevent the promotion of smoking through branding as occurs presently but it would reinforce the health warning messages. Tobacco packaging provides a direct link between consumers and manufacturers and is the main marketing channel, particularly in jurisdictions with tobacco advertising bans. Branding gives the misleading impression some cigarettes are safer than others. The tobacco industry claims that plain packaging would contravene intellectual property law. However, legal analysis concludes that this is incorrect and there are no international legal impediments to the implementation of generic packaging. Replace TNCO quantitative labelling with qualitative information on contents, emissions and quit-lines: The inclusion of machine-based tar, nicotine and carbon monoxide yields on cigarette packs promotes the mistaken belief that some cigarette brands are less harmful than others. We support the proposal to replace numerical measurements with descriptive information on the hazardous effects of tobacco constituents and emissions. We stress the importance of putting quit line numbers on the package. As underlined in the Sambrook research (p46), providing a telephone number on the pack is more effective than telling smokers to seek advice from a doctor or pharmacist. P46 Health warnings on water pipes: There is a growing body of evidence to show that water pipes are at least as hazardous, if not more so, than other forms of tobacco use. Warnings should also be included on the packaging of tobacco used in water pipes.

### **additional comments**

Under Article 5.3 of the TPD 2001, Member States have the option to adopt pictorial warnings. This situation emphasised the right of Member States to go further than the Directive to protect public health as set out in Article 30 of the Treaty of the Union (now article 36). Five years after the adoption of the library of 42 pictorial health warnings by the European commission, seven Member States have adopted legislation to introduce pictorial health warnings (Belgium, Romania, United Kingdom, Latvia, Malta, France and Spain). Such measures are in compliance with the current TPD and are welcomed by the tobacco control community. However, their adoption by some Member States necessarily creates growing discrepancies between Member States. As stated above, there is clear evidence that pictorial warnings are much more powerful than written health warnings. Extending the information and protection to all EU Member States would be in harmony with Article 168 of the TFEU and consistent with the objectives of the internal market stated in Article 114.3 of the TFEU and reiterated in Recital 19 of the Directive. A revision of the TPD should, therefore, aim at making pictorial health warnings of tobacco products subject to common rules. Note: Legislation on labelling, advertising and product regulation put forward by the Commission in the field of tobacco control, has been based on the internal market legislation (Articles 26 and 114 of the TFEU). Article 26 of the TFEU establishes the internal market. Article 114 gives EU institutions the competence to regulate and set rules for the functioning of the internal market. More specifically, article 114.3 also states that when establishing rules for the functioning of the internal market in the context of health, safety, environmental



protection and consumer protection, the Commission “will take as a base a high level of protection, taking account in particular of any new development based on scientific facts.” The European Court of Justice (the “ECJ”) made an extensive analysis of Article 95 EC (now Article 114) throughout the years. In *Spain v. Council*, the Court observed that “recourse to Article 100a (now Article 114) as a legal basis is possible if the aim is to prevent the emergence of future obstacles to trade resulting from multifarious development of national laws.” The TPD was adopted on the basis of Article 114 TFEU (ex Article 95). As a result, Recital 19 of the TPD states that “[t]he presentation of warning labels and yields has continued to remain variable in the different Member States. As a consequence, consumers in one Member State may be better informed as to the risks of tobacco products than in another. Such differences are unacceptable and are liable to constitute a barrier to trade and to impede the operation of the internal market in tobacco products, and should therefore be eliminated.”

### **questions on reporting**

#### **problem definition**

Yes

#### **which option**

Establish a common compulsory reporting format; Introduce fees and sanctions

#### **additional options**

The current situation which allows different formats and reporting mechanisms is unsatisfactory, making it difficult for authorities to compare and analyse the data. All tobacco manufacturers and importers should be subject to the same reporting requirements. The Union believes that tobacco products, which are highly harmful, should be subject to an effective reporting system that allows the gathering and analysis of relevant data, including comparison as appropriate, in order to ensure high levels of consumer safety and information. The format already exists (based on the voluntary reporting format developed by the Commission in May 2007) and it would therefore be very easy to adopt this measure and to implement it. We welcome the introduction of yearly registration fees in order to finance the data collection on ingredients by the national authorities and their analysis work on ingredients. The payment of penalties in case of non-compliance with the requirements of delivery of data on tobacco product ingredients also seems adequate and would contribute to fund the tests conducted on these products. It is crucial that the appropriate toxicological and addictiveness tests are properly conducted. Such tests would allow policy-makers to make more informed decisions in this field, as there would be more scientific evidence. It would enhance the scientific knowledge of the dangers of tobacco products and would contribute to a high protection of health, as stated in Article 95.3 TFEU. Besides, such measures would also have an indirect impact on illicit trade, since only registered products would be allowed on the market.

### **regulation of ingredients**

#### **problem definition**

Yes

#### **which option**

Establish a common list of tobacco ingredients

#### **which one**

Establish a positive common list of tobacco ingredients

**additional comments**

We support the adoption of a positive common list of tobacco ingredients. We believe that tobacco products are highly toxic and addictive, and that their content should therefore be closely regulated, in order to achieve high standards of health protection, as stated under article 114.3. There is a need for such a list at EU level since at the moment, consumers in the internal market are not subject to the same level of protection. Some citizens may be using substances that are banned in other Member States. Apart from creating unequal health protection across the EU, this may constitute an obstacle to free movement of goods within the internal market: some countries can refuse access to their markets of cigarettes from Member States that do not comply with the importing Member State's national requirements.

Regulation of Flavours and Ingredients: Flavourings are an increasingly important part of tobacco industry marketing, particularly to young people. Flavourings enhance attractiveness, encourage youth initiation, and discourage cessation. The prohibition of ingredients that may be used to increase attractiveness, such as sugars and sweeteners, flavouring substances, and spices and herbs, in cigarettes and cigarette-like tobacco products should be introduced. The prohibition of ingredients that may create the impression of a health benefit (e.g. vitamins), ingredients associated with energy and vitality (e.g. caffeine), and ingredients with colouring properties (e.g. pink cigarette paper) should also be banned. Tobacco manufacturers and importers should report sales volume information by brand. This information is essential to help governments ensure that product regulation is effective. The above measures should be compliant with the Guidelines on Art. 9/10, adopted unanimously at the Fourth Conference of the Parties in Uruguay on the 20th November 2010.

**access to tobacco products****problem definition**

Yes

**which option**

Ban

**which one2**

Cross-border retail sales of tobacco to be banned over the Internet; Vending machines to be banned; Promotion and displays in retail stores to be banned

**additional option**

We would like to see the Directive revised to reflect the provisions of the FCTC Article 13 Guidelines with respect to point of sale promotions, vending machines and internet sales.

**additional comments**

Internet: The principle of preventing cross-border promotion of tobacco products in order to protect public health was enshrined in the Tobacco Advertising directive (2001/0119). It is logical, therefore, to extend that principle to the sale of tobacco products between member states via the Internet. We support the prohibition of tobacco sales via the Internet. Vending machines: Considering that only 2 Member States have no legislation on vending machines, we support harmonisation of the legislation on the basis of a prohibition of the sale of tobacco from vending machines . Point of Sale: Evidence shows that a coordinated cross border marketing strategy on the part of the tobacco companies is reflected at point of sale (i.e. point of sale marketing is similar in most EU countries (i.e.: a brand is advertised at point of sale in the same way in Germany and Belgium). There is a growing body of evidence to show that putting tobacco products out of sight in retail outlets can reduce youth smoking. To date, this

measure has been adopted by Ireland and Finland (as well as Iceland and Norway). This measure is also official government policy in Scotland, Wales and Northern Ireland and a decision is awaited in England. We strongly support an EU-wide adoption of a ban on the display of tobacco products at the point of sale.

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## **NGO submission**

### **identification**

#### **affiliation**

NGO

#### **name**

FAI-CISL, Federazione Agricola Alimentare Ambientale Industriale Italiana - Confederazione Italiana Sindacati Lavoratori (Coordinatore settore tabacco - Roberto Vicentini)

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#### **country**

Italia

#### **questions scope**

#### **problem definition**

Yes

#### **which option**

No change

#### **additional comments**

Non reputiamo necessario un allargamento dell'ambito della Direttiva ad altre categorie di prodotti. Seppure riteniamo interessante controllare il mercato delle sigarette senza tabacco, non si può accettare il divieto proposto per tutte le forme di tabacco senza fumo tra cui lo "snus" che rappresenta sbocchi interessanti per alcuni Paesi, non essendo stata dimostrata scientificamente una nocività di questi prodotti analoga a quella degli altri prodotti del tabacco.

#### **questions smokeless**

#### **problem definition**

No

#### **comments**

La spiegazione dettagliata è nello spazio relativo alla scelta dell'opzione.

#### **which option**

Lifting the ban on snus

#### **additional comments**

Riteniamo ingiusto che la commercializzazione del tabacco umido in polvere per uso orale

(c.d. “snus”) sia consentita in un solo Stato dell’UE, ovvero la Svezia, e vietata in tutti gli altri Stati. Il divieto di vendita non è basato su prove scientifiche ed andrebbe rimosso. La nostra posizione è sostenuta anche dal fatto che, in Svezia, diverse ricerche scientifiche dimostrano la riduzione dell’incidenza delle patologie correlate al fumo rispetto alla media UE proprio grazie all’utilizzo dello “snus”. Inoltre, anche la percentuale dei fumatori sul totale della popolazione è inferiore alla media UE. Tale dato dimostrerebbe l’efficacia dello “snus” come potenziale strumento di supporto per smettere di consumare prodotti da fumo. Ci auguriamo, quindi, che lo “snus” venga liberamente commercializzato in tutti gli Stati Membri del mercato unico europeo.

**questions consumer**

**problem definition**

No

**explanations**

La spiegazione dettagliata è nello spazio relativo alla scelta dell’opzione.

**which option**

No change

**additional comments**

Non esistono più fumatori che ignorano i pericoli del consumo. Le foto non hanno dato la prova della loro efficienza. La consapevolezza dei rischi sanitari connessi al prodotto, come sostenuto da più ricerche scientifiche, non aumenta con l’utilizzo di ulteriori avvertenze speciali. A nostro avviso, quindi, la possibilità di inserire avvertenze sotto forma di fotografie a colori o altre illustrazioni dovrebbe essere lasciata alla libera iniziativa degli Stati Membri, come previsto dalla Direttiva attuale. Inoltre, l’introduzione di restrizioni sul pacchetto (es. il c.d. pacchetto generico che riteniamo un’aberrazione per un prodotto da banco e il rischio di mascherare il prodotto a discapito della qualità del tabacco), come suggerito dall’opzione 3, a nostro avviso, mina seriamente la sopravvivenza stessa dell’industria legale a causa del rischio di incremento della contraffazione dei prodotti che va a tutto vantaggio del commercio illecito e delle organizzazioni criminali, rendendo il prodotto più accessibile ai giovani.

**questions on reporting**

**problem definition**

Yes

**which option**

Establish a common compulsory reporting format

**regulation of ingredients**

**problem definition**

No

**explanations**

La spiegazione dettagliata è nello spazio relativo alla scelta dell’opzione.

**which option**

No Change

**additional comments**

Il rischio che alcuni o anche tutti gli ingredienti, vengano vietati, senza fondamento scientifico, è troppo grande. A nostro avviso, la regolamentazione degli ingredienti inseriti nei prodotti del tabacco dovrebbe rimanere competenza degli Stati Membri, come già previsto dall'attuale Direttiva. Questo anche in virtù dei risultati del rapporto del Comitato SCENIHR, incaricato dalla Commissione Europea/DG SANCO di valutare il ruolo degli ingredienti utilizzati in riferimento all'attrattività e all'assuefazione degli stessi. Il rapporto conferma che l'attrattività è un concetto assolutamente soggettivo. L'eventuale divieto di uso degli ingredienti avrebbe gravissime ripercussioni economiche ed occupazionali per il settore del tabacco greggio in Italia. Queste misure, infatti, renderebbero non più economicamente conveniente la coltivazione di alcune varietà di tabacco utilizzato per la produzione di sigarette di tipo American blend e la sopravvivenza dell'intero settore della coltivazione e della prima trasformazione del tabacco in Italia, che occupano circa 60.000 addetti, verrebbe seriamente minata.

**access to tobacco products****problem definition**

Yes

**which option**

Controlled supply and access

**which supply and access**

Age verification of buyers and other legal conditions to be set for cross-border retail sale;  
Access to vending machines to be restricted to adults

**additional comments**

Riteniamo opportuno una discussione sull'accesso controllato, ma non attraverso un approccio di restrizioni globali globale all'interno delle tabaccherie e di internet, che è difficilmente controllabile. A nostro avviso, la determinazione delle misure che stabiliscono i limiti all'accesso ai prodotti a base di tabacco dovrebbe rimanere competenza degli Stati Membri. In particolare, siamo contrari ad ulteriori ed ingiustificate restrizioni, come il divieto totale di esposizione dei prodotti, in quanto determinano una sorta di criminalizzazione del consumo di un prodotto legale, con gravi ripercussioni su tutta la filiera produttiva. Peraltro, auspichiamo che la Direttiva adotti la regolamentazione già presente in Italia, in particolare per quanto riguarda la verifica dell'età dell'acquirente e l'installazione di distributori automatici provvisti di sistema di verifica anagrafica. Infine, supportiamo le restrizioni prospettate per le vendite via internet poiché tali misure, a nostro avviso, preservano il livello qualitativo del prodotto garantito, in Italia, dal sistema di concessione delle licenze ai prodotti del tabacco tutelando, quindi, anche la salute del consumatore.

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**NGO submission****identification****affiliation**

NGO

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**questions scope**

**problem definition**

Yes

**which option**

No change

**questions smokeless**

**problem definition**

Yes

**which option**

No change

**questions consumer**

**problem definition**

Yes

**which option**

No change

**questions on reporting**

**problem definition**

Yes

**which option**

No change

**regulation of ingredients**

**problem definition**

Yes

**which option**

No Change

**access to tobacco products**

**problem definition**

Yes

**which option**

No change

---

**NGO submission**

**identification**

**affiliation**

NGO

**name**

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Switzerland

**age**

64

**gender**

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**questions scope**

**problem definition**

Yes

**which option**

Extend the scope of the Directive

**questions smokeless**

**problem definition**

Yes

**which option**

Ban on all types of smokeless tobacco products

**questions consumer**

**problem definition**

Yes

**which option**

Introduce generic or plain packaging

**questions on reporting**

**problem definition**

Yes

**which option**

Introduce fees and sanctions

**regulation of ingredients**

**problem definition**

Yes

**which option**

Establish a common list of tobacco ingredients

**access to tobacco products**

**problem definition**

Yes

**which option**

Ban

**which one2**

Cross-border retail sales of tobacco to be banned over the Internet; Vending machines to be banned; Promotion and displays in retail stores to be banned

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**NGO submission**

**identification**

**affiliation**

NGO

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Plymouth NHS Stop Smoking Service

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**country**

England, UK

**age**

36

**gender**

female

**questions scope**

**problem definition**

Yes

**which option**

Extend the scope of the Directive

**additional comments**



The Plymouth NHS Stop Smoking Service believes that extending the scope of the Directive will address the problem the most effectively. The Plymouth NHS Stop Smoking Service recommends that the scope of the Directive should be extended to include all smoked products including herbal cigarettes. It is the combustion process and inhalation of smoke that causes most of the harm from smoking. Therefore it is appropriate that herbal cigarettes, which are used in a similar way to nicotine cigarettes, are regulated in the same way as smoked tobacco products, and should be included in the scope of the Directive. However, we do not think that the Directive should include electronic nicotine delivery systems (ENDS or E-cigarettes). These should be brought under the same regulatory framework as pharmaceutical products.

**questions smokeless**

**problem definition**

Yes

**which option**

No change

**additional comments**

The Plymouth NHS Stop Smoking Service believes that more regulation is needed around other legal smokeless products, particularly those used by ethnic minorities. If a ban was implemented then it would create an illegal market which would be difficult to control.

**questions consumer**

**problem definition**

Yes

**which option**

Improve consumer information; Introduce generic or plain packaging

**which improvement**

Picture warnings to become mandatory; Tar, nicotine and carbon monoxide levels to be replaced with general information on harmful substances in tobacco products; Information on harmful substances in tobacco products that cannot be placed on the package would be placed inside the package; Health warnings to be put on water pipes

**additional option**

The Plymouth NHS Stop Smoking Service believes that the minimum size of health warnings should be increased to 80% of the front and back surfaces of all tobacco packaging.

**additional comments**

The Plymouth NHS Stop Smoking Service believes very strongly that picture warnings should be mandatory and that they should occupy a minimum of 80% of the front and back surfaces of all tobacco packaging. This should include hand rolling tobacco, accessories etc. not just cigarettes. The warnings should be placed on the upper portion of the packs for maximum visibility. There should be no differences across the EU to give health protection for all EU citizens. Picture warnings should also be rotated regularly to ensure health messages are communicated to all smokers. There is good evidence to show that health warnings are effective in conveying the dangers of smoking and helping smokers to quit. They also help deter young people from starting to smoke. Picture warnings are more

effective than written warnings. Borland R, Wilson N, Fong GT. et al. Impact of graphic and text warnings on cigarette packs: findings from four countries over five years. *Tob Control* 2009;18:358–64. doi:10.1136/ tc.2008.028043 PMID:19561362 Borland R, Yong HH, Wilson N. et al. How reactions to cigarette packet health warnings influence quitting: findings from the ITC Four-Country survey. *Addiction* 2009;104:669–75. doi:10.1111/j.1360-0443.2009.02508.x PMID:19215595 The Plymouth NHS Stop Smoking Service believes that the information on tar, nicotine & carbon monoxide on cigarette packs is misleading and should be removed. This information promotes the mistaken beliefs that some cigarette brands are less harmful than others and that nicotine causes disease. The EU should not only remove this requirement from the Directive but should prohibit ISO or any other emissions numbers on the pack. It would be more effective to include a helpline number for those who wanted to quit smoking and include descriptive information on the hazardous effects of tobacco constituents and emissions. Koslowski LT, Goldberg ME, Yost BA, et al. Smokers' misperceptions of light and ultra-light cigarettes may keep them smoking. *Am J Prev Med* 1998; 15: 9-16. The Plymouth NHS Stop Smoking Service believes that additional information on harmful substances in tobacco products should be included as inserts inside tobacco packaging and should also include advice on how to quit smoking. The Plymouth NHS Stop Smoking Service believes that there should be Health warnings on water pipes to combat any myths that is a 'healthy' method to smoke. The Plymouth NHS Stop Smoking Service strongly recommends the introduction of plain or generic packaging. This should include not only the removal of all branding from the packaging but the size and shape of the packaging should also be standardised. Not only would this prevent the promotion of smoking through branding as occurs presently but it would reinforce the health warning messages. This is going to be introduced in Australia in 2012. Tobacco packaging provides a direct link between consumers and manufacturers and is the main marketing channel, particularly in jurisdictions with tobacco advertising bans. Branding gives the misleading impression some cigarettes are safer than others. The tobacco industry claims that plain packaging would contravene intellectual property law. However, legal analysis for Action on Smoking and Health concludes that this is incorrect and there are no legal impediments to the implementation of generic packaging in the EU. Wakefield M, Germain D, Durkin S. How does increasingly plainer cigarette packaging influence adult smokers' perceptions about brand image? An experimental study. *Tobacco Control* 2008; 17: 416-421 Hammond D. et al Cigarette pack design and perceptions of risk among UK adults and youth *Eur J Public Health*. 2009 Dec;19(6):631-7. The lawfulness of requiring plain packaging for tobacco products. Opinion of Sir Richard Buxton. Nov 2008

**questions on reporting**

**problem definition**

Yes

**which option**

Establish a common compulsory reporting format; Introduce fees and sanctions

**additional comments**

The Plymouth NHS Stop Smoking Service believes that there should be standardised reporting methods so that data can be compared accurately across the EU.

**regulation of ingredients**

**problem definition**

Yes

**which option**

Establish a common list of tobacco ingredients

**which one**

Establish a positive common list of tobacco ingredients

**additional option**

The Plymouth NHS Stop Smoking Service believes that to address the problem effectively a common list of tobacco ingredients needs to be established and also a positive common list of tobacco ingredients.

**additional comments**

The Plymouth NHS Stop Smoking Service supports the adoption of a positive common list of tobacco ingredients. Tobacco products are highly toxic and addictive; their contents should therefore be regulated in order to achieve high standards of health protection. A positive common list would ensure that only registered products, with ingredients, flavourings and additives that appear on the positive list would be permitted on the EU market. Currently, EU citizens are not subject to the same level of health protection and a common list of permitted ingredients would go some way towards addressing this anomaly. The tobacco industry uses a range of additives to alter the composition of tobacco products. These can make the product more palatable to children or increase the addictiveness of the product. Therefore any flavourings that may be used to enhance the addictiveness or attractiveness of tobacco products should be banned. The revised Product Directive should be fully compliant with the guidelines on Articles 9 & 10 adopted at the fourth Conference of the Parties of the FCTC on 20th November 2010.

**access to tobacco products****problem definition**

Yes

**which option**

Ban

**which one2**

Cross-border retail sales of tobacco to be banned over the Internet; Vending machines to be banned; Promotion and displays in retail stores to be banned

**additional option**

The Plymouth NHS Stop Smoking Service believes that across border retail sales of tobacco to be banned over the Internet. In addition all vending machines need to be banned and the promotion and displays of tobacco be banned. Out of sight out of mind. The Plymouth NHS Stop Smoking Service believes that the example set by Finland is best practice. EU members should be restricted to the amount of tobacco they can import where labelling does not conform to regulations. This should be set at 200 cigarettes, 50 cigars, 100 cigarillos and 250 grams of pipe or cigarette tobacco.

**additional comments**

The Plymouth NHS Stop Smoking Service believes that more can be done with regard to internet tobacco sales. Tobacco sales should be prohibited over the internet. The Plymouth

NHS Stop Smoking Service believes that vending machines selling tobacco should be banned across Europe. Most EU countries have already banned this to deter young people from smoking. The Plymouth NHS Stop Smoking Service believes that there should be an EU wide ban on point of sale for tobacco. Research shows that point of sale displays of tobacco have a direct impact on young people's intention to smoke. Furthermore, there is a growing body of evidence to show that putting tobacco products out of sight in retail outlets can reduce youth smoking. To date, this measure has been adopted by Ireland and Finland (as well as Iceland and Norway) and is going through the parliamentary process in the UK. Tobacco displays at the point of sale. ASH Briefing, Nov. 2010

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## **NGO submission**

### **identification**

#### **affiliation**

NGO

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#### **age**

29

#### **gender**

male

### **questions scope**

#### **problem definition**

No

### **explanations**

Today smokers are educated enough to know that tobacco harms themselves and people around them. Health warnings on each pack supports that, too. Pictures on packs won't strengthen these knowledge. Over and above that, the packaging directive is another restriction without any effectiveness.

### **which option**

No change

### **additional comments**

In times of an information overload it would be better to concentrate on the key message!

### **questions smokeless**

**problem definition**

Yes

**which option**

No change

**questions consumer  
problem definition**

Yes

**which option**

No change

**questions on reporting  
problem definition**

Yes

**which option**

Establish a common compulsory reporting format

**regulation of ingredients  
problem definition**

Yes

**which option**

No Change

**access to tobacco products  
problem definition**

Yes

**which option**

Controlled supply and access

**which supply and access**

Age verification of buyers and other legal conditions to be set for cross-border retail sale;  
Access to vending machines to be restricted to adults

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**NGO submission**

**identification  
affiliation**

NGO

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Belgium

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**gender**

male

**questions scope**

**problem definition**

Yes

**which option**

Extend the scope of the Directive

**recommend option**

All tobacco products are hazardous to health – there is no safe level of usage. Therefore we recommend that the scope of the Directive includes the regulation of any new smoked tobacco products (such as low emission or nicotine-free cigarettes), while the prohibition of any novel forms of oral tobacco, including snus, should be maintained.

**questions smokeless**

**problem definition**

Yes

**which option**

No change

**questions consumer**

**problem definition**

No

**explanations**

The problem definition could be improved. We agree with the Commission that the current situation, whereby some Member States have made graphic warnings compulsory and others not, has led to a disparity in labelling throughout the EU. Consequently, this has an impact on the functioning of the internal market, on consumers' awareness and as a result, on their smoking behaviour. We also agree that packaging as an advertising tool is not covered by the current Directive. Finally, we welcome the acknowledgement that tobacco packaging and product features are increasingly used to attract consumers, to promote products and brand image. In this context, it would have been judicious to highlight the fact that, in the Eurobarometer survey released in 2010, the policy that received the most positive response is that of putting health warnings on all packages of tobacco products (on average, 75% of EU citizens are in favour of mandatory pictorial warnings, and over 54% support plain packaging measures).

**which option**

Introduce generic or plain packaging

### **additional option**

Crucial importance of Graphic health warnings: Evidence shows that text only warning messages are not as effective as graphic warnings. Pictures, especially fear inducing pictures, are proven to be effective in getting consumers more engaged with the warning message. Pictures are able to immediately provoke a reaction and prompt people to read the associated text message. The need for graphic health warnings on both sides of the pack: There is also evidence that pictures on both sides of the packaging have a greater impact. The need for LARGE pictorial health warnings (80%): The global trend is towards larger health warnings. Uruguay, for instance, has implemented legislation to make pictorial health warnings obligatory, covering 80% of the front and the back of cigarette packs. Evidence clearly shows that increasing the size of warning messages (text only and combined text and picture) increases the effectiveness of the warning amongst both young and adult smokers / non smokers. Research carried out in Canada by Createc on behalf of Health Canada in 2007 showed that young and adult smokers/non smokers are sensitive to the size of health warning messages. Results showed that warning messages that cover 100% of the pack are significantly more effective across all measured effectiveness indicators compared with warning messages that cover only 50% of the pack. The importance of Rotation: Warning texts and pictures should be displayed on a rotating basis, so that each message is given equal display and can reach its target audience. The proved effectiveness of shocking health warnings & targeted messages: as specified in the Sambrook Research International report, fear inducing warnings (using strong “shocking” images related to health risks such as rotten teeth or throat cancer) and strong emotion inducing warnings (especially involving children and unborn babies) are the most effective way to educate consumers on the health risks of tobacco use and to achieve changes in attitudes and behaviour. These warnings’ effectiveness is enhanced if they are used in conjunction with a quit line. Generic or plain packaging: We strongly recommend the introduction of standardised/plain packaging. This should include not only the removal of all branding from the packaging but the size and shape of the packaging should also be standardised. Not only would this prevent the promotion of smoking through branding as occurs presently but it would reinforce the health warning messages. Tobacco packaging provides a direct link between consumers and manufacturers and is the main marketing channel, particularly in jurisdictions with tobacco advertising bans. Branding gives the misleading impression some cigarettes are safer than others. The tobacco industry claims that plain packaging would contravene intellectual property law. However, legal analysis concludes that this is incorrect and there are no international legal impediments to the implementation of generic packaging.

### **additional comments**

Replace TNCO quantitative labelling with qualitative information on contents, emissions and quit-lines: The inclusion of machine-based tar, nicotine and carbon monoxide yields on cigarette packs promotes the mistaken belief that some cigarette brands are less harmful than others. We support the proposal to replace numerical measurements with descriptive information on the hazardous effects of tobacco constituents and emissions. We stress the importance of putting quit line numbers on the package. As underlined in the Sambrook research (p46), providing a telephone number on the pack is more effective than telling smokers to seek advice from a doctor or pharmacist. P46 Under Article 5.3 of the TPD 2001, Member States have the option to adopt pictorial warnings. This situation emphasised the right of Member States to go further than the Directive to protect public health as set out in Article 30 of the Treaty of the Union (now article 36). Five years after the adoption of the

library of 42 pictorial health warnings by the European commission, seven Member States have adopted legislation to introduce pictorial health warnings (Belgium, Romania, United Kingdom, Latvia, Malta, France and Spain). Such measures are in compliance with the current TPD and are welcomed by the tobacco control community. However, their adoption by some Member States necessarily creates growing discrepancies between Member States. As stated above, there is clear evidence that pictorial warnings are much more powerful than written health warnings. Extending the information and protection to all EU Member States would be in harmony with Article 168 of the TFEU and consistent with the objectives of the internal market stated in Article 114.3 of the TFEU and reiterated in Recital 19 of the Directive. A revision of the TPD should, therefore, aim at making pictorial health warnings of tobacco products subject to common rules. Health warnings on water pipes: There is a growing body of evidence to show that water pipes are at least as hazardous, if not more so, than other forms of tobacco use. Warnings should also be included on the packaging of tobacco used in water pipes.

**questions on reporting**  
**problem definition**

Yes

**which option**

Establish a common compulsory reporting format

**additional comments**

The current situation which allows different formats and reporting mechanisms is unsatisfactory, making it difficult for authorities to compare and analyse the data. All tobacco manufacturers and importers should be subject to the same reporting requirements. The SFP believes that tobacco products, which are highly harmful, should be subject to an effective reporting system that allows the gathering and analysis of relevant data, including comparison as appropriate, in order to ensure high levels of consumer safety and information. The format already exists (based on the voluntary reporting format developed by the Commission in May 2007) and it would therefore be very easy to adopt this measure and to implement it. We welcome the introduction of yearly registration fees in order to finance the data collection on ingredients by the national authorities and their analysis work on ingredients. The payment of penalties in case of non-compliance with the requirements of delivery of data on tobacco product ingredients also seems adequate and would contribute to fund the tests conducted on these products. It is crucial that the appropriate toxicological and addictiveness tests are properly conducted. Such tests would allow policy-makers to make more informed decisions in this field, as there would be more scientific evidence. It would enhance the scientific knowledge of the dangers of tobacco products and would contribute to a high protection of health, as stated in Article 95.3 TFEU. Besides, such measures would also have an indirect impact on illicit trade, since only registered products would be allowed on the market.

**regulation of ingredients**

**problem definition**

Yes

**which option**

Establish a common list of tobacco ingredients

**additional option**



We support the adoption of a positive common list of tobacco ingredients. We believe that tobacco products are highly toxic and addictive, and that their content should therefore be closely regulated, in order to achieve high standards of health protection, as stated under article 114.3. There is a need for such a list at EU level since at the moment, consumers in the internal market are not subject to the same level of protection. Some citizens may be using substances that are banned in other Member States. Apart from creating unequal health protection across the EU, this may constitute an obstacle to free movement of goods within the internal market: some countries can refuse access to their markets of cigarettes from Member States that do not comply with the importing Member State's national requirements.

**Regulation of Flavours and Ingredients:** Flavourings are an increasingly important part of tobacco industry marketing, particularly to young people. Flavourings enhance attractiveness, encourage youth initiation, and discourage cessation. The prohibition of ingredients that may be used to increase attractiveness, such as sugars and sweeteners, flavouring substances, and spices and herbs, in cigarettes and cigarette-like tobacco products should be introduced. The prohibition of ingredients that may create the impression of a health benefit (e.g. vitamins), ingredients associated with energy and vitality (e.g. caffeine), and ingredients with colouring properties (e.g. pink cigarette paper) should also be banned. Tobacco manufacturers and importers should report sales volume information by brand. This information is essential to help governments ensure that product regulation is effective. The above measures should be compliant with the Guidelines on Art. 9/10, adopted unanimously at the Fourth Conference of the Parties in Uruguay on the 20th November 2010.

#### **access to tobacco products**

##### **problem definition**

Yes

##### **which option**

Ban

##### **which one2**

Cross-border retail sales of tobacco to be banned over the Internet; Vending machines to be banned; Promotion and displays in retail stores to be banned

##### **additional option**

Internet. The principle of preventing cross-border promotion of tobacco products in order to protect public health was enshrined in the Tobacco Advertising directive (2001/0119). It is logical, therefore, to extend that principle to the sale of tobacco products between member states via the Internet. We support the prohibition of tobacco sales via the Internet. Vending machines. Considering that only 2 Member States have no legislation on vending machines, we support harmonisation of the legislation on the basis of a prohibition of the sale of tobacco from vending machines .Point of Sale. Evidence shows that a coordinated cross border marketing strategy on the part of the tobacco companies is reflected at point of sale (i.e. point of sale marketing is similar in most EU countries (i.e.: a brand is advertised at point of sale in the same way in Germany and Belgium). There is a growing body of evidence to show that putting tobacco products out of sight in retail outlets can reduce youth smoking. To date, this measure has been adopted by Ireland and Finland (as well as Iceland and Norway). This measure is also official government policy in Scotland, Wales and Northern Ireland and a decision is awaited in England. We strongly support an EU-wide adoption of a ban on the display of tobacco products at the point of sale.

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## **NGO submission**

### **identification**

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NGO

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### **questions scope**

#### **problem definition**

Yes

#### **which option**

Extend the scope of the Directive

### **questions smokeless**

#### **problem definition**

Yes

#### **which option**

Ban on all types of smokeless tobacco products

### **questions consumer**

#### **problem definition**

Yes

#### **which option**

Improve consumer information; Introduce generic or plain packaging

### **which improvement**

Picture warnings to become mandatory; Information on harmful substances in tobacco products that cannot be placed on the package would be placed inside the package; Health warnings to be put on water pipes

### **additional comments**

Seria muy interesante introducir el empaquetado genérico, siempre que ello no vaya en detrimento de la inclusión de las advertencias sanitarias y la información sobre la composición del producto. De esta forma, se evitará que se utilice el diseño gráfico de la

marca como reclamo publicitario del producto.

**questions on reporting**

**problem definition**

Yes

**which option**

Establish a common compulsory reporting format; Introduce fees and sanctions

**regulation of ingredients**

**problem definition**

Yes

**which option**

Establish a common list of tobacco ingredients

**which one**

Establish a positive common list of tobacco ingredients

**access to tobacco products**

**problem definition**

Yes

**which option**

Ban

**which one2**

Cross-border retail sales of tobacco to be banned over the Internet; Vending machines to be banned; Promotion and displays in retail stores to be banned

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**NGO submission**

**identification**

**affiliation**

NGO

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Spain

**questions scope**

**problem definition**

Yes

**which option**

No change

**recommend option**

The bans must be based on scientific references.

**questions smokeless**

**problem definition**

Yes

**which option**

Lifting the ban on snus

**questions consumer**

**problem definition**

No

**explanations**

¿ It is always the bigger warning the best way to improve the effectiveness of a measure? There is a risk of illegal use of brands or a black market of cigarettes.

**which option**

No change

**questions on reporting**

**problem definition**

No

**explanations**

Members states can introduce sanctions and fees.

**which option**

Establish a common compulsory reporting format

**regulation of ingredients**

**problem definition**

No

**explanations**

Tests must be focused on the risk of increasing toxicity by the use of any ingredients

**which option**

No Change

**access to tobacco products**

**problem definition**

No

**which option**

No change

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**NGO submission****identification****affiliation**

NGO

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Sweden

**questions scope****problem definition**

No

**explanations**

The Confederation of Swedish Conservative and Liberal Students is an organization which promotes a society with individual liberty, low taxes and a free market economy. We mobilize around 2500 members and have a long tradition in participating in the public debate and development of political ideas. Among our former members of the national board you can find the current Swedish minister of Foreign affairs, Carl Bildt and current Swedish minister of Finance, Anders Borg. We also takes part in international activities in the co-operation organization for Nordic centre-right student organizations, the Nordic Conservative Student Union; in the European centre-right student organizations, the European Democrat Students and in the global centre-right youth and student organizations, the International Young Democrat Union. Public health is an uncontroversial concept in politics, the idea that there would be a collective health for all people is widespread and widely accepted. But who owns, and therefore has the right to control one person's body? We are of the opinion that it is the individual him/herself who is in charge of his/her body, and therefore has the right to live as he/she wants as long as the person's lifestyle choices do not conflict with any other individual's corresponding right. The basic idea of the ethical liberalism based on rights is the idea of the individual humans' right to life, personality and property. This results in a comprehensive personal autonomy. The limit for one person's freedom of action is the next person's same right – no more and no less. If someone initiates violence against someone else, it is an assault on that person's rights. Sometimes it is the state that restricts our rights and freedom of action, which does not makes the infringement less appalling. A person's autonomy is as important and equal in relation to the state as to others. It is not possible to consider the public health concept without addressing tobacco and the program of measures directed against this product - which indeed is harmful to the health. The attitude towards tobacco smoking is an excellent example of the big brother mentality, which is the foundation for public health policies. Medically speaking, tobacco smoking constitutes high risks.

However, a lot of people also believe that smoking offers a pleasure that outweighs the risk they take with each cigarette, and continue to smoke despite warnings. We have produced a report, which covers several examples of excessive regulation as regards tobacco, and we will send this report as a complement to our online submission. We believe that every sane adult is fully competent to take care of himself. If someone wants to eat fatty foods, watch a lot of TV, or use tobacco products, it should be up to that person. The rest of us may think that the choice is stupid, but we have no right to interfere in the decision. The limit of my freedom of choice is exactly where it infringes on someone else's similar right. Tobacco regulation is the area where public health policy aggressiveness shows itself most clearly. Legislators are waging a war against tobacco and citizens' freedom of choice to smoke. And what will the future look like? There is no rational reason for public health zealots, who put their own ability ahead of the people's, to stop at anti-tobacco measures. We are convinced that this is a slippery slope and that these measures will spread to other areas. Further regulation is not the way forward, the individual should be able to make his/her own decisions.

**which option**

No change

**questions smokeless**

**problem definition**

No

**which option**

Lifting the ban on snus

**questions consumer**

**problem definition**

No

**explanations**

The proposal to determine what tobacco products actually should look like is problematic. Proposals included in this section, such as an increase in the size of the warning messages to cover a significant part of the packaging, and e.g. very large pictures, is a serious violation of trademark rights and freedom of commerce. Further on, the suggestion to introduce plain packaging would not only be a violation of trademark rights but an abolishment of them. The problem is that this is not just about micro-managing certain aspects of the product's actual appearance, such as through mandatory "warning messages". It is about the state taking over responsibility for product design, in a twentieth century version of completely state-controlled products, but it also involves an even deeper dilemma. When a company is not allowed to display the classic design of its products, the state has violated the company's trademark rights. When such design is prohibited, the state has de facto expropriated the value financially tied up in the brand, an almost unimaginable sum for well-know brands, including some cigarette brands. Advertising bans create entry-barriers that cement the existing market structure, making it harder for new companies to set up in this still-legal (which is, it seems, often forgotten) business.

**which option**

No change

**questions on reporting**

**problem definition**

No

**explanations**

The Confederation of Swedish Conservative and Liberal Students does not have an opinion on reporting and registration of ingredients.

**which option**

No change

**regulation of ingredients****problem definition**

No

**explanations**

Over time, public health focus has increasingly shifted to what is known in medical and epidemiological research as “risk factors”, but which in fact could be interpreted as causes as per the theory of causation. The definition of health has with this shift been extended, and becomes an utopian condition that is impossible to achieve, and therefore by default always possible to strive for. Proposing regulation of ingredients in tobacco products based on notions like attractiveness, which is not even related to the harm caused by the products, is an example of the very far-reaching powers that the authorities that are dedicated to improving the collective health of the population, obtains by this approach and shift in focus. By definition, attractiveness is something that is completely based on individual preferences, how could this possibly be an area for state intervention? The most ambitious utopianism can be found in the increasingly popular ‘zero visions’. However, the utopianism that the concept of population health lends itself to is not compatible with a free society. A clear example comes from Robert Nozick, who in the famous Wilt Chamberlain example highlights the fact that anyone advocating the principles of egalitarian allocation of property – or other, more abstract, things – cannot advocate a free society at the same time.<sup>41</sup> “Liberty upsets patterns”, comments Nozick: whatever distribution you assume, people’s free exchange of goods and services will destroy the pattern. Either you accept that the pattern is broken, or you leave the free society. Zero visions are a similar type of pattern visions as the classic utopias: Plato’s Republic, Thomas More’s Utopia and Tommaso Campanella’s City of the Sun, and they are equally unattainable and equally unfree.

**which option**

No Change

**access to tobacco products****problem definition**

No

**explanations**

Most of us agree that tobacco use is harmful to health. It is also addictive, it may disturb people around the user, and it is considered the main cause of death that can be prevented by lifestyle changes. In other words, an extremely useful product to tackle if you wish to promote public health. There are a certain number of steps in the public health policy ladder, and when it comes to tobacco regulation we have now reached the top step. Information campaigns are, in this respect, the mildest form of state coercion, while taxes is rather a form of indirect

violence. Taxes are collected with a rarely expressed, but always present, threat of punishment for non-payment. On the other hand, citizens have greater freedom to decide by which acts the payment is made. Furthermore, it is still legal to acquire vast amounts of tobacco. Taxes distort the equilibrium ratio, thereby creating higher prices for consumers and producers, but it does not make it impossible to legally consume the products that challenge public health policy. However, outright bans, do precisely that. Regulations of tobacco products, cover the manufacture, marketing, import, sale and places for consumption. Current tobacco legislation limits, among other things, the texts and images on, and the shape of, tobacco packaging, prohibits sponsorship of any events to which the public has access, forces all tobacco products to carry a warning text, and stipulates e.g. in Sweden, where smokers are allowed to smoke. It is not an exaggeration to state that the proposed regulatory measures like bans on vending machines, internet sales, and also a ban on the display of tobacco products, will criminalize the users of tobacco products, as there will be much fewer legal ways of obtaining the products. One of the most common measures from the state, used against products that are considered harmful for users (such as alcohol and tobacco), and used to change consumption patterns, is taxes. However, often it is recognized that too high taxes may lead to an increase of the illicit trade, which more often than not is linked organized crime, and which already is a significant problem in society. Public health policy makers, should consider this consequence carefully as regards all other measures as well. The new health culprits that have been identified are mainly fat and sugar. For many years, politicians and public health advocates have preached the negative effects of fat on human health. An obesity epidemic has been predicted and there have been calls for dramatic government action to curb this. It is easy to see the link between tobacco, alcohol, sugar and fat when it comes to policy making. So the question is what will happen to retailers in 10 years if we start telling retailers which legal products to display and not to display. Following the development it does not seem unrealistic that it will not stop at tobacco products, but move on to banning candy and soda from being displayed in stores. No question is too small to avoid regulation by people with good intentions.

**which option**

No change

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**NGO submission**

**identification**

**affiliation**

NGO

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Italia



**questions scope**  
**problem definition**

Yes

**which option**

No change

**additional comments**

Non reputiamo necessario un allargamento dell'ambito della Direttiva ad altre categorie di prodotti. Seppure riteniamo interessante controllare il mercato delle sigarette senza tabacco, non si può accettare il divieto proposto per tutte le forme di tabacco senza fumo tra cui lo "snus" che rappresenta sbocchi interessanti per alcuni Paesi, non essendo stata dimostrata scientificamente una nocività di questi prodotti analoga a quella degli altri prodotti del tabacco.

**questions smokeless**  
**problem definition**

No

**comments**

La spiegazione dettagliata è nello spazio relativo alla scelta dell'opzione.

**which option**

Lifting the ban on snus

**additional comments**

Riteniamo ingiusto che la commercializzazione del tabacco umido in polvere per uso orale (c.d. "snus") sia consentita in un solo Stato dell'UE, ovvero la Svezia, e vietata in tutti gli altri Stati. Il divieto di vendita non è basato su prove scientifiche ed andrebbe rimosso. La nostra posizione è sostenuta anche dal fatto che, in Svezia, diverse ricerche scientifiche dimostrano la riduzione dell'incidenza delle patologie correlate al fumo rispetto alla media UE proprio grazie all'utilizzo dello "snus". Inoltre, anche la percentuale dei fumatori sul totale della popolazione è inferiore alla media UE. Tale dato dimostrerebbe l'efficacia dello "snus" come potenziale strumento di supporto per smettere di consumare prodotti da fumo. Ci auguriamo, quindi, che lo "snus" venga liberamente commercializzato in tutti gli Stati Membri del mercato unico europeo.

**questions consumer**  
**problem definition**

No

**explanations**

La spiegazione dettagliata è nello spazio relativo alla scelta dell'opzione.

**which option**

No change

**additional comments**

Non esistono più fumatori che ignorano i pericoli del consumo. Le foto non hanno dato la prova della loro efficienza. La consapevolezza dei rischi sanitari connessi al prodotto, come

sostenuto da più ricerche scientifiche, non aumenta con l'utilizzo di ulteriori avvertenze speciali. A nostro avviso, quindi, la possibilità di inserire avvertenze sotto forma di fotografie a colori o altre illustrazioni dovrebbe essere lasciata alla libera iniziativa degli Stati Membri, come previsto dalla Direttiva attuale. Inoltre, l'introduzione di restrizioni sul pacchetto (es. il c.d. pacchetto generico che riteniamo un'aberrazione per un prodotto da banco e il rischio di mascherare il prodotto a discapito della qualità del tabacco), come suggerito dall'opzione 3, a nostro avviso, mina seriamente la sopravvivenza stessa dell'industria legale a causa del rischio di incremento della contraffazione dei prodotti che va a tutto vantaggio del commercio illecito e delle organizzazioni criminali, rendendo il prodotto più accessibile ai giovani.

### **questions on reporting**

#### **problem definition**

Yes

#### **which option**

Establish a common compulsory reporting format

### **regulation of ingredients**

#### **problem definition**

No

#### **explanations**

La spiegazione dettagliata è nello spazio relativo alla scelta dell'opzione.

#### **which option**

No Change

### **additional comments**

Il rischio che alcuni o anche tutti gli ingredienti, vengano vietati, senza fondamento scientifico, è troppo grande. A nostro avviso, la regolamentazione degli ingredienti inseriti nei prodotti del tabacco dovrebbe rimanere competenza degli Stati Membri, come già previsto dall'attuale Direttiva. Questo anche in virtù dei risultati del rapporto del Comitato SCENIHR, incaricato dalla Commissione Europea/DG SANCO di valutare il ruolo degli ingredienti utilizzati in riferimento all'attrattività e all'assuefazione degli stessi. Il rapporto conferma che l'attrattività è un concetto assolutamente soggettivo. L'eventuale divieto di uso degli ingredienti avrebbe gravissime ripercussioni economiche ed occupazionali per il settore del tabacco greggio in Italia. Queste misure, infatti, renderebbero non più economicamente conveniente la coltivazione di alcune varietà di tabacco utilizzato per la produzione di sigarette di tipo American blend e la sopravvivenza dell'intero settore della coltivazione e della prima trasformazione del tabacco in Italia, che occupano circa 60.000 addetti, verrebbe seriamente minata.

### **access to tobacco products**

#### **problem definition**

Yes

#### **which option**

Controlled supply and access

#### **which supply and access**

Age verification of buyers and other legal conditions to be set for cross-border retail sale;  
Access to vending machines to be restricted to adults

**additional comments**

Riteniamo opportuno una discussione sull'accesso controllato, ma non attraverso un approccio di restrizioni globali globale all'interno delle tabaccherie e di internet, che è difficilmente controllabile. A nostro avviso, la determinazione delle misure che stabiliscono i limiti all'accesso ai prodotti a base di tabacco dovrebbe rimanere competenza degli Stati Membri. In particolare, siamo contrari ad ulteriori ed ingiustificate restrizioni, come il divieto totale di esposizione dei prodotti, in quanto determinano una sorta di criminalizzazione del consumo di un prodotto legale, con gravi ripercussioni su tutta la filiera produttiva. Peraltro, auspichiamo che la Direttiva adotti la regolamentazione già presente in Italia, in particolare per quanto riguarda la verifica dell'età dell'acquirente e l'installazione di distributori automatici provvisti di sistema di verifica anagrafica. Infine, supportiamo le restrizioni prospettate per le vendite via internet poiché tali misure, a nostro avviso, preservano il livello qualitativo del prodotto garantito, in Italia, dal sistema di concessione delle licenze ai prodotti del tabacco tutelando, quindi, anche la salute del consumatore.

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**NGO submission**

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NGO

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**questions scope**

**problem definition**

Yes

**which option**

No change

**questions smokeless**

**problem definition**

Yes

**which option**

Lifting the ban on snus

**questions consumer**

**problem definition**

No

**explanations**

No comments.

**which option**

No change

**questions on reporting  
problem definition**

No

**explanations**

No comments

**which option**

Establish a common compulsory reporting format

**regulation of ingredients**

**problem definition**

No

**explanations**

No comments

**which option**

No Change

**access to tobacco products**

**problem definition**

No

**explanations**

No comments

**which option**

No change

---

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**questions scope****problem definition**

No

**explanations**

The Swedish Association of Retail Grocers do not have an opinion on the scope of the directive

**which option**

No change

**recommend option**

Lift the ban on snus within EU.

**questions smokeless****problem definition**

Yes

**which option**

Lifting the ban on snus

**questions consumer****problem definition**

Yes

**which option**

Improve consumer information

**which improvement**

Picture warnings to become mandatory; Health warnings to be put on water pipes

**additional option**

Harmonized and high levels of tobacco taxes, and harmonized and high fees for smuggling of cigarettes.

**questions on reporting****problem definition**

Yes

**which option**

Establish a common compulsory reporting format; Introduce fees and sanctions

**regulation of ingredients****problem definition**

Yes

**which option**

No Change

**access to tobacco products**

**problem definition**

Yes

**which option**

No change

**additional comments**

The Swedish Association of Retail Grocers, Lvismedelshandlarna, has been active in the debate regarding display ban in Sweden, as it has serious consequences for the trade without leading to any improved health effect. Statistics from countries that have tried a display ban do not demonstrate a reduction in tobacco consumption, but on the other hand shows serious unintended consequences such as increased smuggling. We are also concerned regarding the signal that such a ban will send to the consumer. Today there is a clear distinction between legal and illegal products, hence the legal products are on display and the illegal can be found under the counter in stores run by criminals. A display ban would only benefit the criminals.

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NGO

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**questions scope**

**problem definition**

Yes

**which option**

Extend the scope of the Directive

**recommend option**

We recommend the following: + Extend the scope of the Directive to include all smoked products including herbal cigarettes. + Do NOT extend the Directive to include electronic nicotine delivery systems (ENDS or E-cigarettes). It is the combustion process and inhalation

of smoke that causes most of the harm from smoking. Therefore it is appropriate that herbal cigarettes, which are used in a similar way to nicotine cigarettes, are regulated in the same way as smoked tobacco products, and should be included in the scope of the Directive. Therefore we recommend that the scope of the Directive includes the regulation of any new smoked tobacco products (such as low emission or nicotine-free cigarettes). Novel nicotine based products (that is, products containing nicotine but not tobacco products) have the potential to offer a less hazardous alternative to cigarettes. Currently these include e-cigarettes and nicotine gel. However, as such products are generally marketed as alternatives to cigarettes and in some cases as an aid to quitting smoking, it is appropriate for them to be brought under the same regulatory framework as pharmaceutical products rather than under the scope of the tobacco products directive. The question of how nicotine containing products should be controlled is currently under consideration by the UK's Medicines and Healthcare Regulatory Authority (MHRA) following a recent public consultation on whether to extend its remit on the regulation of nicotine replacement therapies to other nicotine containing products. The outcome of this consultation may assist the Commission in developing its policy on these products.

**questions smokeless**

**problem definition**

Yes

**which option**

No change

**additional comments**

With regard to smokeless products that are not currently illegal, particularly those used by ethnic minority populations, we recommend that they are more tightly regulated but we do not support a total ban on such products. Whilst recognising that such products are harmful, the introduction of an EU-wide ban could create an illegal market that would be more difficult to control than the current situation. Furthermore a ban would make it more difficult to engage with users to offer help in quitting.

**questions consumer**

**problem definition**

Yes

**which option**

Improve consumer information

**which improvement**

Picture warnings to become mandatory; Tar, nicotine and carbon monoxide levels to be replaced with general information on harmful substances in tobacco products; Information on harmful substances in tobacco products that cannot be placed on the package would be placed inside the package; Health warnings to be put on water pipes

**additional option**

The minimum size of health warnings should be increased to 80% of the front and back surfaces of all tobacco packaging.

**additional comments**

**Picture Warnings** We strongly recommend that picture warnings should be mandatory and that they should occupy a minimum of 80% of the front and back surfaces of all tobacco packaging (i.e. not just cigarettes). The warnings should be placed on the upper portion of the packs for maximum visibility. The current situation with some Member States adopting picture warnings whilst others have not done so has created a discrepancy and uneven health protection across the EU. From an internal market perspective, the differences in rules are contrary to the operation of the single market and may constitute a barrier to trade. These obstacles should therefore be removed and pictorial health warnings should be mandatory to ensure optimum health protection for all EU citizens. There is good evidence to show that health warnings are effective in conveying the dangers of smoking and helping smokers to quit. They also help deter young people from starting to smoke. Picture warnings are more effective than written warnings.<sup>2</sup> All warnings should be displayed in rotation so that each message is given equal display to reach its target audience. There is widespread consumer support for pictorial health warnings. A Eurobarometer survey conducted in October 2009 showed that 78% of respondents supported health warnings. Information on tar, nicotine & carbon monoxide (TNCO) Currently the Directive requires the inclusion of machine-based tar, nicotine and carbon monoxide yields on cigarette packs. This promotes the mistaken beliefs that some cigarette brands are less harmful than others and that nicotine causes disease. The EU should not only remove this requirement from the Directive but should prohibit ISO or any other emissions numbers on the pack. We support the proposal to replace numerical measurements with descriptive information on the hazardous effects of tobacco constituents and emissions. The addition of a quitline telephone service should be included on the packaging.

**questions on reporting**

**problem definition**

Yes

**which option**

No change

**regulation of ingredients**

**problem definition**

Yes

**which option**

Establish a common list of tobacco ingredients

**which one**

Establish a positive common list of tobacco ingredients

**additional option**

We support the adoption of a positive common list of tobacco ingredients. Tobacco products are highly toxic and addictive; their contents should therefore be regulated in order to achieve high standards of health protection. A positive common list would ensure that only registered products, with ingredients, flavourings and additives that appear on the positive list would be permitted on the EU market. Currently, EU citizens are not subject to the same level of health protection and a common list of permitted ingredients would go some way towards addressing this anomaly. The tobacco industry uses a range of additives to alter the composition of tobacco products. These can make the product more palatable to children or increase the



addictiveness of the product. Therefore any flavourings that may be used to enhance the addictiveness or attractiveness of tobacco products should be banned. The revised Product Directive should be fully compliant with the guidelines on Articles 9 & 10 adopted at the fourth Conference of the Parties of the FCTC on 20th November 2010.

**access to tobacco products**

**problem definition**

Yes

**which option**

Ban

**which one2**

Cross-border retail sales of tobacco to be banned over the Internet; Vending machines to be banned; Promotion and displays in retail stores to be banned

**additional option**

The EU Directive should follow the lead set by Finland which, as part of its recently passed Tobacco Act, has set limits on the amount of tobacco that can be imported into Finland where the labelling differs from that of tobacco products sold in Finland. We recommend that similar limits should be set at EU level, that is, that for each Member State the amount of tobacco that may be imported for personal use which does not conform to domestic labelling requirements, should be limited to a maximum of 200 cigarettes, 50 cigars, 100 cigarillos and 250 grams of pipe or cigarette tobacco.

**additional comments**

Internet. The principle of preventing cross-border promotion of tobacco products in order to protect public health was enshrined in the Tobacco Advertising directive (2001/0119). It is logical, therefore, to extend that principle to the sale of tobacco products between member states via the Internet. We support the prohibition of tobacco sales via the Internet. Vending machines. The majority of member states (22 out of 27) already prohibit the sale of tobacco products from vending machines in order to deter young people accessing cigarettes from this source. We support this measure. Point of Sale. We support an EU-wide adoption of a ban on the display of tobacco products at the point of sale. Across the EU, most forms of tobacco advertising are now prohibited but the tobacco industry continues to market its products by the use of attractive packaging. Research shows that point of sale displays of tobacco have a direct impact on young people's intention to smoke. Furthermore, there is a growing body of evidence to show that putting tobacco products out of sight in retail outlets can reduce youth smoking. To date, this measure has been adopted by Ireland and Finland (as well as Iceland and Norway) and is going through the parliamentary process in the UK.

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NGO

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Estonia

**questions scope**

**problem definition**

Yes

**which option**

No change

**recommend option**

We admit that the scope of the directive could be extended but when imposing bans then any bans should be based on scientific assessments.

**questions smokeless**

**problem definition**

Yes

**which option**

Lifting the ban on snus

**questions consumer**

**problem definition**

No

**explanations**

It is not clear and there lacks evidence that bigger warnings are more effective. When talking about plain packaging then it is very questionable that this kind of method would improve the internal market or public health. Besides, one cannot ignore that it would be easier to copy illegally those packages.

**which option**

No change

**questions on reporting**

**problem definition**

No

**explanations**

There is a possibility for member states according to the directive to impose fees or sanctions. The exact enforcement of the directive should be in the hands of the member state.

**which option**

Establish a common compulsory reporting format

**regulation of ingredients****problem definition**

No

**explanations**

It is necessary to do more research on this theme and restrictions should be based on objective criteria. For example when there is scientific evidence that some ingredients give rise to toxicity of tobacco smoke then it may be a reason for restriction.

**which option**

No Change

**access to tobacco products****problem definition**

No

**explanations**

There should be clear evidence that those bans improve internal market or public health objectives otherwise we cannot talk about reasonable and necessary bans of this kind.

**which option**

No change

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**NGO submission****identification****affiliation**

NGO

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Polska

**questions scope****problem definition**

Yes

**which option**

No change

**recommend option**

No comments

**additional comments**

No comments

**questions smokeless  
problem definition**

Yes

**which option**

Lifting the ban on snus

**additional option**

No comments

**additional comments**

No comments

**questions consumer  
problem definition**

No

**explanations**

No comments

**which option**

No change

**additional option**

No comments

**additional comments**

No comments

**questions on reporting  
problem definition**

No

**explanations**

No comments

**which option**

Establish a common compulsory reporting format

**additional options**

No comments

**additional comments**

No comments

**regulation of ingredients  
problem definition**

No

**explanations**

No comments

**which option**

No Change

**additional option**

No comments

**additional comments**

No comments

**access to tobacco products  
problem definition**

No

**explanations**

No comments

**which option**

No change

**additional option**

No comments

**additional comments**

No comments

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**questions scope**  
**problem definition**  
Yes

**which option**  
Extend the scope of the Directive

**recommend option**  
regional, nacional

**additional comments**  
no

**questions smokeless**  
**problem definition**  
Yes

**which option**  
Ban on all types of smokeless tobacco products

**additional option**  
no

**additional comments**  
no

**questions consumer**  
**problem definition**  
Yes

**which option**  
Improve consumer information

**which improvement**  
Picture warnings to become mandatory; Information on harmful substances in tobacco products that cannot be placed on the package would be placed inside the package

**additional option**  
no

**additional comments**  
no

**questions on reporting**  
**problem definition**  
Yes

**which option**  
Introduce fees and sanctions

**additional options**

no

**additional comments**

no

**regulation of ingredients**

**problem definition**

Yes

**which option**

Establish a common list of tobacco ingredients

**which one**

Establish a negative common list of tobacco ingredients

**additional option**

no

**additional comments**

no

**access to tobacco products**

**problem definition**

Yes

**which option**

No change; Ban

**which one2**

Promotion and displays in retail stores to be banned

**additional option**

no

**additional comments**

no

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**NGO submission**

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NGO

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**questions scope**  
**problem definition**  
Yes

**which option**  
Extend the scope of the Directive

**recommend option**  
Prohibition of product sale below age of 18, banning of all tobacco ads

**questions smokeless**  
**problem definition**  
Yes

**which option**  
No change

**questions consumer**  
**problem definition**  
Yes

**which option**  
Improve consumer information

**which improvement**  
Picture warnings to become mandatory; Tar, nicotine and carbon monoxide levels to be replaced with general information on harmful substances in tobacco products; Information on harmful substances in tobacco products that cannot be placed on the package would be placed inside the package

**questions on reporting**  
**problem definition**  
Yes

**which option**  
Establish a common compulsory reporting format; Introduce fees and sanctions

**regulation of ingredients**  
**problem definition**



Yes

**which option**

Establish a common list of tobacco ingredients

**which one**

Establish a positive common list of tobacco ingredients; Establish a negative common list of tobacco ingredients

**access to tobacco products**

**problem definition**

Yes

**which option**

Controlled supply and access

**which supply and access**

Age verification of buyers and other legal conditions to be set for cross-border retail sale; Access to vending machines to be restricted to adults; Tobacco display and promotion at points of sales to be restricted

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NGO

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**questions scope**

**problem definition**

Yes

**which option**

Extend the scope of the Directive

**recommend option**

- All kinds of tobacco are harmful, at any dose. The scope of Directive should cover both smoked tobacco and smokeless tobacco products (including e-cigarettes), also some other herbal products which can be used in a similar way to tobacco. - Nicotine based products, which are offered as alternative to cigarettes should be covered by the Directive (excluding nicotine containing pharmaceutical products). - Specific item in the Directive is necessary to regulate water-pipe use, which has been widely promoted during the last years, particularly to the youth. Industry claims that, they produce so called “tobacco-free narghile” and it is served at many places (narghile houses, narghile cafes, etc.) which is almost impossible to detect and evaluate whether tobacco is present or not in.

**questions smokeless****problem definition**

Yes

**which option**

Ban on all types of smokeless tobacco products

**additional option**

Although some forms of smokeless tobacco products seem to be less hazardous than cigarettes, serious health problems may occur due to use of smokeless tobacco products, and they can not be offered as quit aid. Therefore all forms of smokeless tobacco products also should be banned by the new Directive.

**questions consumer****problem definition**

Yes

**which option**

Improve consumer information; Introduce generic or plain packaging

**which improvement**

Picture warnings to become mandatory; Tar, nicotine and carbon monoxide levels to be replaced with general information on harmful substances in tobacco products; Information on harmful substances in tobacco products that cannot be placed on the package would be placed inside the package; Health warnings to be put on water pipes

**additional option**

- Picture warnings on cigarette packages should be mandatory, and should cover at least 65% (preferably 80%) of the front and back surfaces. - Health warnings and pictures should be placed on water pipe and all other forms of tobacco products. - New and more effective health messages and pictures are needed to be developed. - All kinds of misinformation and deceptive information should be eliminated, such as different colors and different packaging, etc. - Number of “toll-free” quit line service should be placed on the packages.

**questions on reporting****problem definition**

Yes

**which option**

Establish a common compulsory reporting format; Introduce fees and sanctions

**additional options**

- There should be an effective reporting system, and all tobacco manufacturers should be subject to the same reporting requirements.

**regulation of ingredients****problem definition**

Yes

**which option**

Establish a common list of tobacco ingredients

**which one**

Establish a positive common list of tobacco ingredients

**additional option**

- Tobacco products, in all forms are toxic. Therefore the ingredients of tobacco should be regulated in parallel to FCTC.

**access to tobacco products****problem definition**

Yes

**which option**

Ban

**which one2**

Cross-border retail sales of tobacco to be banned over the Internet; Vending machines to be banned; Promotion and displays in retail stores to be banned

**additional option**

- Sales of tobacco products through internet and other forms of distant retail sales should be banned - All duty free and duty reduced sales of tobacco products should be banned. - Point of sale regulation should be made to prevent the visibility of tobacco products, and all kinds of promotion at the point of sale should be banned.

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**NGO submission****identification****affiliation**

NGO

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**questions scope**

**problem definition**

No

**explanations**

1a. Generalnie nie zgadzamy się ze sposobem przedstawienia wyrobów tytoniowych w materiałach do konsultacji a przez to z definicjami żadnego z przedstawionych problemów. Problemy są zdefiniowane całkowicie niejasno i nieprawidłowo ponieważ nie brzmią neutralnie lecz sugerują nastawienie do ankiety i odpowiedzi. Dodatkowo opisy problemów nie przedstawiają naukowych i sprawdzonych podstaw dla różnych opcji rozwiązanych w tej ankiecie. Dowodzi to braku rozumienia sektora tytoniowego.

**which option**

No change

**recommend option**

1b. Prowadzone działania w celu denormalizacji rynku tytoniowego na pewno nie realizują zakładanych celów zdrowotnych. Wprowadzona w latach dwudziestych, prohibicja w Stanach Zjednoczonych w żadnej mierze nie rozwiązała problemu, a na dodatek zaowocowała mnóstwem fatalnych konsekwencji społecznych, ekonomicznych i prawnych. Rozważane zmiany mogą jedynie wpłynąć na źródło zaopatrzenia dla konsumentów z legalnego na nielegalne. Jednocześnie spowoduje to brak popytu na produkt naszej pracy. W Polsce istnieją znaczne trudności wprowadzenia innych rodzajów upraw w miejsce tytoniu co wynika z charakterystyki polskich upraw: mały rozmiar gospodarstwa, relatywnie niska jakość ziemi, koncentracja upraw w regionach o słabym poziomie infrastruktury. W regionach Polski gdzie uprawia się tytoń (dolnośląski, lubelski, małopolski, podkarpacki, mazurski i świętokrzyski) rzadko można znaleźć jakakolwiek alternatywę ekonomiczną. Nieprzemysłane rozwiązania regulacyjne oznaczają w naszym kraju utratę jedyne go źródła utrzymania dla tysięcy rodzin. Pewne zachowania i przyzwyczajenia jesteśmy w stanie zmieniać nie groźbami, nakazami i zakazami, lecz mądrą edukacją a także mądrym i stanowczym egzekwowaniem istniejących regulacji.

**additional comments**

**questions smokeless**

**problem definition**

No

**comments**

no comments

**which option**

Lifting the ban on snus

**questions consumer  
problem definition**

No

**explanations**

no comments

**which option**

No change

**questions on reporting  
problem definition**

No

**explanations**

no comments

**which option**

Establish a common compulsory reporting format

**regulation of ingredients**

**problem definition**

No

**explanations**

5a. Sposób przedstawienia używania składników w definicji problemu jest całkowicie nieprawidłowy. Składniki są wykorzystywane ponieważ są niezbędne w procesie produkcyjnym z technologicznego punktu widzenia lub też w celu odróżniania produktów. Nie są dodawane po to aby przyciągać osoby niepalące. Wg naszej wiedzy nie ma wiarygodnych i naukowych podstaw które popierałyby przypuszczenie że składniki w ilościach w jakich są używane w wyrobach tytoniowych wzmacniają właściwości uzależniające. Opinia SCENIHR jasno mówi że nie ma dowodów na to że składniki zwiększają poziom uzalenienia od wyrobów tytoniowych albo że same w sobie sa uzależniające. W naszym przekonaniu zupełnie niedopuszczalne jest odwoływanie się do "atrakcyjności" jako wyznacznika takiego lub innego kształtu regulacji bo jest to z natury bardzo subiektywne i arbitralne. Uznaniowość w stanowieniu prawa, szczególnie w tym przypadku pociągnie za sobą katastrofalne skutki społeczne i gospodarcze, pozbawiając tysiące plantatorów pracy a ich rodziny jedyne źródła utrzymania. Składniki są używane aby możliwy był przerób tytoniu który uprawiamy. Bez niego nie będzie możliwe używanie produktu naszej pracy. Prawo i regulacje powinny być stanowione w oparciu o dowody że będzie ono skuteczne. Skutkiem rozważanych opcji może być jedynie doprowadzenie do utraty jedyne źródła utrzymania całej rzeszy plantatorów w całej Europie, w tym kilku tysięcy tych którzy są członkami naszego związku. Ostatecznie z pełną stanowczością sprzeciwiamy się tym nieprzemyślanym pomysłom, ponieważ nie realizując w najmniejszym stopniu celów zdrowotnych, pociągnęłyby za sobą ogromne, negatywne implikacje gospodarcze i społeczne.

**which option**

No Change

**additional option**

5b. Zgadza się z tym że np. palenie nieletnich jest poważnym problemem i wymaga naprawy. W naszym przekonaniu problem w dużym stopniu będzie rozwiązany poprzez lepsze egzekwowanie istniejącego prawa. Nowe regulacje, w tym te które dotyczą dodatków i ich potencjalnego wpływu na wielkość problemu, powinny być rozważane tylko i dopiero wtedy kiedy będą istniały naukowe podstawy dowodzące przyczynowo skutkowej zależności między poszczególnymi składnikami a paleniem nieletnich lub też właściwościami uzależniającymi.

**access to tobacco products**

**problem definition**

No

**explanations**

no comments

**which option**

No change

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**NGO submission**

**identification**

**affiliation**

NGO

**name**

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**email**

nma-hungary@t-online.hu

**country**

Hungary

**questions scope**

**problem definition**

No

**explanations**

No, we disagree with the problem definition. The problem definition is incorrect, vague and unclear. For example it quotes that “the tobacco products market has increasingly diversified” but then goes on to list non-tobacco products including, electronic cigarettes and nicotine drinks and no actual tobacco products. Non-tobacco products containing nicotine are substantially different from tobacco products. They should be regulated separately. This confusion clearly demonstrates a fundamental lack of understanding of the tobacco sector. This lack of understanding is compounded by the fact that the problem definition fails to provide any scientific basis or evidence for the different options considered in this section. We do not consider that the Consultation identifies a problem in any of the areas it mentions in this section. HATI cautions that indiscriminately banning novel forms of oral tobacco could

impact the future development of potentially reduced exposure products. Finally, we note that the Consultation contains no analysis of Union competence to adopt the different options, the implications of those options for the functioning of the internal market or their proportionality. Nor is any evidence provided in the Consultation for the different options discussed in this section. We are concerned that the Commission will refer to the Final RAND Report in this regard. Therefore we will send our critique on the report separately. As the problem definition is fundamentally flawed, we are not in a position to comment on the proposed change options.

**which option**

No change

**recommend option**

See response to Question 1 above

**questions smokeless**

**problem definition**

No

**comments**

HATI is a cigarette manufacturers' association. It is not an association of manufacturers of smokeless tobacco products.

**which option**

Lifting the ban on snus

**additional option**

See response to Question 1 above

**questions consumer**

**problem definition**

No

**explanations**

The problem definition is based upon a series of assumptions and assertions that are wrong, and which have the effect of incorrectly defining the debate regarding consumer information. First, despite being entitled “consumer information”, Section 3 only addresses tobacco packaging. Regulators have access to a variety of vehicles to communicate information to consumers, including television, print media, magazines and the internet. The “problem” is defined overly narrowly, and so fails to identify relevant policy options. Secondly, tobacco packaging and pack labelling is not a predictor of youth smoking. The considerable body of evidence and research which exists on the predictors for smoking initiation does not substantiate any link between packaging and youth uptake. The problem definition is, however, concerned with packaging from this perspective. As a result of this flaw, none of the proposed measures in Section 3 regarding packaging are likely to have an impact on youth smoking initiation. Thirdly, the problem definition confuses tobacco packaging and advertising. Packaging and pack labelling are an essential means by which consumers identify, obtain information about and choose tobacco products, easily and without confusion. HATI does not accept the contention that the cigarette pack constitutes a form of promotional advertising. The distinction between advertising and packaging and pack labelling is

confirmed by the way EU tobacco legislation and the FCTC articles 11 and 13 addresses these issues separately. ....

#### **which option**

No change

#### **additional option**

In the absence of any analysis in the Consultation of the Union competence to adopt the different options, the implications of those options for the functioning of the internal market, and their proportionality, HATI considers that only Option 1 – no change – is appropriate. For the options already referenced in the Commission’s problem definition, HATI repeats its comments set out in response to question 1, above. For HATI’s positions and comments on options or subjects which are mentioned for the first time in this section of the consultation document, please see below.

#### **additional comments**

DG SANCO should assess and evaluate existing legislation and other, less restrictive and more proportionate options to remind consumers of the risks associated with smoking before proposing new measures. These could include an expansion of it’s or the Member States’ public health information campaigns through audio-visual or print media or the internet (which have the added advantage of reaching the entire population rather than only existing smokers) or youth retail access prevention programmes.

#### **questions on reporting**

##### **problem definition**

No

#### **explanations**

We agree with the part of the definition referring to the divergence of formats and mechanism for ingredient reporting across the EU and confirming that there are concerns on the manner by which trade secrets are dealt with. The problem definition makes no reference to the common reporting format, communicated via the European Commission’s Practical Guide on tobacco product ingredients reporting. It was communicated as a non-binding format to the EU Member States but with the expectation that it should be adopted by manufacturers, importers and Member States with the desire for data to be submitted in electronic form. Despite the guidance given from the Commission, to date not all Member States have adopted the new common reporting format for ingredients disclosure or have fully implemented the new templates into their submission process. We acknowledge the significant progress that has been made in terms of defining an appropriate reporting regime for ingredients used in the manufacture of tobacco products and will continue to implement the new templates in accordance with Member State requirements. We would like to point out that problems still remain to be resolved in respect of the templates and the systems. However, it is vital that ongoing dialogue is developed and maintained in order to obtain a clear understanding of where data gaps occur, and what is meant by an incomplete data set. We note that part of the problem definition relating to the situation, i.e., “Collection and analysis of the reported data on ingredients requires substantial resources for national competent authorities”, is made without reference to the EMTOC project and the progress made in this context. Furthermore, the problem definition goes on to state: “It has proven difficult to get financing for the development, validation and carrying out of the appropriate toxicological and addictiveness tests”, without providing any foundation for the statement. Tobacco industry members have



provided extensive toxicological data to Member States, none of which to our knowledge has been analysed or commented on. Numerous Member States have regulations on ingredients use, e.g. Germany, France, UK, Belgium, and our members only use permitted ingredients. The Commission has never set out a science-based toxicological framework or established any scientific forum for discussing these matters. The problem definition fails to mention the opinion of SCENIHR on the use of ingredients and attractiveness and addictiveness or their conclusion that they found no evidence to suggest that any ingredient adds to, or of itself contributes to tobacco products addictiveness. We note that the Consultation contains no analysis of Union competence to adopt the different options, the implications of those options for the functioning of the internal market or their proportionality. Nor is any evidence provided in the Consultation for the different options discussed in this section. We are concerned that the Commission will refer to the Final RAND Report in this regard.

### **which option**

Establish a common compulsory reporting format

### **additional options**

HATI members support option two, the principle of a common reporting format, with the qualification that it must be embodied in an EMTOC type solution. Our members support the principle of the common reporting format for ingredients disclosure and recognise that some of the data is commercially sensitive and contains trade secrets and should be held in confidence. We support the principle of an electronic sustainable, robust and secure database system of the type under development by EMTOC that could be used for collecting and holding ingredient data and potentially other brand specific information. • HATI would welcome any initiative from the Commission to make the said Practical Guide binding and to incorporate the EMTOC system and proposed solutions to the outstanding issues in the Practical Guide. • All EU Member States need to agree to and adopt the common reporting format for ingredients disclosure and accept tobacco product ingredients submission via the latest set of templates in order to move to the EMTOC reporting system. This adoption should be facilitated and/or endorsed by the Commission. • The EMTOC system should continue to develop, with involvement from the tobacco manufacturers and importers, an agreed set of Standard Operating Procedures (SOPs) and adequate protection for competitively sensitive and trade secret information. We understand that within the EMTOC system the term “Instructions” means, and is fully interchangeable in both definition and principle with, SOPs. Following resolution of the issues concerning EMTOC, successful trial and initial roll-out of the EMTOC system in the partner countries currently signed up to EMTOC, the system should be subsequently adopted in all remaining EU Member States. Once a fully harmonized reporting system has been developed this should be considered as best practice for by-brand ingredients reporting. Manufacturers agree to participate to the financing of the EMTOC system with regard to the running costs. Fees and Sanctions for Ingredients Registration and Registration of Products The issue of sanctions and penalties is already addressed at Member State level

### **additional comments**

HATI refers to its response to question 2 above.

### **regulation of ingredients**

#### **problem definition**

No

**explanations**

Our members, as responsible manufacturers, do not use ingredients to attract non-smokers (minors or otherwise) and only use tobacco ingredients to maintain the integrity of the product, to create a particular taste & flavour signature for their brands and to differentiate their products in the market place. It has been proposed that some ingredients may have either direct or indirect rewarding or reinforcing properties. We are not aware of any credible scientific evidence to support the allegation that, at the levels of use observed in tobacco product, tobacco ingredients have rewarding or reinforcing properties. SCENIHR in its final opinion concluded that there is no evidence that ingredients enhance addictiveness or in and of themselves are addictive. It is our view that ingredients do not influence initiation of smoking or the ability of smokers determined to quit. HATI members do not add ingredients in order to promote smoking initiation or to hinder the ability of those smokers determined to quit. The problem definition incorrectly defines the use of ingredients and claims without foundation that the majority form carcinogens, mutagens and/or toxic for reproduction. For example, mentholated cigarettes have been available for several decades yet there is no credible scientific evidence to suggest that their use is associated with increased smoking incidence, increased consumption, change in smoking behavior, reduced quitting rates compared to non-mentholated cigarettes, or that smokers of mentholated cigarettes inhale more deeply. HATI believes that sound scientific evidence and a criteria-based approach should be the foundation for any restriction of ingredients use. We reject the notion of “attractiveness” as a valid public policy objective against which ingredients should be regulated. “Attractiveness” per se fails established criteria for issue definition in terms of it being a regulatory goal or objective: it is lacking in any evidential foundation and is inherently uncertain and arbitrary. We accept that various objectives, such as youth initiation and youth smoking prevention, constitute valid public policy objectives for regulation, provided that the particular legislative measure proposed meets accepted principles of Better Regulation, and is based on credible evidence. We are concerned that certain regulators have used the term “attractiveness” in the context of tobacco product ingredients’ use without defining meaning, scope or context. Instead it is generally used by regulators to imply that ingredients are used to make the product appealing, smoke-able and inhalable by non-smoking minors when initiating cigarette use. We are not aware of any credible evidence on the use of ingredients and their appeal to minors. We would like to understand the basis of the Commission’s concerns regarding ingredient use and smoking initiation by minors. We also maintain that to ensure the proper functioning of a market economy, legitimate tobacco companies have the right to compete by developing and differentiating their products to facilitate adult consumer choice. Our members would welcome further discussion on this matter and would welcome SCENIHR’s involvement in developing criteria for assessment of tobacco ingredients through science-based evaluation. Furthermore, we would recommend that a scientific team, including SCENIHR and other relevant stakeholders like the industry, is requested to discuss the establishment of the principles for the risk assessment framework. We note that the Consultation contains no analysis of Union competence to adopt the different options, the implications of those options for the functioning of the internal market or their proportionality. We are concerned that the Commission will refer to the Final RAND Report in this regard. Therefore we will send our critique on the report separately.

**which option**

No Change

**additional option**

In our view, in the absence of a proper problem definition and a valid scientific assessment

framework for ingredients, we support Option 1, but make the following points as a basis to facilitate discussion on the issues: HATI member companies believe that any decision to allow, restrict or ban the use of a specific ingredient should be based on a full scientific assessment of whether the ingredient increases the inherent risks associated with smoking. We support the application of the scientific principle of “inhalation threshold of toxicological concern” to address the safety evaluation of ingredients added to tobacco. The principle of threshold of toxicological concern has been successfully applied internationally to the safety evaluation of many chemical substances and food additives. We support the principle that new ingredients should be allowed subject to a proper and appropriate toxicological risk assessment in deciding acceptability for use. In this respect industry scientists should be consulted as they have a valuable contribution to make. We support the objective of a common list of authorized ingredients which reflects the scientific principles developed jointly by the WHO/FAO Codex Alimentarius Commission (CAC). HATI, however, rejects Option 2 or 3, which state that the list would be based on the toxicity, the attractiveness and the addictiveness of a product when consumed (oral tobacco) or smoked (the combustion/inhalation effect). We are not aware of a credible scientific basis upon which the Commission considers that some ingredients may be addiction enhancing. Our members would like to ask the Commission for clarification on this point. Based on the scientific research to date, we do not accept that any ingredients are “addiction enhancing”. We note that SCENIHR came to the same conclusion. It is also clear that no ingredient(s) prevent or hinder a determined smoker from being able to quit. Our member companies do not manufacture and sell products with the intention of appealing to minors. We are not aware of any credible evidence on the use of ingredients and their appeal to minors. We would like to understand the basis of the Commission’s concerns regarding ingredient use and smoking initiation by minors. HATI rejects the notion of “attractiveness” as a valid public policy objective against which ingredients should be regulated. “Attractiveness” per se fails established criteria for issue definition in terms of it being a regulatory goal or objective: it is lacking in any evidential foundation and is inherently uncertain and arbitrary. We accept that various objectives, such as youth initiation and youth smoking prevention, constitute valid public policy objectives for regulation, provided that the particular legislative measure proposed meets accepted principles of Better Regulation, and is based on credible evidence. We also maintain that to ensure the proper functioning of a market economy, legitimate tobacco companies have the right to compete by developing and differentiating their products to facilitate adult consumer choice. We note that the Commission has sought advice from its expert committee (SCENHIR) on the scientific bases of attractiveness and addictiveness, and that SCENHIR has published its opinion. However, we note that neither the Consultation nor the Final RAND Report makes any reference to this opinion. In order to consider and implement a ban on any ingredients, there will be a requirement for the Commission to develop a clear definition and scientific basis for such action. Regulation should be science-based and should support the development of potentially reduced exposure products and the assessments of smoke emissions resulting from their use.

#### **additional comments**

We believe that only once sound scientific principles and criteria as set out in our comments on Item 2 have been defined, it would be possible to develop a common list of authorised ingredients

#### **access to tobacco products problem definition**

No

**explanations**

We note that the Consultation contains no analysis of Union competence to adopt the different options, the implications of those options for the functioning of the internal market, or their proportionality. Nor is any evidence provided in the Consultation for the different options discussed in this section. We are concerned that the Commission will refer to the Final RAND Report in this regard. Therefore we will send our critique on the report separately. Vending We believe that access to cigarette vending machines should be strictly controlled to prevent sales to children. We do not however, support the prohibition of vending machines, which would prevent the legitimate access by adult smokers. The display of tobacco products at PoS is important to the proper operation of a market economy in the sale of legal tobacco products. It informs the consumer of the products available, their characteristics, their price and the pack sizes available. Particularly in situations where other channels of communication may be restricted, consumers must be able to identify easily, quickly and effectively the existence and availability of tobacco products and to distinguish between them. Due to the high turnover and value of tobacco products, display is essential to retailers in maintaining efficient trade operations. Display bans would have significant and extensive negative impacts and would be disproportionate for a number of reasons. Further, product display bans at the PoS are likely to exacerbate the illicit trade in contraband and counterfeit tobacco products. In accordance with the principles of Better Regulation, we encourage national authorities to give consideration to regulatory solutions that are proportionate, effective, evidence based and do not go further than necessary to achieve policy objectives. We believe that such measures can be managed through the cooperation of the tobacco industry and retailers with national authorities.

**which option**

No change

**additional option**

No, HATI refers to its response to Question 1, above.

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**NGO submission****identification****affiliation**

NGO

**name**

SYNDICAT DES BURALISTES DU VAR

**email**

alanelis@wanadoo.fr

**country**

france

**questions scope****problem definition**

Yes

**which option**

No change

**questions smokeless**

**problem definition**

No

**comments**

il n'y a pas d'études scientifiques efficaces prouvant les risques concernant les produits du tabac sans fumée.

**which option**

Lifting the ban on snus

**questions consumer**

**problem definition**

No

**explanations**

aucune étude ne prouve l'efficacité des paquets neutres. aucune étude ne prouve l'efficacité des photos chocs, ni même de plus grands avertissements sanitaires sur les paquets. la mise en place de paquets neutres risque d'entraîner une guerre des prix du tabac (puisque cela restera le seul moyen pour les fabricants de se différencier). la mise en place de photos chocs sur les 2 faces des paquets ou de paquets génériques va pousser les consommateurs français à aller s'approvisionner sur les marchés parallèles du tabac (achats à l'étranger ou de contrebande, ou sur internet. de telles mesures risquent de déstabiliser et pénaliser économiquement le réseau des 28000 buralistes français organisés dans un réseau réglementé et sous tutelle de l'Etat.

**which option**

No change

**questions on reporting**

**problem definition**

Yes

**which option**

Establish a common compulsory reporting format

**regulation of ingredients**

**problem definition**

No

**explanations**

cela risque d'entraîner une standardisation de la production avec comme conséquence une diminution de l'offre au fumeur adulte et responsable, et le risque de voir apparaître une augmentation des produits du tabac contrefaits.

**which option**

No Change

**access to tobacco products**

**problem definition**

Yes

**which option**

Controlled supply and access; Ban

**which supply and access**

Age verification of buyers and other legal conditions to be set for cross-border retail sale

**which one2**

Cross-border retail sales of tobacco to be banned over the Internet; Vending machines to be banned

**additional comments**

il n'y a pas de corrélation prouvée entre disparition des linéaires tabac et la lutte contre le tabagisme. la FRANCE dispose d'un réseau de 28 000 buralistes, préposés de l'administration responsables et professionnels, seuls habilités à vendre du tabac. ce réseau est fortement réglementé par l'Etat Français ce qui permet déjà de contrôler efficacement l'accès au produit tabac.

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**NGO submission**

**identification**

**affiliation**

NGO

**name**

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**email**

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**country**

UK

**questions scope**

**problem definition**

Yes

**which option**

Extend the scope of the Directive

**additional comments**

We recommend the following: + Extend the scope of the Directive to include all smoked products including herbal cigarettes. + Maintain the ban on any novel forms of oral tobacco

products including snus. + Do NOT extend the Directive to include electronic nicotine delivery systems (ENDS or E-cigarettes). It is the combustion process and inhalation of smoke that causes most of the harm from smoking. Therefore it is appropriate that herbal cigarettes, which are used in a similar way as nicotine cigarettes, are regulated in the same way as smoked tobacco products, and should be included in the scope of the Directive. All tobacco products are hazardous to health – there is no safe level of usage. Therefore we recommend that the scope of the Directive includes the regulation of any new smoked tobacco products (such as low emission or nicotine-free cigarettes), while the prohibition of any novel forms of oral tobacco, including snus, should be maintained. Novel nicotine based products (that is, products containing nicotine but not tobacco products) have the potential to offer a less hazardous alternative to cigarettes. Currently these include e-cigarettes and nicotine gel. However, as such products are generally marketed as alternatives to cigarettes and in some cases as an aid to quitting smoking, it is appropriate for them to be brought under the same regulatory framework as pharmaceutical products rather than under the scope of the tobacco products directive. The question of how nicotine containing products should be controlled is currently under consideration by the UK's Medicines and Healthcare Regulatory Authority (MHRA) following a recent public consultation on whether to extend its remit on the regulation of nicotine replacement therapies to other nicotine containing products. The outcome of this consultation may assist the Commission in developing its policy on these products.

**questions smokeless**

**problem definition**

Yes

**which option**

No change

**additional comments**

The ban on snus should remain. Although research suggests that use of Swedish snus is less hazardous compared to cigarettes with regard to the risk of contracting most forms of cancer, the product is not without risk and there is some evidence of an increased risk of cardiovascular disease. There is therefore no legitimate reason to justify bringing a new hazardous product onto the market. There is little evidence that smokers in EU countries other than Sweden would find snus to be an acceptable alternative to cigarettes, were it to be legalised. If the ban on snus were to be lifted, it could encourage dual use of cigarettes and smokeless tobacco and discourage total abstinence from tobacco, thus weakening any potential health gains. With regard to other smokeless products, particularly those used by ethnic minority populations, we recommend that they are more tightly regulated but we do not support a total ban on such products. A ban would likely be counter-productive and make it more difficult to engage with users and to offer help in quitting.

**questions consumer**

**problem definition**

Yes

**which option**

Improve consumer information; Introduce generic or plain packaging

**which improvement**

Picture warnings to become mandatory; Tar, nicotine and carbon monoxide levels to be replaced with general information on harmful substances in tobacco products; Information on harmful substances in tobacco products that cannot be placed on the package would be placed inside the package; Health warnings to be put on water pipes

### **additional comments**

**Picture Warnings** We strongly recommend that picture warnings should be mandatory and that they should occupy a minimum of 80% of the front and back surfaces of all tobacco packaging (i.e not just cigarettes). The warnings should be placed on the upper portion of the packs for maximum visibility. The current situation with some Member States adopting picture warnings whilst others have not done so has created a discrepancy and uneven health protection across the EU. From an internal market perspective, the differences in rules are contrary to the operation of the single market and may constitute a barrier to trade. These obstacles should therefore be removed and pictorial health warnings should be mandatory to ensure optimum health protection for all EU citizens. There is good evidence to show that health warnings are effective in conveying the dangers of smoking and helping smokers to quit. They also help deter young people from starting to smoke. Picture warnings are more effective than written warnings.<sup>4</sup> All warnings should be displayed in rotation so that each message is given equal display to reach its target audience. There is widespread consumer support for pictorial health warnings. A Eurobarometer survey conducted in October 2009 showed that 78% of respondents supported health warnings. Information on Tar, nicotine & carbon monoxide (TNCO) Currently the Directive requires the inclusion of machine-based tar, nicotine and carbon monoxide yields on cigarette packs. This promotes the mistaken belief that some cigarette brands are less harmful than others. The EU should not only remove this requirement from the Directive but should prohibit ISO or any other emissions numbers on the pack. We support the proposal to replace numerical measurements with descriptive information on the hazardous effects of tobacco constituents and emissions. The addition of a quitline telephone service should be included on the packaging. Additional information on harmful substances in tobacco products We support the proposal to include additional information on the health effects of tobacco consumption on inserts inside the packaging. This should include advice on quitting smoking. Health warnings on water pipes There is a growing body of evidence to show that water pipes are at least as hazardous, if not more so, than other forms of tobacco use. However, there is a common perception that tobacco smoke is 'cleansed' by the water and therefore not as dangerous and some users believe flavoured shisha is not in fact tobacco. It is important that these myths are countered by the inclusion of a health warning on water pipes. Warnings should also be included on the packaging of tobacco used in water pipes. Generic or plain packaging We strongly recommend the introduction of plain or generic packaging. This should include not only the removal of all branding from the packaging but the size and shape of the packaging should also be standardised. Not only would this prevent the promotion of smoking through branding as occurs presently but it would reinforce the health warning messages. Tobacco packaging provides a direct link between consumers and manufacturers and is the main marketing channel, particularly in jurisdictions with tobacco advertising bans. Branding gives the misleading impression some cigarettes are safer than others. The tobacco industry claims that plain packaging would contravene intellectual property law. However, legal analysis concludes that this is incorrect and there are no international legal impediments to the implementation of generic packaging.

### **questions on reporting problem definition**



Yes

**which option**

Establish a common compulsory reporting format; Introduce fees and sanctions

**additional comments**

The current situation which allows different formats and reporting mechanisms is unsatisfactory, making it difficult for authorities to compare and analyse the data. Tobacco companies should be required to use a standardised reporting format. Additionally the companies should be required to pay a yearly registration fee to cover the costs of administering this data collection. The above measures should be compliant with Articles 9 & 10 of the Framework Convention on Tobacco Control (FCTC).

**regulation of ingredients**

**problem definition**

Yes

**which option**

Establish a common list of tobacco ingredients

**access to tobacco products**

**problem definition**

Yes

**which option**

Ban

**which one2**

Cross-border retail sales of tobacco to be banned over the Internet; Vending machines to be banned; Promotion and displays in retail stores to be banned

**additional comments**

Internet. The principle of preventing cross-border promotion of tobacco products in order to protect public health was enshrined in the Tobacco Advertising directive (2001/0119). It is logical, therefore, to extend that principle to the sale of tobacco products between member states via the Internet. We support the prohibition of tobacco sales via the Internet. Vending machines. The majority of member states (22 out of 27) already prohibit the sale of tobacco products from vending machines in order to deter young people accessing cigarettes from this source. We support this measure. However, as this does not have cross-border effects, we urge the Commission to make the prohibition of tobacco vending machines a non-mandatory measure as part of the product directive. Point of Sale. Similarly, there is a growing body of evidence to show that putting tobacco products out of sight in retail outlets can reduce youth smoking. To date, this measure has been adopted by Ireland, the UK and Finland. We support an EU-wide adoption of a ban on the display of tobacco products at the point of sale. As with vending machines, we urge the Commission to make the prohibition of tobacco vending machines a non-mandatory measure as part of the product directive. The Directive should also remind national governments that they should adopt a comprehensive ban on all forms of tobacco advertising, promotion and sponsorship in accordance with Article 13 of the FCTC.

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## **NGO submission**

### **identification**

#### **affiliation**

NGO

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#### **country**

UK

#### **age**

24

#### **gender**

male

#### **questions scope**

#### **problem definition**

Yes

#### **which option**

Extend the scope of the Directive

#### **additional comments**

We recommend the following: + Extend the scope of the Directive to include all smoked products including herbal cigarettes. + Maintain the ban on any novel forms of oral tobacco products including snus. + Do NOT extend the Directive to include electronic nicotine delivery systems (ENDS or E-cigarettes). It is the combustion process and inhalation of smoke that causes most of the harm from smoking. Therefore it is appropriate that herbal cigarettes, which are used in a similar way as nicotine cigarettes, are regulated in the same way as smoked tobacco products, and should be included in the scope of the Directive. All tobacco products are hazardous to health – there is no safe level of usage. Therefore we recommend that the scope of the Directive includes the regulation of any new smoked tobacco products (such as low emission or nicotine-free cigarettes), while the prohibition of any novel forms of oral tobacco, including snus, should be maintained. Novel nicotine based products (that is, products containing nicotine but not tobacco products) have the potential to offer a less hazardous alternative to cigarettes. Currently these include e-cigarettes and nicotine gel. However, as such products are generally marketed as alternatives to cigarettes and in some cases as an aid to quitting smoking, it is appropriate for them to be brought under the same regulatory framework as pharmaceutical products rather than under the scope of the tobacco products directive. The question of how nicotine containing products should be controlled is currently under consideration by the UK's Medicines and Healthcare Regulatory Authority (MHRA) following a recent public consultation on whether to extend its remit on the regulation of nicotine replacement therapies to other nicotine containing products. The

outcome of this consultation may assist the Commission in developing its policy on these products.

**questions smokeless**

**problem definition**

Yes

**which option**

No change

**additional comments**

The ban on snus should remain. Although research suggests that use of Swedish snus is less hazardous compared to cigarettes with regard to the risk of contracting most forms of cancer, the product is not without risk and there is some evidence of an increased risk of cardiovascular disease. There is therefore no legitimate reason to justify bringing a new hazardous product onto the market. There is little evidence that smokers in EU countries other than Sweden would find snus to be an acceptable alternative to cigarettes, were it to be legalised. If the ban on snus were to be lifted, it could encourage dual use of cigarettes and smokeless tobacco and discourage total abstinence from tobacco, thus weakening any potential health gains. With regard to other smokeless products, particularly those used by ethnic minority populations, we recommend that they are more tightly regulated but we do not support a total ban on such products. A ban would likely be counter-productive and make it more difficult to engage with users and to offer help in quitting.

**questions consumer**

**problem definition**

Yes

**which option**

Improve consumer information; Introduce generic or plain packaging

**which improvement**

Picture warnings to become mandatory; Tar, nicotine and carbon monoxide levels to be replaced with general information on harmful substances in tobacco products; Information on harmful substances in tobacco products that cannot be placed on the package would be placed inside the package; Health warnings to be put on water pipes

**additional comments**

Picture Warnings We strongly recommend that picture warnings should be mandatory and that they should occupy a minimum of 80% of the front and back surfaces of all tobacco packaging (i.e not just cigarettes). The warnings should be placed on the upper portion of the packs for maximum visibility. The current situation with some Member States adopting picture warnings whilst others have not done so has created a discrepancy and uneven health protection across the EU. From an internal market perspective, the differences in rules are contrary to the operation of the single market and may constitute a barrier to trade. These obstacles should therefore be removed and pictorial health warnings should be mandatory to ensure optimum health protection for all EU citizens. There is good evidence to show that health warnings are effective in conveying the dangers of smoking and helping smokers to quit. They also help deter young people from starting to smoke. Picture warnings are more effective than written warnings. All warnings should be displayed in rotation so that each

message is given equal display to reach its target audience. There is widespread consumer support for pictorial health warnings. A Eurobarometer survey conducted in October 2009 showed that 78% of respondents supported health warnings. Information on Tar, nicotine & carbon monoxide (TNCO) Currently the Directive requires the inclusion of machine-based tar, nicotine and carbon monoxide yields on cigarette packs. This promotes the mistaken belief that some cigarette brands are less harmful than others. The EU should not only remove this requirement from the Directive but should prohibit ISO or any other emissions numbers on the pack. We support the proposal to replace numerical measurements with descriptive information on the hazardous effects of tobacco constituents and emissions. The addition of a quitline telephone service should be included on the packaging. Additional information on harmful substances in tobacco products We support the proposal to include additional information on the health effects of tobacco consumption on inserts inside the packaging. This should include advice on quitting smoking. Health warnings on water pipes There is a growing body of evidence to show that water pipes are at least as hazardous, if not more so, than other forms of tobacco use. However, there is a common perception that tobacco smoke is 'cleansed' by the water and therefore not as dangerous and some users believe flavoured shisha is not in fact tobacco. It is important that these myths are countered by the inclusion of a health warning on water pipes. Warnings should also be included on the packaging of tobacco used in water pipes. Generic or plain packaging We strongly recommend the introduction of plain or generic packaging. This should include not only the removal of all branding from the packaging but the size and shape of the packaging should also be standardised. Not only would this prevent the promotion of smoking through branding as occurs presently but it would reinforce the health warning messages. Tobacco packaging provides a direct link between consumers and manufacturers and is the main marketing channel, particularly in jurisdictions with tobacco advertising bans. Branding gives the misleading impression some cigarettes are safer than others. The tobacco industry claims that plain packaging would contravene intellectual property law. However, legal analysis concludes that this is incorrect and there are no international legal impediments to the implementation of generic packaging.

### **questions on reporting**

#### **problem definition**

Yes

#### **which option**

Establish a common compulsory reporting format; Introduce fees and sanctions

#### **additional comments**

The current situation which allows different formats and reporting mechanisms is unsatisfactory, making it difficult for authorities to compare and analyse the data. Tobacco companies should be required to use a standardised reporting format. Additionally the companies should be required to pay a yearly registration fee to cover the costs of administering this data collection. The above measures should be compliant with Articles 9 & 10 of the Framework Convention on Tobacco Control (FCTC).

### **regulation of ingredients**

#### **problem definition**

Yes

#### **which option**

Establish a common list of tobacco ingredients

**access to tobacco products**

**problem definition**

Yes

**which option**

Ban

**which one2**

Cross-border retail sales of tobacco to be banned over the Internet; Vending machines to be banned; Promotion and displays in retail stores to be banned

**additional comments**

Internet. The principle of preventing cross-border promotion of tobacco products in order to protect public health was enshrined in the Tobacco Advertising directive (2001/0119). It is logical, therefore, to extend that principle to the sale of tobacco products between member states via the Internet. We support the prohibition of tobacco sales via the Internet. Vending machines. The majority of member states (22 out of 27) already prohibit the sale of tobacco products from vending machines in order to deter young people accessing cigarettes from this source. We support this measure. However, as this does not have cross-border effects, we urge the Commission to make the prohibition of tobacco vending machines a non-mandatory measure as part of the product directive. Point of Sale. Similarly, there is a growing body of evidence to show that putting tobacco products out of sight in retail outlets can reduce youth smoking. To date, this measure has been adopted by Ireland, the UK and Finland. We support an EU-wide adoption of a ban on the display of tobacco products at the point of sale. As with vending machines, we urge the Commission to make the prohibition of tobacco vending machines a non-mandatory measure as part of the product directive. The Directive should also remind national governments that they should adopt a comprehensive ban on all forms of tobacco advertising, promotion and sponsorship in accordance with Article 13 of the FCTC.

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NGO

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**questions scope**  
**problem definition**

Yes

**which option**

Extend the scope of the Directive

**additional comments**

We recommend the following: + Extend the scope of the Directive to include all smoked products including herbal cigarettes. + Do NOT extend the Directive to include electronic nicotine delivery systems (ENDS or E-cigarettes). It is the combustion process and inhalation of smoke that causes most of the harm from smoking. Therefore it is appropriate that herbal cigarettes, which are used in a similar way to nicotine cigarettes, are regulated in the same way as smoked tobacco products, and should be included in the scope of the Directive. Therefore we recommend that the scope of the Directive includes the regulation of any new smoked tobacco products (such as low emission or nicotine-free cigarettes). Novel nicotine based products (that is, products containing nicotine but not tobacco products) have the potential to offer a less hazardous alternative to cigarettes. Currently these include e-cigarettes and nicotine gel. However, as such products are generally marketed as alternatives to cigarettes and in some cases as an aid to quitting smoking, it is appropriate for them to be brought under the same regulatory framework as pharmaceutical products rather than under the scope of the tobacco products directive. The question of how nicotine containing products should be controlled is currently under consideration by the UK's Medicines and Healthcare Regulatory Authority (MHRA) following a recent public consultation on whether to extend its remit on the regulation of nicotine replacement therapies to other nicotine containing products. The outcome of this consultation may assist the Commission in developing its policy on these products. (Ref. Medicines and Healthcare Regulatory Authority. Public consultation (MLX 364): The regulation of nicotine containing products (NCPs). June 2010 <http://www.mhra.gov.uk/Publications/Consultations/Medicinesconsultations/MLXs/CON065617>)

**questions smokeless**  
**problem definition**

Yes

**which option**

No change

**additional comments**

With regard to smokeless products that are not currently illegal, particularly those used by ethnic minority populations, we recommend that they are more tightly regulated but we do not support a total ban on such products. Whilst recognising that such products are harmful, the introduction of an EU-wide ban could create an illegal market that would be more difficult to control than the current situation. Furthermore a ban would make it more difficult to engage with users to offer help in quitting.

**questions consumer**  
**problem definition**

Yes

**which option**

Improve consumer information; Introduce generic or plain packaging

**which improvement**

Picture warnings to become mandatory; Tar, nicotine and carbon monoxide levels to be replaced with general information on harmful substances in tobacco products; Information on harmful substances in tobacco products that cannot be placed on the package would be placed inside the package; Health warnings to be put on water pipes

**additional option**

The minimum size of health warnings should be increased to 80% of the front and back surfaces of all tobacco packaging.

**additional comments**

**Picture Warnings** We strongly recommend that picture warnings should be mandatory and that they should occupy a minimum of 80% of the front and back surfaces of all tobacco packaging (i.e. not just cigarettes). The warnings should be placed on the upper portion of the packs for maximum visibility. The current situation with some Member States adopting picture warnings whilst others have not done so has created a discrepancy and uneven health protection across the EU. From an internal market perspective, the differences in rules are contrary to the operation of the single market and may constitute a barrier to trade. These obstacles should therefore be removed and pictorial health warnings should be mandatory to ensure optimum health protection for all EU citizens. There is good evidence to show that health warnings are effective in conveying the dangers of smoking and helping smokers to quit. They also help deter young people from starting to smoke. Picture warnings are more effective than written warnings.<sup>2</sup> All warnings should be displayed in rotation so that each message is given equal display to reach its target audience. There is widespread consumer support for pictorial health warnings. A Eurobarometer survey conducted in October 2009 showed that 78% of respondents supported health warnings.

**Information on tar, nicotine & carbon monoxide (TNCO)** Currently the Directive requires the inclusion of machine-based tar, nicotine and carbon monoxide yields on cigarette packs. This promotes the mistaken beliefs that some cigarette brands are less harmful than others and that nicotine causes disease. The EU should not only remove this requirement from the Directive but should prohibit ISO or any other emissions numbers on the pack. We support the proposal to replace numerical measurements with descriptive information on the hazardous effects of tobacco constituents and emissions. The addition of a quitline telephone service should be included on the packaging.

**Additional information on harmful substances in tobacco products** We support the proposal to include additional information on the health effects of tobacco consumption on inserts inside the packaging. This should include advice on quitting smoking.

**Health warnings on water pipes** There is a growing body of evidence to show that water pipes are at least as hazardous, if not more so, than other forms of tobacco use. However, there is a common perception that tobacco smoke is 'cleansed' by the water and therefore not as dangerous and some users believe flavoured shisha is not in fact tobacco. It is important that these myths are countered by requiring the inclusion of a health warning on all water pipes. Warnings should also be included on the packaging of tobacco used in water pipes.

**Generic or plain packaging** We strongly recommend the introduction of plain or generic packaging. This should include not only the removal of all branding from the packaging but the size and shape of the packaging should also be standardised. Not only would this prevent the promotion of smoking through branding as occurs presently but it would reinforce the health warning messages. The

Australian federal government has recently announced its intention to introduce plain packaging in 2012, setting a standard that the EU should follow. Tobacco packaging provides a direct link between consumers and manufacturers and is the main marketing channel, particularly in jurisdictions with tobacco advertising bans. Branding gives the misleading impression some cigarettes are safer than others. The tobacco industry claims that plain packaging would contravene intellectual property law. However, legal analysis for Action on Smoking and Health concludes that this is incorrect and there are no legal impediments to the implementation of generic packaging in the EU.

**questions on reporting**

**problem definition**

Yes

**which option**

Establish a common compulsory reporting format; Introduce fees and sanctions

**additional comments**

The current situation which allows different formats and reporting mechanisms is unsatisfactory, making it difficult for authorities to compare and analyse the data. Tobacco companies should be required to use a standardised reporting format. Additionally the companies should be required to pay a yearly registration fee to cover the costs of administering this data collection. The above measures should be compliant with Articles 9 & 10 of the Framework Convention on Tobacco Control (FCTC).

**regulation of ingredients**

**problem definition**

Yes

**which option**

Establish a common list of tobacco ingredients

**which one**

Establish a positive common list of tobacco ingredients

**additional comments**

We support the adoption of a positive common list of tobacco ingredients. Tobacco products are highly toxic and addictive; their contents should therefore be regulated in order to achieve high standards of health protection. A positive common list would ensure that only registered products, with ingredients, flavourings and additives that appear on the positive list would be permitted on the EU market. Currently, EU citizens are not subject to the same level of health protection and a common list of permitted ingredients would go some way towards addressing this anomaly. The tobacco industry uses a range of additives to alter the composition of tobacco products. These can make the product more palatable to children or increase the addictiveness of the product. Therefore any flavourings that may be used to enhance the addictiveness or attractiveness of tobacco products should be banned. The revised Product Directive should be fully compliant with the guidelines on Articles 9 & 10 adopted at the fourth Conference of the Parties of the FCTC on 20th November 2010.

**access to tobacco products**

**problem definition**



Yes

**which option**

Ban

**which one2**

Cross-border retail sales of tobacco to be banned over the Internet; Vending machines to be banned; Promotion and displays in retail stores to be banned

**additional option**

New limits on cross-border purchasing of tobacco for personal consumption. The EU Directive should follow the lead set by Finland which, as part of its recently passed Tobacco Act, has set limits on the amount of tobacco that can be imported into Finland where the labelling differs from that of tobacco products sold in Finland. We recommend that similar limits should be set at EU level, that is, that for each Member State the amount of tobacco that may be imported for personal use which does not conform to domestic labelling requirements, should be limited to a maximum of 200 cigarettes, 50 cigars, 100 cigarillos and 250 grams of pipe or cigarette tobacco.

**additional comments**

Internet. The principle of preventing cross-border promotion of tobacco products in order to protect public health was enshrined in the Tobacco Advertising directive (2001/0119). It is logical, therefore, to extend that principle to the sale of tobacco products between member states via the Internet. We support the prohibition of tobacco sales via the Internet. Vending machines. The majority of member states (22 out of 27) already prohibit the sale of tobacco products from vending machines in order to deter young people accessing cigarettes from this source. We support this measure. Point of Sale. We support an EU-wide adoption of a ban on the display of tobacco products at the point of sale. Across the EU, most forms of tobacco advertising are now prohibited but the tobacco industry continues to market its products by the use of attractive packaging. Research shows that point of sale displays of tobacco have a direct impact on young people's intention to smoke. Furthermore, there is a growing body of evidence to show that putting tobacco products out of sight in retail outlets can reduce youth smoking. To date, this measure has been adopted by Ireland and Finland (as well as Iceland and Norway) and is going through the parliamentary process in the UK. Refs: Point of Sale Display of Tobacco Products. The Centre for Tobacco Control Research. University of Stirling, 2008. Tobacco displays at the point of sale. ASH Briefing, Nov. 2010

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NGO

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UK

**questions scope**  
**problem definition**  
Yes

**which option**  
Extend the scope of the Directive

**additional comments**

Cancer Research UK (CR-UK)(1) is the world's leading charity dedicated to cancer research and the largest independent funder of cancer research in Europe. Cancer Research UK's work is entirely funded by the public and in 2009/10 we spent €400 million on research, supporting the work of more than 4,000 scientists, doctors and nurses. We're fighting cancer on all fronts, finding new ways to prevent, diagnose and treat it to save lives. Our research is entirely funded by the public, through fundraising activities and donations (2). While Cancer Research UK is a British charity, our world-class scientists and doctors collaborate with cancer experts in over 50 countries, working together to fight cancer. As tobacco causes more than a quarter (29%) of all deaths from cancer (3), tobacco control is a key priority for the charity. We work in partnership with others to achieve the greatest impact in the global fight against cancer and we are partners in the European Smokefree Partnership. We are pleased to respond to this consultation as it covers a very important area of public health, given that tobacco remains the single largest cause of premature death and disease across the EU and is responsible for over a quarter of all cancer deaths in the UK, all entirely preventable. All tobacco products are harmful to health and there is no safe level of use. Therefore all smoked and oral tobacco products should come under the Tobacco Products Directive (TPD), including any new products such as low emission cigarettes and novel forms of oral tobacco. Herbal cigarettes should be included within the TPD because they involve inhalation of smoke and the associated health hazards are poorly understood. Non-tobacco nicotine products should be regulated as pharmaceutical products. The manufacturers should be required to demonstrate consistent dose delivery and safety, but should not be allowed to make claims about aiding quitting unless their products have been subject to appropriate clinical trials. Regulation of non-tobacco nicotine products should not fall under the TPD. (1) Cancer Research UK is a registered charity in England and Wales (1089464) and in Scotland (SC041666) (2) Based on the exchange rate on 15 September 2010. (3) Peto, R., et al., Mortality from smoking in developed countries 1950-2000, second edition June 2006, 498.

**questions smokeless**  
**problem definition**  
Yes

**which option**  
No change

**additional comments**

While snus is less harmful than smoked tobacco, there are known health risks associated with its use particularly increased risk of cardiovascular disease and of pancreatic cancer (4). There is no legitimate reason to introduce a new tobacco product on to the market. We do not know

whether this could create a new cohort of smokeless tobacco users who would not have smoked tobacco. Also as they remain addicted to the nicotine in tobacco, smokers who switch to oral tobacco could return to smoking with its attendant greater health risks. We do not advocate the banning of chewing tobacco used traditionally by South Asian communities, as this could drive it underground. Such products should be regulated in the same way as other tobacco products already on the market (5) (4) Luo J et al 2007. Oral use of Swedish moist snuff (snus) and risk for cancer of the mouth, lung and pancreas in male construction workers; a retrospective cohort study *The Lancet*, online, 10 May 2007 (5) JM Longman et al. *Journal of Public Health* | pp. 1–7 | doi:10.1093/pubmed/fdq035

### **questions consumer**

#### **problem definition**

Yes

#### **which option**

Improve consumer information; Introduce generic or plain packaging

#### **which improvement**

Picture warnings to become mandatory; Tar, nicotine and carbon monoxide levels to be replaced with general information on harmful substances in tobacco products; Information on harmful substances in tobacco products that cannot be placed on the package would be placed inside the package; Health warnings to be put on water pipes

#### **additional comments**

Option 2: The evidence shows picture warnings encourage smokers to think about quitting and are more salient than text warnings (6). We support the recommendation for mandatory picture warnings front and back of pack covering at least 80% of the surface (7). As well as enhancing the health message this prevents the pack being used as a marketing tool (8). The tar, nicotine and carbon monoxide yields on packs are based on machine readings not on actual smokers' intakes resulting in misleading consumers that some brands are less harmful when this is not the case. No quantitative information should be on pack rather qualitative information about harmful constituents and telephone quitline numbers. In-pack information should be provided with further advice about the harmful effects of smoking and advice on quitting. Water pipes have been shown to be as harmful as cigarettes yet consumers often believe they are less harmful because the smoke has passed through water (and often flavourings have been added to the tobacco). There should be clear messages about the harm to health posed by smoking water pipes. Option 3. Standardised packaging can benefit health in 3 main ways: making health warnings more prominent; decreasing the promotional power of the pack; and preventing use of labels and creative devices that may deceive consumers. The Australian federal government has announced its intention to introduce plain packaging in 2012, setting a standard that the EU should follow. Research shows that: on-pack warnings are an effective way to inform about the harms of smoking and encourage quitting; the tobacco industry acknowledges the pack as a marketing tool; and deceptive devices like light colours do deceive people into believing they are less harmful. There is a large body of evidence that: standardised packaging: is less attractive than branded packs to both adults and children who feel it would be easier to quit and less appealing to start; undermines brand values; and boosts health warnings (9). Recently young adults were asked to use plain packs and asked how they felt about them. Compared to branded packs, plain packs increased negative perceptions about the pack and about smoking and also increased avoidant behaviour (10). It is strongly recommended that the names of products should be in standard

font/size/colour with no logo or other branding allowed, and that packaging should be brown/cardboard colour only as white/black/grey can be made to look attractive (11). The tobacco industry claims that plain packaging would contravene intellectual property law. However, legal analysis for Action on Smoking and Health concludes that this is incorrect and there are no legal impediments to the implementation of generic packaging in the EU (12). (6) eg Borland R et al (2009). Impact of graphic and text warnings on cigarette packs: findings from four countries over five years. Tobacco Control 18:358-364 (7) Moodie C (2010). 'You don't have to look at the back of your fag packet anyway.' Young adult smokers' perceptions of pictorial health warnings in the UK. Submitted for publication (8) Moodie C and Hastings G (2009). Making the pack the hero, tobacco industry response to marketing restrictions in the UK: findings from a long-term audit. Int J Ment Health Addiction DOI 10.1007/s11469-009-9247-8 (9) Moodie C et al (2009). A brief review of plain packaging research for tobacco products. Report prepared for the Department of Health, England. (10) Moodie C (2010). Young adult smokers' perceptions of plain packaging: a pilot ecological study. Submitted (11) Wakefield M et al (2008). How does increasingly plainer cigarette packaging influence adult smokers' perceptions about brand image? An experimental study. Tobacco Control 17:416-421 (12) The lawfulness of requiring plain packaging for tobacco products. Opinion of Sir Richard Buxton. Nov 2008

### **questions on reporting**

#### **problem definition**

Yes

#### **which option**

Establish a common compulsory reporting format; Introduce fees and sanctions

#### **additional comments**

A standard reporting format should be introduced to facilitate monitoring and analysis. The current situation which allows different formats and reporting mechanisms is unsatisfactory, making it difficult for authorities to compare and analyse the data. The collection and analysis of data should be financed by the tobacco industry through collection of fees. These measures should be in line with FCTC Articles 9 and 10.

### **regulation of ingredients**

#### **problem definition**

Yes

#### **which option**

Establish a common list of tobacco ingredients

#### **which one**

Establish a positive common list of tobacco ingredients

#### **additional comments**

We support the adoption of a positive common list of tobacco ingredients. No additives should be allowed that enhance the attractiveness or addictiveness of the product. Flavourings have been shown to encourage youth initiation and discourage cessation and ingredients such as sugars and sweeteners, flavourings, spices and herbs should not be permitted. The TPD should restrict the use of additives in line with the recently agreed FCTC guidelines for Articles 9 and 10.

## **access to tobacco products**

### **problem definition**

Yes

### **which option**

Ban

### **which one2**

Cross-border retail sales of tobacco to be banned over the Internet; Vending machines to be banned; Promotion and displays in retail stores to be banned

### **additional comments**

The Directive should also remind national governments that they should adopt a comprehensive ban on all forms of tobacco advertising, promotion and sponsorship in accordance with Article 13 of the FCTC as the only way to properly protect children. 3a Prevent cross border tobacco sales over the internet We support the prohibition of tobacco sales via the internet as this contradicts the principle in the Tobacco Advertising Directive (2001/0119) that sought to prevent cross-border promotion of tobacco products. The EU Directive should follow the lead set by Finland which, as part of its recently passed Tobacco Act, has set limits on the amount of tobacco that can be imported into Finland where the labelling differs from that of tobacco products sold in Finland. We recommend that similar limits should be set at EU level, that is, that for each Member State the amount of tobacco that may be imported for personal use which does not conform to domestic labelling requirements, should be limited to a maximum of 200 cigarettes, 50 cigars, 100 cigarillos and 250 grams of pipe or cigarette tobacco. 3b and 3c Removal of tobacco point of sale displays and vending machines These measures are essential if we are to protect children from tobacco marketing and access. The evidence has been detailed in submissions to the Governments of the UK (13). Point of sale displays are more noticed by children and increase their susceptibility to try smoking (14). Research from Ireland has shown that removing point of sale displays helps to denormalise smoking among children while not impacting on shop sales. (15,16) . Research also shows that children use vending machines more often than adults as a source of cigarettes in the UK and that they have a higher rate of failure in test purchasing. (13) Smokefree Action Coalition Briefing (2009) Putting Tobacco Out of Sight and Out of Reach.

<http://info.cancerresearchuk.org/publicpolicy/Ourpolicypositions/prevention/tobaccocontrol/> (14) Hastings, G et al. (2008) Point of Sale Display of Tobacco Products. The Centre for Tobacco Control Research, University of Stirling.

[http://info.cancerresearchuk.org/images/pdfs/tobcon\\_pointofsalereport1](http://info.cancerresearchuk.org/images/pdfs/tobcon_pointofsalereport1) (15) McNeill A et al (2010). Evaluation of removal of point of sale tobacco displays in Ireland. Tobacco Control doi:10.1136/tc.2010.038141 (16) Quinn C et al (2010) Economic evaluation of removal of tobacco promotional displays in Ireland. Tobacco Control . doi:10.1136/tc.2010.039602

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## **NGO submission**

### **identification**

#### **affiliation**

NGO

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**country**

Polska

**questions scope****problem definition**

Yes

**which option**

No change

**questions smokeless****problem definition**

Yes

**which option**

Lifting the ban on snus

**questions consumer****problem definition**

No

**explanations**

Wyrażamy sprzeciw wobec propozycji, które przyczynią się do zmniejszenia obrotu legalnymi papierosami oraz doprowadzą do wzrostu przemytu. Przemycem i podrabianiem papierosów zajmują się zorganizowane grupy przestępcze. Państwo Polskie, mimo dużych wysiłków nie jest w stanie wyeliminować tego zjawiska. Polska Straż Graniczna i Służba Celną przyznają, że przemyt to poważny problem gospodarczy. Legalne punkty sprzedaży sprzedają tylko i wyłącznie legalne papierosy.

**which option**

No change

**questions on reporting****problem definition**

No

**explanations**

bez komentarza

**which option**

Establish a common compulsory reporting format

**regulation of ingredients****problem definition**

No

**explanations**

Unia Europejska winna dążyć do zmniejszenia właściwości nieuzależniających papierosów.

**which option**

No Change

**access to tobacco products**

**problem definition**

No

**explanations**

Wprowadzony w Kandzie analogiczny zakaz nie doprowadził do ograniczenia konsumpcji wyrobów tytoniowych, przyczynił się natomiast do do zwiększenia przemytu. Papierosy są produktem, od którego odprowadzany jest VAT i podatek akcyzowy. Są legalnym produktem, ze sprzedaży którego Polskie Państwo czerpie ok. 20 mld złotych rocznie. Te pieniądze to również efekt naszej pracy. Reprezentowane przez nas punkty sprzedaży sprzedają legalne produkty.

**which option**

No change

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**NGO submission**

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NGO

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**questions scope**

**problem definition**

Yes

**which option**

Extend the scope of the Directive

**recommend option**

Be more strict to tobacco products killing people

**questions smokeless  
problem definition**  
Yes

**which option**  
Ban on all types of smokeless tobacco products

**questions consumer  
problem definition**  
Yes

**which option**  
Introduce generic or plain packaging

**questions on reporting  
problem definition**  
Yes

**which option**  
Establish a common compulsory reporting format; Introduce fees and sanctions

**regulation of ingredients  
problem definition**  
Yes

**which option**  
Establish a common list of tobacco ingredients

**which one**  
Establish a positive common list of tobacco ingredients; Establish a negative common list of tobacco ingredients

**access to tobacco products  
problem definition**  
Yes

**which option**  
Controlled supply and access

**which supply and access**  
Tobacco display and promotion at points of sales to be restricted

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**NGO submission**

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NGO



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Deutschland

**questions scope****problem definition**

No

**explanations**

Kein Kommentar.

**which option**

No change

**questions smokeless****problem definition**

No

**comments**

Freier Bürger der EU.

**which option**

No change

**questions consumer****problem definition**

No

**explanations**

Kein Kommentar.

**which option**

No change

**questions on reporting****problem definition**

No

**explanations**

Kein Kommentar.

**which option**

No change

**additional options**

Kein Kommentar.

**regulation of ingredients**

**problem definition**

No

**explanations**

Kein Kommentar

**which option**

No Change

**access to tobacco products**

**problem definition**

No

**explanations**

Kein Kommentar.

**which option**

No change

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**age**

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**gender**

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**questions scope**

**problem definition**

Yes

**which option**

Extend the scope of the Directive

**recommend option**

Nya tobaksprodukter och nya former av oral tobak ska förbjudas i likhet med snus. Örtcigaretter bör inkluderas i direktivet. Alla produkter som innehåller nikotin och som nu inte är klassade som tobaksprodukter, elektroniska cigaretter, nikotingel, nikotindrinkar och nikotingodis som marknadsförs som stöd vid rökavvänjning bör vara underställda samma säkerhets- och kvalitetskrav som gäller för farmaceutiska produkter.

**questions smokeless**

**problem definition**

Yes

**which option**

No change

**additional option**

Mycket viktigt att försäljningsförbudet för snus bibehålls. Erfarenheter från Sverige visar att snusbruk uppmuntrar till samtidig användning av cigaretter och snus och ökar därmed risken till fortsatt tobaksbruk. 40 % av snusarna är också rökare. Snus attraherar ungdomar till tobaksbruk. 40 % av snusarna har aldrig rökt. I samband med rökavvänjning finns effektiva läkemedel bl a rena nikotinläkemedel som bör rekommenderas. Fortsatt forskning på detta område bör intensifieras. Rökproblemet kan inte få sin lösning genom en ny tobaksprodukt från tobaksindustrin.

**additional comments**

Andra rökfria produkter marknadsförs inom EU. Användningen är marginell men produkterna bör regleras som tobaksprodukter.

**questions consumer**

**problem definition**

Yes

**which option**

Improve consumer information; Introduce generic or plain packaging

**which improvement**

Picture warnings to become mandatory; Tar, nicotine and carbon monoxide levels to be replaced with general information on harmful substances in tobacco products; Information on harmful substances in tobacco products that cannot be placed on the package would be placed inside the package; Health warnings to be put on water pipes

**additional option**

Olikheten i märkning av tobaksprodukter på den inre marknaden är otillfredsställande några länder har infört obligatoriska varningsbilder men de flesta har det inte. I Sverige är enligt Eurobarometerns 69 % av befolkningen positiva till införande av bildvarningar. 41 % av befolkningen i Sverige välkomnar införande av neutrala tobaksförpackningar enligt Eurobarometerna 2010. Det är högsta prioritet att göra bildvarningar obligatoriska! Bildvarningar är mer effektiva än textvarningar. Bildvarningar ska finnas på förpackningens två största sidor. Varningsbudskapets storlek är viktig - ju större desto mer effektiva.

Budskapen ska växlas på paketen i ett roterande system. Bilder av hälsoskador orsakade av rökning har, tillsammans med "känslamma" bilder på barn och foster visat sig vara mest effektiva. Bilderna ska kombineras med telenummer till Sluta röka linje och gendranpassas i enlighet med Tobakskonventionen artikel 4.2.d. Det är högsta prioritet att neutrala tobaksförpackningar införs! Detta innebär en standardisering av storlek och form och frånvaro av märkesspecifika kännetecken. Det finns inga juridiska hinder för detta enligt juridisk analys med anledning av Australiens pågående arbete. Det är högsta prioritet att numeriska uppgifter om nivå på nikotin och kolmonoxid ersätts med kvalitativ beskrivning av skadlig inverkan av innehållet i tobak och tobaksrök. De nu förekommande numeriska värdena har erhållits vid maskinrökta tester och är vilseledande. Hälsovarningar ska också finnas på vattenpipor och tobak som röks i dessa.

### **questions on reporting**

#### **problem definition**

Yes

#### **which option**

Establish a common compulsory reporting format; Introduce fees and sanctions

#### **additional options**

Den nuvarande situationen med olika format och rapporteringssystem är helt otillfredsställande för alla parter. Ett nytt system - baserat på det Kommissionen utarbetat 2007 - är det minsta man kan kräva för tobaksprodukter som ju dödar i förtid varannan av sina långtidsanvändare. Årliga avgifter bör också tas ut för att bekosta hantering, analys och bedömning av detta material samt kommunikering av resultat till medborgarna.

### **regulation of ingredients**

#### **problem definition**

Yes

#### **which option**

Establish a common list of tobacco ingredients

#### **which one**

Establish a positive common list of tobacco ingredients

#### **additional option**

En gemensam lista som tillåter ett antal ingredienser bör sakapas med avsikt att konsumenterna i alla medlemsländer ska ha tillgång till samma nivå av hälsoskydd. Reglering av smaktillsatser är högt prioriterad eftersom sådana har ökat markant i produktionen för att öka attraktionen, särskilt bland unga, och minska benägenheten att sluta. Även ingredienser som ger sken av att ha hälsoeffekt t ex vitamin, ge energi t ex koffein eller färgämne bör regleras. Riktlinjerna till Tobakskonventionens artiklar 9/10, nyligen antagna vid COP 4, ska beaktas.

### **access to tobacco products**

#### **problem definition**

Yes

#### **which option**

Ban

**which one2**

Cross-border retail sales of tobacco to be banned over the Internet; Vending machines to be banned; Promotion and displays in retail stores to be banned

**additional option**

Riktlinjerna till Tobakskonventionen artikel 13 innehåller krav på dolda tobaksprodukter på säljstället och förbud mot försäljning genom tobaksautomater. Dessa riktlinjer måste respekteras. Principen att förbjuda gränsöverskridande reklam för tobaksprodukter för att skydda folkhälsan slås fast i Tobacco Advertising Directive (2001/01 19) Det är logiskt att också förbjuda försäljning av tobaksvaror mellan länder via Internet. Tobaksautomater är redan förbjudna i 22 av 27 medlemsländer för att begränsa tillgängligheten för unga. Det är konsekvent att införa samma reglering i alla medlemsländer. Det finns en ökad grad av evidens för att dolda tobaksförpackningar på säljställen kan minska ungas rökning. Denna ordning bör därför införas i alla medlemsländer.

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**NGO submission**

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UK

**questions scope**

**problem definition**

Yes

**which option**

Extend the scope of the Directive

**recommend option**

FRESH recommend the following: + Extend the scope of the Directive to include all smoked products including herbal cigarettes. + Maintain the ban on any novel forms of oral tobacco products including snus. + Do NOT extend the Directive to include electronic nicotine delivery systems (ENDS or E-cigarettes). It is the combustion process and inhalation of smoke that causes most of the harm from smoking. Therefore it is appropriate that herbal cigarettes, which are used in a similar way as nicotine cigarettes, are regulated in the same way as smoked tobacco products, and should be included in the scope of the Directive. All tobacco products are hazardous to health – there is no safe level of usage. Tobacco kills over

5000 people from the North East region of England annually. Therefore we recommend that the scope of the Directive includes the regulation of any new smoked tobacco products (such as low emission or nicotine-free cigarettes), while the prohibition of any novel forms of oral tobacco, including snus, should be maintained. Novel nicotine based products (that is, products containing nicotine but not tobacco products) have the potential to offer a less hazardous alternative to cigarettes. Currently these include e- cigarettes and nicotine gel. However, as such products are generally marketed as alternatives to cigarettes and in some cases as an aid to quitting smoking, it is appropriate for them to be brought under the same regulatory framework as pharmaceutical products rather than under the scope of the tobacco products directive. The question of how nicotine containing products should be controlled is currently under consideration by the UK's Medicines and Healthcare Regulatory Authority (MHRA) following a recent public consultation on whether to extend its remit on the regulation of nicotine replacement therapies to other nicotine containing products. The outcome of this consultation may assist the Commission in developing its policy on these products.

**questions smokeless**

**problem definition**

Yes

**which option**

No change

**additional comments**

The ban on snus should remain. Although research suggests that use of Swedish snus is less hazardous compared to cigarettes with regard to the risk of contracting most forms of cancer, the product is not without risk and there is some evidence of an increased risk of cardiovascular disease. There is therefore no legitimate reason to justify bringing a new hazardous product onto the market. There is little evidence that smokers in EU countries other than Sweden would find snus to be an acceptable alternative to cigarettes, were it to be legalised. If the ban on snus were to be lifted, it could encourage dual use of cigarettes and smokeless tobacco and discourage total abstinence from tobacco, thus weakening any potential health gains. With regard to other smokeless products, particularly those used by ethnic minority populations, we recommend that they are more tightly regulated but we do not support a total ban on such products. A ban would likely be counter-productive and make it more difficult to engage with users and to offer help in quitting.

**questions consumer**

**problem definition**

Yes

**which option**

Improve consumer information; Introduce generic or plain packaging

**which improvement**

Picture warnings to become mandatory; Tar, nicotine and carbon monoxide levels to be replaced with general information on harmful substances in tobacco products; Information on harmful substances in tobacco products that cannot be placed on the package would be placed inside the package; Health warnings to be put on water pipes

**additional comments**

**Picture Warnings** We strongly recommend that picture warnings should be mandatory and that they should occupy a minimum of 80% of the front and back surfaces of all tobacco packaging (i.e not just cigarettes). The current situation with some Member States adopting picture warnings whilst others have not done so has created a discrepancy and uneven health protection across the EU. From an internal market perspective, the differences in rules are contrary to the operation of the single market and may constitute a barrier to trade. These obstacles should therefore be removed and pictorial health warnings should be mandatory to ensure optimum health protection for all EU citizens. There is good evidence to show that health warnings are effective in conveying the dangers of smoking and helping smokers to quit. They also help deter young people from starting to smoke. Picture warnings are more effective than written warnings. All warnings should be displayed in rotation so that each message is given equal display to reach its target audience. There is widespread consumer support for pictorial health warnings. A Eurobarometer survey conducted in October 2009 showed that 78% of respondents supported health warnings.

**Information on Tar, nicotine & carbon monoxide (TNCO)** Currently the Directive requires the inclusion of machine-based tar, nicotine and carbon monoxide yields on cigarette packs. This promotes the mistaken belief that some cigarette brands are less harmful than others. The EU should not only remove this requirement from the Directive but should prohibit ISO or any other emissions numbers on the pack. We support the proposal to replace numerical measurements with descriptive information on the hazardous effects of tobacco constituents and emissions. The addition of a quitline telephone service should be included on the packaging. Additional information on harmful substances in tobacco products We support the proposal to include additional information on the health effects of tobacco consumption on inserts inside the packaging. This should include advice on quitting smoking.

**Health warnings on water pipes** There is a growing body of evidence to show that water pipes are at least as hazardous, if not more so, than other forms of tobacco use. However, there is a common perception that tobacco smoke is 'cleansed' by the water and therefore not as dangerous and some users believe flavoured shisha is not in fact tobacco. It is important that these myths are countered by the inclusion of a health warning on water pipes. Warnings should also be included on the packaging of tobacco used in water pipes.

**Generic or plain packaging** We strongly recommend the introduction of plain or generic packaging. This should include not only the removal of all branding from the packaging but the size and shape of the packaging should also be standardised. Not only would this prevent the promotion of smoking through branding as occurs presently but it would reinforce the health warning messages. Tobacco packaging provides a direct link between consumers and manufacturers and is the main marketing channel, particularly in jurisdictions with tobacco advertising bans. Branding gives the misleading impression some cigarettes are safer than others. The tobacco industry claims that plain packaging would contravene intellectual property law. However, legal analysis concludes that this is incorrect and there are no international legal impediments to the implementation of generic packaging.

**questions on reporting****problem definition**

Yes

**which option**

Establish a common compulsory reporting format; Introduce fees and sanctions

**additional comments**

The current situation which allows different formats and reporting mechanisms is unsatisfactory, making it difficult for authorities to compare and analyse the data. Tobacco companies should be required to use a standardised reporting format. Additionally the companies should be required to pay a yearly registration fee to cover the costs of administering this data collection. The above measures should be compliant with Articles 9 & 10 of the Framework Convention on Tobacco Control (FCTC).

**regulation of ingredients**

**problem definition**

Yes

**which option**

Establish a common list of tobacco ingredients

**which one**

Establish a positive common list of tobacco ingredients; Establish a negative common list of tobacco ingredients

**access to tobacco products**

**problem definition**

Yes

**which option**

Ban

**which one2**

Cross-border retail sales of tobacco to be banned over the Internet; Vending machines to be banned; Promotion and displays in retail stores to be banned

**additional comments**

Internet. The principle of preventing cross-border promotion of tobacco products in order to protect public health was enshrined in the Tobacco Advertising directive (2001/0119). It is logical, therefore, to extend that principle to the sale of tobacco products between member states via the Internet. We support the prohibition of tobacco sales via the Internet. Vending machines. The majority of member states (22 out of 27) already prohibit the sale of tobacco products from vending machines in order to deter young people accessing cigarettes from this source. We support this measure. However, as this does not have cross-border effects, we urge the Commission to make the prohibition of tobacco vending machines a non-mandatory measure as part of the product directive. Point of Sale. Similarly, there is a growing body of evidence to show that putting tobacco products out of sight in retail outlets can reduce youth smoking. To date, this measure has been adopted by Ireland, the UK and Finland. We support an EU-wide adoption of a ban on the display of tobacco products at the point of sale. As with vending machines, we urge the Commission to make the prohibition of tobacco vending machines a non-mandatory measure as part of the product directive. The Directive should also remind national governments that they should adopt a comprehensive ban on all forms of tobacco advertising, promotion and sponsorship in accordance with Article 13 of the FCTC.



**identification****affiliation**

NGO

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Italy

**questions scope****problem definition**

Yes

**which option**

No change

**questions smokeless****problem definition**

No

**comments**

No scientific evidence concerning the risks related to smokeless tobacco products consumption (see attached file, sent by e-mail)).

**which option**

Lifting the ban on snus

**questions consumer****problem definition**

No

**explanations**

No scientific evidence proving that bigger warnings determine a better knowledge of the suggested messages; no scientific evidence on the relation between the use of a particular graphic and the impact on consumers (see attached file).

**which option**

No change

**additional comments**

The knowledge of how harmful tobacco would be is already of a high level, also on the basis of the existing warnings; no value added by the increase of information; negative impact on the fulfilments of sector's operators and of tobacco retailers; full aversion to plain packaging because of the confusion on manufacturers identification brands, with a consequent

proliferation of illegal trade of counterfeited as well as smuggled products (see attached file).

**questions on reporting**

**problem definition**

Yes

**which option**

Establish a common compulsory reporting format

**additional comments**

We agree on this point with the considerations expressed in the Public Consultation Document (please see attached file).

**regulation of ingredients**

**problem definition**

No

**explanations**

It is not possible to prove in advance which is the possible impact of an ingredient in terms of toxicity; targeting lists in advance, positively or negatively, would be in contrast with this statement; risk of product standardisation with a consequent reduction of the principle of free market and the risk of increase of counterfeited products (see attached file).

**which option**

No Change

**access to tobacco products**

**problem definition**

Yes

**which option**

Controlled supply and access

**which supply and access**

Age verification of buyers and other legal conditions to be set for cross-border retail sale;  
Access to vending machines to be restricted to adults

**additional option**

Sale to be carried out only within a network of specialized shops, provided with an appropriate license, which main activity is tobacco sale (see attached file).

**additional comments**

There is no evidence of the correlation between display ban and consumption bent. In other experiences – see Canada – important loss have been recorded for the tobacco retailers: structural reorganization of the shop, higher management costs and important reduction of the profitability with the consequent risk of giving up the business. Also increasing of illegal products sale, counterfeited and smuggled. Please attached file, sent by e-mail.

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## **NGO submission**

### **identification**

#### **affiliation**

NGO

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Italia

### **questions scope**

#### **problem definition**

Yes

#### **which option**

No change

### **questions smokeless**

#### **problem definition**

Yes

#### **which option**

Lifting the ban on snus

### **questions consumer**

#### **problem definition**

No

### **explanations**

Oggi sono ben conosciuti dai consumatori i danni molto gravi causati dal fumo e dalla combustione delle sigarette. L'assunto per cui è necessario introdurre l'obbligo di avvertenze sanitarie illustrate per informare più efficacemente il pubblico sui pericoli del fumo appare assolutamente poco fondato scientificamente. Le opzioni di riforma della Direttiva 2001/37/EC includono anche l'adozione del cosiddetto "pacchetto generico". Non si comprende tuttavia la ratio di questa norma perchè difficilmente contribuirebbe alla diminuzione della diffusione del fumo. Peraltro rappresenterebbe un'opportunità per le organizzazioni criminali, le quali avrebbero maggiore facilità ad introdurre sul mercato pacchetti di sigarette completamente bianchi, privi di loghi e colori. A danno questo, sia per le libere scelte dei consumatori che potenzialmente delle entrate erariali.

#### **which option**

No change

### **questions on reporting**

**problem definition**

Yes

**which option**

Establish a common compulsory reporting format

**regulation of ingredients****problem definition**

No

**explanations**

Giudichiamo con preoccupazione le valutazioni su come regolamentare l'uso degli ingredienti nella fabbricazione delle sigarette. Parlare di ingredienti come elementi attrattivi appare soggettivo ed arbitrario. Tutte le sigarette fanno male, sia che contengano ingredienti, sia che non ne contengano. Le preferenze dei fumatori mondiali si dividono proprio tra prodotti con e prodotti senza ingredienti. In particolare, i prodotti con ingredienti sono quelli cosiddetti miscelati, che utilizzano diversi tipi di tabacchi, tra cui la varietà Burley, che per sua caratteristica necessita dell'impiego di ingredienti. Per quale ragione si va a discriminare quest'ultimo tipo di prodotti, quando tutti i prodotti di tabacco sono dannosi? L'adozione di una norma che limita l'uso degli ingredienti avrebbe effetti devastanti sulla filiera del tabacco di tutto il mondo e dell'Italia in particolare. Il nostro paese è leader europeo nella produzione di Burley: vietare gli ingredienti significherebbe dire addio alla coltivazione di una varietà di tabacco che oggi dà lavoro a migliaia di famiglie in alcune delle aree più difficili del paese, come le provincie di Caserta e di Benevento. E tutto questo, quale beneficio reale produrrebbe alla salute pubblica?

**which option**

No Change

**access to tobacco products****problem definition**

No

**explanations**

Non concordiamo con la definizione del problema perchè questa in effetti manca. Si elencano solo i paesi in cui sono state già introdotte le proposte di modifica della Direttiva più avanzate. E tuttavia non sono portati a sostegno numeri, dati concreti, che ne sostanziano il beneficio reale per la salute pubblica. Si ritiene che con riferimento all'accesso, il sistema esistente in Italia costituisca una garanzia efficace di controllo. Bisognerebbe andare in quella direzione, piuttosto che introdurre ulteriori restrizioni e divieti che spesso non aiutano a perseguire gli obiettivi importanti, come quello della tutela della salute pubblica, che tutta la filiera del tabacco condivide e intende perseguire con strumenti e normative più efficaci.

**which option**

No change

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**NGO submission**

**identification****affiliation**

NGO

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UK

**questions scope****problem definition**

Yes

**which option**

Extend the scope of the Directive

**additional comments**

All tobacco products are hazardous to health – there is no safe level of usage. Therefore, we recommend that the scope of the Directive include the regulation of any new smoked tobacco products (such as low emission or nicotine-free cigarettes), while the prohibition of any novel forms of oral tobacco, including snus, should be maintained. However, do NOT extend the Directive to include electronic nicotine delivery systems. Novel nicotine based products (that is, products containing nicotine but not tobacco products) have the potential to offer a less hazardous alternative to cigarettes. Currently these include e-cigarettes and nicotine gel. However, as such products are generally marketed as alternatives to cigarettes and in some cases as an aid to quitting smoking, it is appropriate for them to be brought under the same regulatory framework as pharmaceutical products rather than under the scope of the tobacco products directive. The question of how nicotine containing products should be controlled is currently under consideration by the UK's Medicines and Healthcare Regulatory Authority (MHRA) following a recent public consultation on whether to extend its remit on the regulation of nicotine replacement therapies to other nicotine containing products.[1] The outcome of this consultation may assist the Commission in developing its policy on these products. [1] Medicines and Healthcare Regulatory Authority. Public consultation (MLX 364): The regulation of nicotine containing products (NCPs). June 2010 <http://www.mhra.gov.uk/Publications/Consultations/Medicinesconsultations/MLXs/CON065617>.

**questions smokeless****problem definition**

Yes

**which option**

No change

**additional comments**

The ban on snus should remain. Although research suggests that use of Swedish snus is less

hazardous than cigarettes with regard to the risk of contracting most forms of cancer,[2] the product is not without risk and there is some evidence of an increased risk of cardiovascular disease.[3] There is therefore no legitimate reason to justify bringing a new hazardous product onto the market. There is little evidence that smokers in EU countries other than Sweden would find snus to be an acceptable alternative to cigarettes, were it to be legalised. If the ban on snus were to be lifted, it could encourage dual use of cigarettes and smokeless tobacco and discourage total abstinence from tobacco, thus weakening any potential health gains.[2] With regard to other smokeless products, particularly those used by ethnic minority populations, we recommend that they be more tightly regulated but we do not support a total ban on such products. A ban would likely be counter-productive and make it more difficult to engage with users and to offer help in quitting. [2] Broadstock M. Systematic review of the health effects of modified smokeless tobacco products. New Zealand Health Technology Assessment. Christchurch School of Medicine and Health Sciences. NZHTA Report 2007, Volume 10 Number 1. [3] Piano MR, Benowitz NL, FitzGerald GA et al. Impact of smokeless tobacco products on cardiovascular disease: Implications for policy, prevention, and treatment. A policy statement from the American Heart Association. *Circulation*, 2010; DOI: 10.1161/CIR.0b013e3181f432c3.

**questions consumer**

**problem definition**

Yes

**which option**

Improve consumer information; Introduce generic or plain packaging

**which improvement**

Picture warnings to become mandatory; Tar, nicotine and carbon monoxide levels to be replaced with general information on harmful substances in tobacco products; Information on harmful substances in tobacco products that cannot be placed on the package would be placed inside the package; Health warnings to be put on water pipes

**additional comments**

Picture Warnings The current situation has created a discrepancy in health protection across the EU. Pictorial health warnings should be mandatory to ensure optimal health protection for all EU citizens. There is good evidence to show that health warnings are effective in conveying the dangers of smoking and helping smokers to quit.[4,5] They also help deter young people from starting to smoke. Picture warnings are more effective than written warnings.IV All warnings should be displayed in rotation so that each message is given equal visibility to its target audience. There is widespread consumer support for pictorial health warnings. A Eurobarometer survey conducted in October 2009 showed that 78 per cent of respondents supported health warnings.[4] Information on Tar, nicotine & carbon monoxide (TNCO) Currently the Directive requires the inclusion of machine-based tar, nicotine and carbon monoxide yields on cigarette packs. This promotes the mistaken belief that some cigarette brands are less harmful than others.[6] The EU should not only remove this requirement from the Directive but should prohibit ISO or any other emissions numbers on the pack. We support the proposal to replace numerical measurements with descriptive information on the hazardous effects of tobacco constituents and emissions. The addition of a quitline telephone service should be included on the packaging. Health warnings on water pipes There is a growing body of evidence to show that water pipes are at least as hazardous as other forms of tobacco use. However, there is a common perception that tobacco smoke is

“cleansed” by the water and therefore not as dangerous, and some users believe flavoured shisha is not tobacco. It is important that these myths are countered by the inclusion of a health warning on water pipes. Warnings should also be included on the packaging of tobacco used in water pipes. Generic or plain packaging This should not only involve the removal of all branding from the packaging but the size and shape of the packaging should also be standardised. This would prevent the promotion of smoking through branding and reinforce the health warning messages. Tobacco packaging provides a direct link between consumers and manufacturers and is the main marketing channel, particularly in jurisdictions with tobacco advertising bans. Branding gives the misleading impression some cigarettes are safer than others. [4] Borland R, Wilson N, Fong GT et al. Impact of graphic and text warnings on cigarette packs: findings from four countries over five years. *Tob Control*, 2009; 18: 358-64. doi:10.1136/tc.2008.028043. [5] Borland R, Yong HH, Wilson N. et al. How reactions to cigarette packet health warnings influence quitting: findings from the ITC Four-Country survey. *Addiction*, 2009; 104: 669-75. doi:10.1111/j.1360-0443.2009.02508.x. [6] Koslowski LT, Goldberg ME, Yost BA, et al. Smokers’ misperceptions of light and ultra-light cigarettes may keep them smoking. *Am J Prev Med*, 1998; 15: 9-16.

### **questions on reporting**

#### **problem definition**

Yes

#### **which option**

Establish a common compulsory reporting format; Introduce fees and sanctions

#### **additional comments**

The current situation which allows different formats and reporting mechanisms is unsatisfactory, making it difficult for authorities to compare and analyse the data. Tobacco companies should be required to use a standardised reporting format. Additionally the companies should be required to pay a yearly registration fee to cover the costs of administering this data collection. The above measures should be compliant with Articles 9 and 10 of the Framework Convention on Tobacco Control (FCTC).

### **regulation of ingredients**

#### **problem definition**

Yes

#### **which option**

Establish a common list of tobacco ingredients

#### **which one**

Establish a positive common list of tobacco ingredients

### **access to tobacco products**

#### **problem definition**

Yes

#### **which option**

Ban

#### **which one2**

Cross-border retail sales of tobacco to be banned over the Internet; Vending machines to be banned; Promotion and displays in retail stores to be banned

### **additional comments**

New evidence supporting the effectiveness of a ban on display at point of sale: Recent research at Nottingham University's UK Centre for Tobacco Control Studies has examined the effects of the ban on tobacco display at point of sale in Ireland. Recall of displays was found to have fallen significantly in both adults and teenagers, and fewer young people believed smoking to be widespread among their peers after the ban.[7] The research also indicated that support for placing tobacco out of sight rose from 58 per cent to 66 per cent after the display ban came into force. The studies found no substantial revenue losses or closures of small retailers as a result of the removal of promotional displays.[8] Internet. The principle of preventing cross-border promotion of tobacco products in order to protect public health was enshrined in the Tobacco Advertising directive (2001/0119). It is logical, therefore, to extend that principle to the sale of tobacco products between member states via the Internet. We support the prohibition of tobacco sales via the Internet. Vending machines. Most member states (22 out of 27) already prohibit the sale of tobacco products from vending machines, in order to prevent young people from accessing cigarettes from this source. We support this measure. However, as this does not have cross-border effects, we urge the Commission to make the prohibition of tobacco vending machines a non-mandatory measure as part of the product directive. [7] McNeill, A, Lewis S, Quinn C, Mulcahy M, Clancy L, Hastings G, Edwards R. Evaluation of the removal of point of sale tobacco promotional displays in Ireland, 2010. Tobacco Control, 2010. Funded by Cancer Research UK, the Office of Tobacco Control in Ireland, the Irish Cancer Society and ASH New Zealand. [8] Quinn C, Lewis S, Edwards R, McNeill A. Economic evaluation of the removal of point of sale tobacco promotional displays in Ireland, 2010. Tobacco Control, 2010. Funded by Cancer Research UK and the Office of Tobacco Control in Ireland.

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### **NGO submission**

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NGO

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Norway

##### **questions scope**

##### **problem definition**

Yes



**which option**

Extend the scope of the Directive

**recommend option**

New tobacco products and novel forms of oral tobacco should be banned similarly to snus. A Royal Decree concerning the prohibition against new tobacco and nicotine products was introduced in Norway in 1989. TobaccoFree Norway recommends that DG SANCO consider introducing regulations similar to the Norwegian prohibition against new tobacco and nicotine products (submitted in separate email) and is also available on internet.

<http://www.regjeringen.no/en/dep/hod/Subjects/Folkehelse/Norways-National-Strategy-for-Tobacco-Co.html?id=451948&epslanguage=EN-GB>

**questions smokeless****problem definition**

Yes

**which option**

Ban on all types of smokeless tobacco products

**additional option**

When snus was banned it was argued that a new addictive and harmful tobacco products should not be introduced in EU. Since other smokeless tobacco products at present has only limited use in EU they should be banned. The danger is that suddenly such a product may become popular and the use may explode (see section below on the use of snus in Norway).

**additional comments**

Use of snuff in Norway Up to 1970 snuff was primarily used by men with outdoor work in the countryside. Few started to use snuff before the age of 20 years. It was generally assumed that the use of snuff would end. However, by the end of the 1980-ties the use of snuff started to increase. The use of snuff is especially worrying among young people. In 2009, in the age group 16 – 24 years, 21% of all men used snuff daily and in addition, 15% used snuff occasionally (in the age group 45 – 64 about 7% use snuff daily). In 2005, 5% of 13-year old boys used snuff daily or occasionally and 30% of 15-year old boys used snuff daily or occasionally. At present the use of snuff is also becoming more popular among women 7% in the age group 16 – 24 years are using snuff daily (snuff is not used at all in the age group 45 – 64). During the last 7 years the sale of snuff in Norway has increased by 265%. Health effects Snuff was recently evaluated by EU (SCENHIR, 2008). After this evaluation it has been found that snuff can cause cancer of the esophagus in addition to cancer of the oral cavity and pancreas (Secretan et al, Lancet oncology 10: 1033, 2009). Furthermore, maternal use of snuff increases the risk of stillbirth (Wikström et al, Epidemiology 21: 772, 2010). SCENHIR concluded in 2008 that “there are no published randomised clinical trials of use of smokeless tobacco in smoking cessation, and in the absence of such evidence it is not possible to draw reliable conclusions as to the relative effectiveness of smokeless tobacco as an aid to clinical smoking cessation in comparison with either placebo or other established therapies”. A Norwegian group has later in two publications claimed that the use of snuff is efficient in smoking cessation. However, no data was presented on the length of cessation, one week or one month or one year). In a study from USA (Tomar et al, Tobacco Control 19: 104, 2010) it was concluded that the “study also found that adult male daily smokers who also use snuff on some days expressed greater interest in quitting smoking than other groups but were more likely than any other group to have had unsuccessful quit attempts in the preceding year.”

**questions consumer**

**problem definition**

Yes

**which option**

Improve consumer information; Introduce generic or plain packaging

**which improvement**

Picture warnings to become mandatory; Tar, nicotine and carbon monoxide levels to be replaced with general information on harmful substances in tobacco products; Information on harmful substances in tobacco products that cannot be placed on the package would be placed inside the package; Health warnings to be put on water pipes

**additional option**

Pictorial health warnings should also be mandatory on all types of oral tobacco.

**questions on reporting**

**problem definition**

Yes

**which option**

Establish a common compulsory reporting format; Introduce fees and sanctions

**regulation of ingredients**

**problem definition**

Yes

**which option**

Establish a common list of tobacco ingredients

**which one**

Establish a positive common list of tobacco ingredients

**access to tobacco products**

**problem definition**

Yes

**which option**

Ban

**which one2**

Cross-border retail sales of tobacco to be banned over the Internet; Vending machines to be banned; Promotion and displays in retail stores to be banned

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**NGO submission**

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**questions scope****problem definition**

Yes

**which option**

Extend the scope of the Directive

**additional comments**

All tobacco products are hazardous to health – there is no safe level of usage. Therefore we recommend that the scope of the Directive includes the regulation of any new smoked tobacco products (such as low emission or nicotine-free cigarettes), while the prohibition of any novel forms of oral tobacco, including snus, should be maintained. Herbal cigarettes are also harmful because it is the combustion and inhalation of smoke that causes most of the harm from smoking. Therefore, herbal cigarettes should be included in the scope Tobacco Products Directive and should also be subject to health warnings requirements. Finally, all forms of nicotine based products (that is, products containing nicotine but which are not tobacco products, such as electronic cigarettes, nicotine gel, drinks, and sweets) are often marketed as alternatives to cigarettes and in some cases as an aid to quitting smoking. Therefore, they should only be sold as quitting aids and comply with specific safety and quality requirements under the same regulatory framework as pharmaceutical products rather than under the scope of the Tobacco Products Directive.

**questions smokeless****problem definition**

Yes

**which option**

No change

**additional option**

The ban on snus should definitely be maintained. This is high priority. Indeed, there is no legitimate reason to introduce a dangerous product onto the market, particularly as, from an internal market point of view, we have no idea how snus would be perceived or used in other countries. A small study conducted by the University of Nottingham by Professor Ann McNeil showed that, in the UK, people could not see the point of snus unless it was as a cessation aid (i.e. there is currently no demand). For internal market purposes, it really does not make sense to lift the ban. Furthermore, if the ban on snus were to be lifted, it could encourage dual use of cigarettes and smokeless tobacco and discourage total abstinence from

tobacco, thus weakening any potential health gains. In this context, we stress that there are already available effective treatments for nicotine addiction, including medicinal or 'clean' nicotine (NRT), that do not carry the risks associated with the use of snus. These should be promoted first and foremost. It is clear that the public health interest can be served even more by encouraging a) greater use of these treatments and b) the development of more effective cessation aids, especially those that mimic more closely the nicotine 'hit' delivered by cigarettes. Regarding other forms of smokeless tobacco products, the SFP does not believe that they should be "marketed" in all Member States. We recognise that they are as addictive and dangerous as smoked tobacco. As stated in the Opinion of the Scientific Committee on Emerging and Newly Identified Health Risks (SCENIHR), many forms of smokeless tobacco increase the risk of mouth, esophageal, pancreatic and liver cancer, and other conditions including gum and heart disease. However, we also know that these products are mostly consumed in the UK and used by South Asian communities; introducing an EU-wide ban on these products now could lead to the creation of an unnecessary illegal market, pushing consumption underground. This is why we do not recommend an immediate ban on all types of smokeless tobacco products; we do recommend that they should be regulated in the same way as tobacco products.

### **questions consumer**

#### **problem definition**

No

#### **explanations**

The problem definition could be improved. We agree with the Commission that the current situation, whereby some Member States have made graphic warnings compulsory and others not, has led to a disparity in labelling throughout the EU. Consequently, this has an impact on the functioning of the internal market, on consumers' awareness and as a result, on their smoking behaviour. We also agree that packaging as an advertising tool is not covered by the current Directive. Finally, we welcome the acknowledgement that tobacco packaging and product features are increasingly used to attract consumers, to promote products and brand image. In this context, it would have been judicious to highlight the fact that, in the Eurobarometer survey released in 2010, the policy that received the most positive response is that of putting health warnings on all packages of tobacco products (on average, 75% of EU citizens are in favour of mandatory pictorial warnings, and over 54% support plain packaging measures).

#### **which option**

Improve consumer information; Introduce generic or plain packaging

#### **which improvement**

Picture warnings to become mandatory; Tar, nicotine and carbon monoxide levels to be replaced with general information on harmful substances in tobacco products; Information on harmful substances in tobacco products that cannot be placed on the package would be placed inside the package; Health warnings to be put on water pipes

#### **additional option**

Crucial importance of Graphic health warnings: Evidence shows that text only warning messages are not as effective as graphic warnings. Pictures, especially fear inducing pictures, are proven to be effective in getting consumers more engaged with the warning message. Pictures are able to immediately provoke a reaction and prompt people to read the associated

text message. The need for graphic health warnings on both sides of the pack: There is also evidence that pictures on both sides of the packaging have a greater impact. The need for LARGE pictorial health warnings (80%): Evidence clearly shows that increasing the size of warning messages (text only and combined text and picture) increases the effectiveness of the warning amongst both young and adult smokers / non smokers. Research carried out in Canada by Createc on behalf of Health Canada in 2007 showed that young and adult smokers/non smokers are sensitive to the size of health warning messages. Results showed that warning messages that cover 100% of the pack are significantly more effective across all measured effectiveness indicators compared with warning messages that cover only 50% of the pack. The importance of Rotation: Warning texts and pictures should be displayed on a rotating basis, so that each message is given equal display and can reach its target audience. The proved effectiveness of shocking health warnings & targeted messages: as specified in the Sambrook Research International report, fear inducing warnings (using strong “shocking” images related to health risks such as rotten teeth or throat cancer) and strong emotion inducing warnings (especially involving children and unborn babies) are the most effective way to educate consumers on the health risks of tobacco use and to achieve changes in attitudes and behaviour. These warnings’ effectiveness is enhanced if they are used in conjunction with a quit line. Generic or plain packaging: We strongly recommend the introduction of standardised/plain packaging. This should include not only the removal of all branding from the packaging but the size and shape of the packaging should also be standardised. Not only would this prevent the promotion of smoking through branding as occurs presently but it would reinforce the health warning messages. Tobacco packaging provides a direct link between consumers and manufacturers and is the main marketing channel, particularly in jurisdictions with tobacco advertising bans. Branding gives the misleading impression some cigarettes are safer than others. The tobacco industry claims that plain packaging would contravene intellectual property law. However, legal analysis concludes that this is incorrect and there are no international legal impediments to the implementation of generic packaging. Replace TNCO quantitative labelling with qualitative information on contents, emissions and quit-lines: The inclusion of machine-based tar, nicotine and carbon monoxide yields on cigarette packs promotes the mistaken belief that some cigarette brands are less harmful than others. We support the proposal to replace numerical measurements with descriptive information on the hazardous effects of tobacco constituents and emissions. We stress the importance of putting quit line numbers on the package. As underlined in the Sambrook research (p46), providing a telephone number on the pack is more effective than telling smokers to seek advice from a doctor or pharmacist. P46 Health warnings on water pipes: There is a growing body of evidence to show that water pipes are at least as hazardous, if not more so, than other forms of tobacco use. Warnings should also be included on the packaging of tobacco used in water pipes.

### **additional comments**

Under Article 5.3 of the TPD 2001, Member States have the option to adopt pictorial warnings. This situation emphasised the right of Member States to go further than the Directive to protect public health as set out in Article 30 of the Treaty of the Union (now article 36). Ten years after the entering into force of the TPD, four countries (the UK, Belgium, Romania and Malta) have adopted the option. More countries such as Spain and France are planning to adopt mandatory pictorial warnings. Such measures are in compliance with the current TPD and are welcomed by the tobacco control community. However, their adoption by some Member States necessarily creates growing discrepancies between Member States. As stated above, there is clear evidence that pictorial warnings are much more powerful than written health warnings. Extending the information and protection to all EU

Member States would be in harmony with Article 168 of the TFEU and consistent with the objectives of the internal market stated in Article 114.3 of the TFEU and reiterated in Recital 19 of the Directive. A revision of the TPD should, therefore, aim at making pictorial health warnings of tobacco products subject to common rules. Note: Legislation on labelling, advertising and product regulation put forward by the Commission in the field of tobacco control, has been based on the internal market legislation (Articles 26 and 114 of the TFEU). Article 26 of the TFEU establishes the internal market. Article 114 gives EU institutions the competence to regulate and set rules for the functioning of the internal market. More specifically, article 114.3 also states that when establishing rules for the functioning of the internal market in the context of health, safety, environmental protection and consumer protection, the Commission “will take as a base a high level of protection, taking account in particular of any new development based on scientific facts.” The European Court of Justice (the “ECJ”) made an extensive analysis of Article 95 EC (now Article 114) throughout the years. In *Spain v. Council*, the Court observed that “recourse to Article 100a (now Article 114) as a legal basis is possible if the aim is to prevent the emergence of future obstacles to trade resulting from multifarious development of national laws.” The TPD was adopted on the basis of Article 114 TFEU (ex Article 95). As a result, Recital 19 of the TPD states that “[t]he presentation of warning labels and yields has continued to remain variable in the different Member States. As a consequence, consumers in one Member State may be better informed as to the risks of tobacco products than in another. Such differences are unacceptable and are liable to constitute a barrier to trade and to impede the operation of the internal market in tobacco products, and should therefore be eliminated.”

### **questions on reporting**

#### **problem definition**

Yes

#### **which option**

Establish a common compulsory reporting format; Introduce fees and sanctions

#### **additional comments**

The current situation which allows different formats and reporting mechanisms is unsatisfactory, making it difficult for authorities to compare and analyse the data. All tobacco manufacturers and importers should be subject to the same reporting requirements. The SFP believes that tobacco products, which are highly harmful, should be subject to an effective reporting system that allows the gathering and analysis of relevant data, including comparison as appropriate, in order to ensure high levels of consumer safety and information. The format already exists (based on the voluntary reporting format developed by the Commission in May 2007) and it would therefore be very easy to adopt this measure and to implement it. We welcome the introduction of yearly registration fees in order to finance the data collection on ingredients by the national authorities and their analysis work on ingredients. The payment of penalties in case of non-compliance with the requirements of delivery of data on tobacco product ingredients also seems adequate and would contribute to fund the tests conducted on these products. It is crucial that the appropriate toxicological and addictiveness tests are properly conducted. Such tests would allow policy-makers to make more informed decisions in this field, as there would be more scientific evidence. It would enhance the scientific knowledge of the dangers of tobacco products and would contribute to a high protection of health, as stated in Article 95.3 TFEU. Besides, such measures would also have an indirect impact on illicit trade, since only registered products would be allowed on the market.

**regulation of ingredients****problem definition**

Yes

**which option**

Establish a common list of tobacco ingredients

**which one**

Establish a positive common list of tobacco ingredients

**additional comments**

We support the adoption of a positive common list of tobacco ingredients. We believe that tobacco products are highly toxic and addictive, and that their content should therefore be closely regulated, in order to achieve high standards of health protection, as stated under article 114.3. There is a need for such a list at EU level since at the moment, consumers in the internal market are not subject to the same level of protection. Some citizens may be using substances that are banned in other Member States. Apart from creating unequal health protection across the EU, this may constitute an obstacle to free movement of goods within the internal market: some countries can refuse access to their markets of cigarettes from Member States that do not comply with the importing Member State's national requirements. Regulation of Flavours and Ingredients: Flavourings are an increasingly important part of tobacco industry marketing, particularly to young people. Flavourings enhance attractiveness, encourage youth initiation, and discourage cessation. The prohibition of ingredients that may be used to increase attractiveness, such as sugars and sweeteners, flavouring substances, and spices and herbs, in cigarettes and cigarette-like tobacco products should be introduced. The prohibition of ingredients that may create the impression of a health benefit (e.g. vitamins), ingredients associated with energy and vitality (e.g. caffeine), and ingredients with colouring properties (e.g. pink cigarette paper) should also be banned. Tobacco manufacturers and importers should report sales volume information by brand. This information is essential to help governments ensure that product regulation is effective. The above measures should be compliant with the Guidelines on Art. 9/10, adopted unanimously at the Fourth Conference of the Parties in Uruguay on the 20th November 2010.

**access to tobacco products****problem definition**

Yes

**which option**

Ban

**which one2**

Cross-border retail sales of tobacco to be banned over the Internet; Vending machines to be banned; Promotion and displays in retail stores to be banned

**additional option**

We urge the Commission to call for a ban on the promotion of tobacco products at point of sale and a ban on vending machines as described in the Art 13 Guidelines of the FCTC.

**additional comments**

Internet. The principle of preventing cross-border promotion of tobacco products in order to

protect public health was enshrined in the Tobacco Advertising directive (2001/0119). It is logical, therefore, to extend that principle to the sale of tobacco products between member states via the Internet. We support the prohibition of tobacco sales via the Internet. Vending machines. The majority of member states (22 out of 27) already prohibit the sale of tobacco products from vending machines in order to deter young people accessing cigarettes from this source. We support this measure. Point of Sale. Evidence shows that a coordinated cross border marketing strategy on the part of the tobacco companies is reflected at point of sale (i.e. point of sale marketing is similar in most EU countries (i.e.: a brand is advertised at point of sale in the same way in Germany and Belgium). There is a growing body of evidence to show that putting tobacco products out of sight in retail outlets can reduce youth smoking. To date, this measure has been adopted by Ireland and Finland (as well as Iceland and Norway). This measure is also official government policy in Scotland, Wales and Northern Ireland and a decision is awaited in England. We strongly support an EU-wide adoption of a ban on the display of tobacco products at the point of sale.

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## **NGO submission**

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NGO

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### **questions scope**

#### **problem definition**

Yes

#### **which option**

No change

### **additional comments**

Ellentmondásos a tervezet, mert már a hatáskör definiálásakor tiltásokat fogalmaz meg bizonyos termékkörökre, anélkül, hogy erre vonatkozó részletekkel szolgálna- legyen szó akár a bevezetőről, akár a konzultációs anyag egyéb fejezetéről.

### **questions smokeless**

#### **problem definition**

Yes

#### **which option**

Lifting the ban on snus



**additional comments**

Ennek a kérdéskörnek a szabályozását tagállami hatáskörben lenne érdemes meghagyni. Mindezek mellett úgy gondoljuk, hogy a snüsszel kapcsolatos svéd példa alapján a füstmentes dohánytermékeket tiltás helyett inkább reklámozni kellene.

**questions consumer  
problem definition**

No

**explanations**

Véleményünk szerint az egészségvédő feliratok méretének eltúlzása nincs arányban az elérni kívánt céllal. Az egyencsomagolás bevezetése egyértelműen utat nyit a feketekereskedelem növekedésének.

**which option**

No change

**questions on reporting  
problem definition**

No

**explanations**

Tagállami szinten a kérdéskör megoldott és a tagállamok szuverenitásának fenntartása szükséges, mivel a jelenlegi direktíva megfelelő alapot biztosít ehhez.

**which option**

No change

**regulation of ingredients****problem definition**

No

**explanations**

A tiltó jellegű szabályozásnak megfelelő tudományos alapokon kell nyugodnia, nem pedig szubjektív értékelésen. Az FCTC9-10 cikkelyeinek vitái alapján is látszik, hogy egy nem átgondolt tiltó szabályozás dohánytermelők munkahelyeit veszélyezteti, így Magyarországon 10,000 ember megélhetését tervezi ellehetetleníteni.

**which option**

No Change

**access to tobacco products****problem definition**

No

**explanations**

A túlzott szabályozás a feketekereskedelem kapuit nyitja tágabbra, és így a legális értékesítés csökkenésén keresztül a termelői érdekeket hátrányosan befolyásolja.

**which option**

No change

---

**NGO submission**

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**age**

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**questions scope**

**problem definition**

Yes

**which option**

Extend the scope of the Directive

**questions smokeless**

**problem definition**

Yes

**which option**

Ban on all types of smokeless tobacco products

**questions consumer**

**problem definition**

Yes

**which option**

Introduce generic or plain packaging

**questions on reporting**

**problem definition**

Yes

**which option**

Introduce fees and sanctions

**regulation of ingredients**

**problem definition**

Yes

**which option**

Establish a common list of tobacco ingredients

**access to tobacco products**

**problem definition**

Yes

**which option**

Ban

**which one2**

Cross-border retail sales of tobacco to be banned over the Internet; Vending machines to be banned; Promotion and displays in retail stores to be banned

---

**NGO submission**

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**questions scope**

**problem definition**

No

**explanations**

The problem definition is incorrect, vague and unclear. It fails to provide a scientific basis or evidence for the different options considered in this section

**which option**

No change

**questions smokeless  
problem definition**

No

**which option**

Lifting the ban on snus

**questions consumer  
problem definition**

No

**explanations**

The problem is defined overly narrowly, and so fails to identify relevant policy options

**which option**

No change

**questions on reporting  
problem definition**

No

**explanations**

No evidence provided for the different options discussed in this section

**which option**

Establish a common compulsory reporting format

**regulation of ingredients  
problem definition**

No

**explanations**

The problem definition incorrectly defines the use of ingredients

**which option**

No Change

**access to tobacco products  
problem definition**

No

**which option**

No change

---

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### **questions scope**

#### **problem definition**

No

### **explanations**

EU should provide freedom for the people of EU. Many smokers are discriminated in their home country today. It should be EU's function to secure the freedom for these people. EU should not promote more rules for smokers that is already discriminated.

#### **which option**

No change

### **questions smokeless**

#### **problem definition**

No

### **comments**

Again there is no discussion if its okay to take away the freedom from people of EU. EU should protect peoples right to use smokeless tobacco products. If one Member State allows a product, the product should be legal in all member states.

#### **which option**

Lifting the ban on snus

### **questions consumer**

#### **problem definition**

No

### **explanations**

I noted that the statement: "Evidence shows that pictorial warnings if properly sized and well placed are an efficient measure to inform the public about the dangers of smoking, and they are particularly effective among vulnerable groups. The bigger the size of the picture warning, the more effective it is." came without a footnote. Some evidence tells us that picture

warnings doesn't help. Its mostly seems as picture warnings a discriminating towards the tobacco companys and that smokers get more and more stigmatized in the member states because of laws made in EU. EU should remove all picture warnings from products that is sold legal in EU.

**which option**

No change

**additional comments**

There is missing a less regulations option.

**questions on reporting**

**problem definition**

Yes

**which option**

No change

**regulation of ingredients**

**problem definition**

Yes

**which option**

No Change

**additional option**

If a tobacco ingredients is legal in one Member State it should be legal in all Member States. Its an easy way to help tobacco companys from getting discriminated in some Member States.

**access to tobacco products**

**problem definition**

No

**explanations**

If people buy a tobacco product from another Member State, than the Member State that they live in, is not because they get tricked into buying from an internet company. Its because the laws of their Member State is wrongful. The problem is not the internet companys. The problem is the Member State with laws that some people of the Member State doesn't want. EU should protect the people of EU - not protect discrimination of citizens of EU.

**which option**

No change

---

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**questions scope****problem definition**

No

**explanations**

no change

**which option**

No change

**questions smokeless****problem definition**

No

**which option**

No change

**questions consumer****problem definition**

No

**explanations**

no change

**which option**

No change

**questions on reporting****problem definition**

No

**explanations**

no change

**which option**

No change

**regulation of ingredients****problem definition**

No

**explanations**

no change

**which option**

No Change

**access to tobacco products**

**problem definition**

No

**explanations**

no change

**which option**

No change

---

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**questions scope**

**problem definition**

Yes

**which option**

Extend the scope of the Directive

**questions smokeless**

**problem definition**

Yes

**which option**

Ban on all types of smokeless tobacco products



**questions consumer  
problem definition**  
Yes

**which option**  
Introduce generic or plain packaging

**questions on reporting  
problem definition**  
Yes

**which option**  
Introduce fees and sanctions

**regulation of ingredients  
problem definition**  
Yes

**which option**  
Establish a common list of tobacco ingredients

**which one**  
Establish a negative common list of tobacco ingredients

**access to tobacco products  
problem definition**  
Yes

**which option**  
Controlled supply and access

**which supply and access**  
Age verification of buyers and other legal conditions to be set for cross-border retail sale;  
Access to vending machines to be restricted to adults; Tobacco display and promotion at  
points of sales to be restricted

---

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**questions scope**  
**problem definition**  
Yes

**which option**  
No change

**questions smokeless**  
**problem definition**  
Yes

**which option**  
Ban on all types of smokeless tobacco products

**questions consumer**  
**problem definition**  
Yes

**which option**  
Improve consumer information; Introduce generic or plain packaging

**which improvement**  
Picture warnings to become mandatory; Tar, nicotine and carbon monoxide levels to be replaced with general information on harmful substances in tobacco products; Information on harmful substances in tobacco products that cannot be placed on the package would be placed inside the package; Health warnings to be put on water pipes

**questions on reporting**  
**problem definition**  
Yes

**which option**  
Establish a common compulsory reporting format; Introduce fees and sanctions

**regulation of ingredients**  
**problem definition**  
Yes

**which option**  
Establish a common list of tobacco ingredients

**which one**

Establish a negative common list of tobacco ingredients

**access to tobacco products**

**problem definition**

Yes

**which option**

Controlled supply and access; Ban

**which supply and access**

Age verification of buyers and other legal conditions to be set for cross-border retail sale; Access to vending machines to be restricted to adults; Tobacco display and promotion at points of sales to be restricted

**which one2**

Cross-border retail sales of tobacco to be banned over the Internet; Vending machines to be banned; Promotion and displays in retail stores to be banned

---

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**questions scope**

**problem definition**

Yes

**which option**

Extend the scope of the Directive

**additional comments**

All tobacco products are hazardous to health – there is no safe level of usage. Therefore we recommend that the scope of the Directive includes the regulation of any new smoked tobacco products (such as low emission or nicotine-free cigarettes), while the prohibition of any novel forms of oral tobacco, including snus, should be maintained. Herbal cigarettes are also harmful because it is the combustion and inhalation of smoke that causes most of the harm from smoking. Therefore, herbal cigarettes should be included in the scope Tobacco Products Directive and should also be subject to health warnings requirements. Finally, all forms of nicotine based products (that is, products containing nicotine but which are not tobacco products, such as electronic cigarettes, nicotine gel, drinks, and sweets) are often marketed as alternatives to cigarettes and in some cases as an aid to quitting smoking. Therefore, they should only be sold as quitting aids and comply with specific safety and quality requirements under the same regulatory framework as pharmaceutical products rather than under the scope of the Tobacco Products Directive.

**questions smokeless****problem definition**

Yes

**which option**

No change

**additional comments**

The ban on snus should definitely be maintained. This is high priority. Indeed, there is no legitimate reason to reintroduce a carcinogenic and addictive product onto the EU market. Furthermore, if the ban on snus were to be lifted, it could encourage dual use of cigarettes and smokeless tobacco and discourage total abstinence from tobacco, thus weakening any potential health gains. In this context, we stress that there are already available effective treatments for nicotine addiction, including medicinal or ‘clean’ nicotine (NRT), that do not carry the risks associated with the use of snus. These should be promoted first and foremost. It is clear that the public health interest can be served even more by encouraging a) greater use of these treatments and b) the development of more effective cessation aids, especially those that mimic more closely the nicotine ‘hit’ delivered by cigarettes. Regarding other forms of smokeless tobacco products, ECL does not believe that they should be “marketed” in all Member States. We recognise that they are as addictive and dangerous as smoked tobacco. As stated in the Opinion of the Scientific Committee on Emerging and Newly Identified Health Risks (SCENIHR), many forms of smokeless tobacco increase the risk of mouth, esophageal, pancreatic and liver cancer, and other conditions including gum and heart disease. However, we also know that these products are mostly consumed in the UK and used by South Asian communities; introducing an EU-wide ban on these products now could lead to the creation of an unnecessary illegal market, pushing consumption underground. This is why we do not recommend an immediate ban on all types of smokeless tobacco products; we do recommend that they should be regulated in the same way as tobacco products.

**questions consumer****problem definition**

No

**explanations**

The problem definition could be improved. We agree with the Commission that the current

situation, whereby some Member States have made graphic warnings compulsory and others not, has led to a disparity in labelling throughout the EU. Consequently, this has an impact on the functioning of the internal market, on consumers' awareness and as a result, on their smoking behaviour. We also agree that packaging as an advertising tool is not covered by the current Directive. Finally, we welcome the acknowledgement that tobacco packaging and product features are increasingly used to attract consumers, to promote products and brand image. In this context, it would have been judicious to highlight the fact that, in the Eurobarometer survey released in 2010, the policy that received the most positive response is that of putting health warnings on all packages of tobacco products (on average, 75% of EU citizens are in favour of mandatory pictorial warnings, and over 54% support plain packaging measures).

### **which option**

Improve consumer information

### **which improvement**

Picture warnings to become mandatory; Tar, nicotine and carbon monoxide levels to be replaced with general information on harmful substances in tobacco products; Information on harmful substances in tobacco products that cannot be placed on the package would be placed inside the package; Health warnings to be put on water pipes

### **additional option**

Crucial importance of Graphic health warnings: Evidence shows that text only warning messages are not as effective as graphic warnings. Pictures, especially fear inducing pictures, are proven to be effective in getting consumers more engaged with the warning message. Pictures are able to immediately provoke a reaction and prompt people to read the associated text message. The need for graphic health warnings on both sides of the pack: There is also evidence that pictures on both sides of the packaging have a greater impact. The need for LARGE pictorial health warnings (80%): The global trend is towards larger health warnings. Uruguay, for instance, has implemented legislation to make pictorial health warnings obligatory, covering 80% of the front and the back of cigarette packs. Evidence clearly shows that increasing the size of warning messages (text only and combined text and picture) increases the effectiveness of the warning amongst both young and adult smokers / non smokers. Research carried out in Canada by Createc on behalf of Health Canada in 2007 showed that young and adult smokers/non smokers are sensitive to the size of health warning messages. Results showed that warning messages that cover 100% of the pack are significantly more effective across all measured effectiveness indicators compared with warning messages that cover only 50% of the pack. The importance of Rotation: Warning texts and pictures should be displayed on a rotating basis, so that each message is given equal display and can reach its target audience. The proved effectiveness of shocking health warnings & targeted messages: as specified in the Sambrook Research International report, fear inducing warnings (using strong "shocking" images related to health risks such as rotten teeth or throat cancer) and strong emotion inducing warnings (especially involving children and unborn babies) are the most effective way to educate consumers on the health risks of tobacco use and to achieve changes in attitudes and behaviour. These warnings' effectiveness is enhanced if they are used in conjunction with a quit line. Generic or plain packaging: We strongly recommend the introduction of standardised/plain packaging. This should include not only the removal of all branding from the packaging but the size and shape of the packaging should also be standardised. Not only would this prevent the promotion of smoking through branding as occurs presently but it would reinforce the health warning messages. Tobacco

packaging provides a direct link between consumers and manufacturers and is the main marketing channel, particularly in jurisdictions with tobacco advertising bans. Branding gives the misleading impression some cigarettes are safer than others. The tobacco industry claims that plain packaging would contravene intellectual property law. However, legal analysis concludes that this is incorrect and there are no international legal impediments to the implementation of generic packaging. Replace TNCO quantitative labelling with qualitative information on contents, emissions and quit-lines: The inclusion of machine-based tar, nicotine and carbon monoxide yields on cigarette packs promotes the mistaken belief that some cigarette brands are less harmful than others. We support the proposal to replace numerical measurements with descriptive information on the hazardous effects of tobacco constituents and emissions. We stress the importance of putting quit line numbers on the package. As underlined in the Sambrook research (p46), providing a telephone number on the pack is more effective than telling smokers to seek advice from a doctor or pharmacist. P46 Health warnings on water pipes: There is a growing body of evidence to show that water pipes are at least as hazardous, if not more so, than other forms of tobacco use. Warnings should also be included on the packaging of tobacco used in water pipes.

### **additional comments**

Under Article 5.3 of the TPD 2001, Member States have the option to adopt pictorial warnings. This situation emphasised the right of Member States to go further than the Directive to protect public health as set out in Article 30 of the Treaty of the Union (now article 36). Five years after the adoption of the library of 42 pictorial health warnings by the European commission, seven Member States have adopted legislation to introduce pictorial health warnings (Belgium, Romania, United Kingdom, Latvia, Malta, France and Spain). Such measures are in compliance with the current TPD and are welcomed by the tobacco control community. However, their adoption by some Member States necessarily creates growing discrepancies between Member States. As stated above, there is clear evidence that pictorial warnings are much more powerful than written health warnings. Extending the information and protection to all EU Member States would be in harmony with Article 168 of the TFEU and consistent with the objectives of the internal market stated in Article 114.3 of the TFEU and reiterated in Recital 19 of the Directive. A revision of the TPD should, therefore, aim at making pictorial health warnings of tobacco products subject to common rules.

### **questions on reporting problem definition**

Yes

### **which option**

Establish a common compulsory reporting format; Introduce fees and sanctions

### **additional comments**

The current situation which allows different formats and reporting mechanisms is unsatisfactory, making it difficult for authorities to compare and analyse the data. All tobacco manufacturers and importers should be subject to the same reporting requirements. The SFP believes that tobacco products, which are highly harmful, should be subject to an effective reporting system that allows the gathering and analysis of relevant data, including comparison as appropriate, in order to ensure high levels of consumer safety and information. The format already exists (based on the voluntary reporting format developed by the Commission in May 2007) and it would therefore be very easy to adopt this measure and to implement it. We

welcome the introduction of yearly registration fees in order to finance the data collection on ingredients by the national authorities and their analysis work on ingredients. The payment of penalties in case of non-compliance with the requirements of delivery of data on tobacco product ingredients also seems adequate and would contribute to fund the tests conducted on these products. It is crucial that the appropriate toxicological and addictiveness tests are properly conducted. Such tests would allow policy-makers to make more informed decisions in this field, as there would be more scientific evidence. It would enhance the scientific knowledge of the dangers of tobacco products and would contribute to a high protection of health, as stated in Article 95.3 TFEU. Besides, such measures would also have an indirect impact on illicit trade, since only registered products would be allowed on the market.

## **regulation of ingredients**

### **problem definition**

Yes

### **which option**

Establish a common list of tobacco ingredients

### **which one**

Establish a positive common list of tobacco ingredients

### **additional comments**

We support the adoption of a positive common list of tobacco ingredients. We believe that tobacco products are highly toxic and addictive, and that their content should therefore be closely regulated, in order to achieve high standards of health protection, as stated under article 114.3. There is a need for such a list at EU level since at the moment, consumers in the internal market are not subject to the same level of protection. Some citizens may be using substances that are banned in other Member States. Apart from creating unequal health protection across the EU, this may constitute an obstacle to free movement of goods within the internal market: some countries can refuse access to their markets of cigarettes from Member States that do not comply with the importing Member State's national requirements. Regulation of Flavours and Ingredients: Flavourings are an increasingly important part of tobacco industry marketing, particularly to young people. Flavourings enhance attractiveness, encourage youth initiation, and discourage cessation. The prohibition of ingredients that may be used to increase attractiveness, such as sugars and sweeteners, flavouring substances, and spices and herbs, in cigarettes and cigarette-like tobacco products should be introduced. The prohibition of ingredients that may create the impression of a health benefit (e.g. vitamins), ingredients associated with energy and vitality (e.g. caffeine), and ingredients with colouring properties (e.g. pink cigarette paper) should also be banned. Tobacco manufacturers and importers should report sales volume information by brand. This information is essential to help governments ensure that product regulation is effective. The above measures should be compliant with the Guidelines on Art. 9/10, adopted unanimously at the Fourth Conference of the Parties in Uruguay on the 20th November 2010.

## **access to tobacco products**

### **problem definition**

Yes

### **which option**

Ban

**which one2**

Cross-border retail sales of tobacco to be banned over the Internet; Vending machines to be banned; Promotion and displays in retail stores to be banned

**additional option**

We urge the Commission to call for a ban on the promotion of tobacco products at point of sale and a ban on vending machines as described in the Art 13 Guidelines of the FCTC.

**additional comments**

Internet. The principle of preventing cross-border promotion of tobacco products in order to protect public health was enshrined in the Tobacco Advertising directive (2001/0119). It is logical, therefore, to extend that principle to the sale of tobacco products between member states via the Internet. We support the prohibition of tobacco sales via the Internet. Vending machines. Considering that only 2 Member States have no legislation on vending machines, we support harmonisation of the legislation on the basis of a prohibition of the sale of tobacco from vending machines . Point of Sale. Evidence shows that a coordinated cross border marketing strategy on the part of the tobacco companies is reflected at point of sale (i.e. point of sale marketing is similar in most EU countries (i.e.: a brand is advertised at point of sale in the same way in Germany and Belgium). There is a growing body of evidence to show that putting tobacco products out of sight in retail outlets can reduce youth smoking. To date, this measure has been adopted by Ireland and Finland (as well as Iceland and Norway). This measure is also official government policy in Scotland, Wales and Northern Ireland and a decision is awaited in England. We strongly support an EU-wide adoption of a ban on the display of tobacco products at the point of sale.

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**NGO submission****identification****affiliation**

NGO

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**gender**

female

**questions scope****problem definition**

Yes



**which option**

Extend the scope of the Directive

**additional comments**

Alla tobaksprodukter är hälsofarliga. Vi menar därför att direktivet ska inkludera alla nya tobaksprodukter avsedda för rökning, samtidigt som förbud mot alla nya former av oral tobak, inkluderande snus, bibehålls. All inandning av förbränningsprodukter vid rökning är skadlig varför också örtcigaretter bör inkluderas i direktivet. Alla produkter som innehåller nikotin och som nu inte är klassade som tobaksprodukter, t ex elektroniska cigaretter, nikotingel, nikotindrinkar och nikotingodis, och marknadsförs som stöd vid rökavvänjning bör vara underställda samma säkerhets- och kvalitetskrav som gäller för farmaceutiska produkter.

**questions smokeless****problem definition**

Yes

**which option**

No change

**additional option**

Det är av högsta prioritet att behålla försäljningsförbudet för snus. Det finns ingen anledning att introducera ytterligare en hälsofarlig produkt. Erfarenheter från Sverige visar att snusbruk uppmuntrar till samtidig användning av cigaretter och snus och därigenom riskerar att minska benägenheten att komma ur nikotinberoendet. Fyra av tio dagligbrukare av snus är också rökare. Snus attraherar ungdomar till tobaksbruk. Fyra av tio dagligbrukare av snus har aldrig rökt. Det finns på marknaden i dag effektiva produkter inkluderande rena nikotinläkemedel som stöd för att sluta röka. Dessa ska i första hand användas som stöd och forskning intensifieras för att få fram ännu bättre läkemedel. Rökproblemet kan inte lösas genom att en ny tobaksprodukt introduceras av tobaksindustrin. Det är också värt att notera att andra rökfria produkter än snus marknadsförs i unionen. Eftersom användningen av dessa är marginell – mest framträdande i Storbritannien av invandrargrupper – kan man, å ena sidan, anse att ett försäljningsförbud för alla orala produkter inte är särskilt relevant. Å andra sidan kan man hävda att också dessa mindre befolkningsgrupper har rätt till det skydd för hälsan som ett försäljningsförbud avser att ge. I vilket fall bör dessa produkter regleras som tobaksprodukter.

**questions consumer****problem definition**

No

**explanations**

Olikheten i märkning av tobaksprodukter på den inre marknaden är otillfredsställande – några länder har infört obligatoriska varningsbilder men de flesta har det inte. I dessa senare länder saknas den konsumentmedvetenhet och påverkan på konsumtionen som varningsbilder visat sig medföra. I Sverige är enligt Eurobarometern 2010 69 procent av befolkningen positiva till införande av bildvarningar. Vi välkomnar också insikten att tobaksförpackningar i sig alltmer utnyttjas som reklampelare för att öka konsumtionen. Fyrtioen procent av befolkningen i Sverige välkomnar införande av neutrala tobaksförpackningar enligt Eurobarometern 2010.

**which option**

Improve consumer information; Introduce generic or plain packaging

**which improvement**

Picture warnings to become mandatory; Tar, nicotine and carbon monoxide levels to be replaced with general information on harmful substances in tobacco products; Information on harmful substances in tobacco products that cannot be placed on the package would be placed inside the package; Health warnings to be put on water pipes

**additional option**

Bildvarningar är överlägsna textvarningar. Det finns evidens för att bildvarningar är mer effektiva än textvarningar. Bilder ger en mer omedelbar reaktion och leder till att textvarningen uppmärksammas bättre. Bildvarningar ska finnas på förpackningens två största sidor. Varningsbudskapets (text + bild) storlek har betydelse – ju större desto mer effektiva. Varningsbudskapen ska även växlas på förpackningarna i ett roterande system. Bilder av hälsoskador orsakade av rökning har, tillsammans med "känslösa" bilder på barn och foster, visat sig vara mest effektiva. Effektiviteten ökar ytterligare om bilderna kombineras med telefonnummer till Sluta Röka-linje och om de i större utsträckning anpassas i enlighet med Tobakskonventionens artikel 4.2.d. Det är av högsta prioritet att neutrala tobaksförpackningar införs! Detta innebär en standardisering av storlek och form och frånvaro av märkesspecifika kännetecken. Juridisk analys i samband med pågående införande i Australien visar att det inte finns några internationella juridiska hinder för införande av neutrala paket så som tobaksindustrin hävdar. Det är av högsta prioritet att numeriska uppgifter om nivå på nikotin och kolmonoxid ersätts med kvalitativ beskrivning av skadlig inverkan av innehållet i tobak och tobaksrök. De nu förekommande numeriska värdena har erhållits vid maskinrökta tester och är vilseledande. Hälsövarningar ska också finnas på vattenpipor och tobak som röks i dessa.

**questions on reporting****problem definition**

Yes

**which option**

Establish a common compulsory reporting format; Introduce fees and sanctions

**additional comments**

Den nuvarande situationen med olika format och rapporteringssystem är helt otillfredsställande för alla parter. Ett nytt system – baserat på det Kommissionen utarbetat 2007 – är det minsta man kan kräva för tobaksprodukter som ju dödar i förtid varannan av sina långtidsanvändare. Årliga avgifter bör också tas ut för att bekosta hantering, analys, och bedömning av detta material samt kommunikering av resultatet till medborgarna

**regulation of ingredients****problem definition**

Yes

**which option**

Establish a common list of tobacco ingredients

**which one**

Establish a positive common list of tobacco ingredients

**additional comments**

En gemensam lista som tillåter ett antal ingredienser bör skapas med avsikt att konsumenter i alla medlemsländer ska ha tillgång till samma nivå av hälsoskydd. Reglering av smaktillsatser är högt prioriterad eftersom sådana har ökat markant i produktionen för att öka attraktionen, särskilt hos unga, och minska benägenheten att sluta. Även ingredienser som ger sken av att ha hälsoeffekt, t ex vitamin, ge energi, t ex koffein, eller färgämnen bör regleras. Riktlinjerna till Tobakskonventionens artiklar 9/10, nyligen antagna vid COP 4, ska beaktas.

**access to tobacco products****problem definition**

Yes

**which option**

Ban

**which one2**

Cross-border retail sales of tobacco to be banned over the Internet; Vending machines to be banned; Promotion and displays in retail stores to be banned

**additional option**

Riktlinjerna till Tobakskonventionens artikel 13 innehåller krav på dolda tobaksprodukter på säljstället och förbud mot försäljning genom tobaksautomater. Dessa riktlinjer måste respekteras.

**additional comments**

Principen att förbjuda gränsöverskridande reklam för tobaksprodukter för att skydda folkhälsan slås fast i Tobacco Advertising Directive (2001/01 19). Det är därför logiskt att också förbjuda försäljningen av tobaksvaror mellan länder via Internet. Tobaksautomater är redan förbjudna i 22 av 27 medlemsländer för att försvåra tillgängligheten för unga. Det är konsekvent att införa samma reglering i alla medlemsländer. Det finns en ökande grad av evidens för att dolda tobaksförpackningar på säljställen kan minska ungas rökning. Denna ordning bör därför införas i alla medlemsländer.

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NGO

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**age**  
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**gender**  
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**questions scope**  
**problem definition**  
Yes

**which option**  
No change

**questions smokeless**  
**problem definition**  
Yes

**which option**  
Ban on all types of smokeless tobacco products

**questions consumer**  
**problem definition**  
Yes

**which option**  
Introduce generic or plain packaging

**questions on reporting**  
**problem definition**  
Yes

**which option**  
Establish a common compulsory reporting format

**regulation of ingredients**  
**problem definition**  
Yes

**which option**  
Introducing the basic criteria on the EU level without a common list

**access to tobacco products**  
**problem definition**  
Yes

**which option**  
No change

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**NGO submission**

**identification**

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NGO

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**questions scope**

**problem definition**

Yes

**which option**

No change

**questions smokeless**

**problem definition**

Yes

**which option**

No change

**questions consumer**

**problem definition**

Yes

**which option**

No change

**questions on reporting**

**problem definition**

Yes

**which option**

No change

**regulation of ingredients****problem definition**

Yes

**which option**

No Change

**access to tobacco products****problem definition**

Yes

**which option**

No change

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**NGO submission****identification****affiliation**

NGO

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**questions scope****problem definition**

Yes

**which option**

Extend the scope of the Directive

**additional comments**

All tobacco products are hazardous to health – there is no safe level of usage or exposure to tobacco smoke. Therefore we recommend that the scope of the Directive includes the regulation of any new smoked tobacco products (such as low emission or nicotine-free cigarettes), while the prohibition of any novel forms of oral tobacco, including snus, should be maintained. Herbal cigarettes are also harmful because it is the combustion and inhalation of smoke that causes most of the harm from smoking. Therefore, herbal cigarettes should be included in the scope Tobacco Products Directive and should also be subject to health warnings requirements.

**questions smokeless****problem definition**

Yes

**which option**

No change

**additional option**

he ban on snus should definitely be maintained. This is high priority. Indeed, there is no legitimate reason to introduce a dangerous product onto the market, particularly as, from an internal market point of view, we have no idea how snus would be perceived or used in other countries. A small study conducted by the University of Nottingham by Professor Ann McNeil showed that, in the UK, people could not see the point of snus unless it was as a cessation aid<sup>1</sup> (i.e. there is currently no demand). For internal market purposes, it really does not make sense to lift the ban. Furthermore, if the ban on snus were to be lifted, it could encourage dual use of cigarettes and smokeless tobacco and discourage total abstinence from tobacco, thus weakening any potential health gains. In this context, we stress that there are already available effective treatments for nicotine addiction, including medicinal or ‘clean’ nicotine (NRT), that do not carry the risks associated with the use of snus. These should be promoted first and foremost. It is clear that the public health interest can be served even more by encouraging a) greater use of these treatments and b) the development of more effective cessation aids, especially those that mimic more closely the nicotine ‘hit’ delivered by cigarettes. Regarding other forms of smokeless tobacco products, the SFP does not believe that they should be “marketed” in all Member States. We recognise that they are as addictive and dangerous as smoked tobacco. As stated in the Opinion of the Scientific Committee on Emerging and Newly Identified Health Risks (SCENIHR), many forms of smokeless tobacco increase the risk of mouth, esophageal, pancreatic and liver cancer, and other conditions including gum and heart disease. However, we also know that these products are mostly consumed in the UK and used by South Asian communities; introducing an EU-wide ban on these products now could lead to the creation of an unnecessary illegal market, pushing consumption underground. This is why we do not recommend an immediate ban on all types of smokeless tobacco products ; we do recommend that they should be regulated in the same way as tobacco products.

**questions consumer**

**problem definition**

No

**explanations**

The problem definition could be improved. We agree with the Commission that the current situation, whereby some Member States have made graphic warnings compulsory and others not, has led to a disparity in labelling throughout the EU. Consequently, this has an impact on the functioning of the internal market, on consumers' awareness and as a result, on their smoking behaviour. We also agree that packaging as an advertising tool is not covered by the current Directive. Finally, we welcome the acknowledgement that tobacco packaging and product features are increasingly used to attract consumers, to promote products and brand image. In this context, it would have been judicious to highlight the fact that, in the Eurobarometer survey released in 2010, the policy that received the most positive response is that of putting health warnings on all packages of tobacco products (on average, 75% of EU citizens are in favour of mandatory pictorial warnings, and over 54% support plain packaging measures).

**which option**

Improve consumer information; Introduce generic or plain packaging

**which improvement**

Picture warnings to become mandatory; Tar, nicotine and carbon monoxide levels to be replaced with general information on harmful substances in tobacco products; Information on harmful substances in tobacco products that cannot be placed on the package would be placed inside the package; Health warnings to be put on water pipes

**additional option**

Crucial importance of Graphic health warnings: Evidence shows that text only warning messages are not as effective as graphic warnings. Pictures, especially fear inducing pictures, are proven to be effective in getting consumers more engaged with the warning message. Pictures are able to immediately provoke a reaction and prompt people to read the associated text message.<sup>1</sup> The need for graphic health warnings on both sides of the pack: There is also evidence that pictures on both sides of the packaging have a greater impact.<sup>2</sup> The need for LARGE pictorial health warnings (80%): Evidence clearly shows that increasing the size of warning messages (text only and combined text and picture) increases the effectiveness of the warning amongst both young and adult smokers / non smokers. Research carried out in Canada by Createc<sup>3</sup> on behalf of Health Canada in 2007 showed that young and adult smokers/non smokers are sensitive to the size of health warning messages. Results showed that warning messages that cover 100% of the pack are significantly more effective across all measured effectiveness indicators compared with warning messages that cover only 50% of the pack. The importance of Rotation: Warning texts and pictures should be displayed on a rotating basis, so that each message is given equal display and can reach its target audience. The proved effectiveness of shocking health warnings & targeted messages: as specified in the Sambrook Research International report, fear inducing warnings (using strong “shocking” images related to health risks such as rotten teeth or throat cancer) and strong emotion inducing warnings (especially involving children and unborn babies) are the most effective way to educate consumers on the health risks of tobacco use and to achieve changes in attitudes and behaviour. These warnings’ effectiveness is enhanced if they are used in conjunction with a quit line. Generic or plain packaging: We strongly recommend the introduction of standardised/plain packaging. This should include not only the removal of all branding from the packaging but the size and shape of the packaging should also be standardised. Not only would this prevent the promotion of smoking through branding as occurs presently but it would reinforce the health warning messages. Tobacco packaging provides a direct link between consumers and manufacturers and is the main marketing channel, particularly in jurisdictions with tobacco advertising bans. Branding gives the misleading impression some cigarettes are safer than others. The tobacco industry claims that plain packaging would contravene intellectual property law. However, legal analysis concludes that this is incorrect and there are no international legal impediments to the implementation of generic packaging.<sup>4</sup> Replace TNCO quantitative labelling with qualitative information on contents, emissions and quit-lines: The inclusion of machine-based tar, nicotine and carbon monoxide yields on cigarette packs promotes the mistaken belief that some cigarette brands are less harmful than others.<sup>5</sup> We support the proposal to replace numerical measurements with descriptive information on the hazardous effects of tobacco constituents and emissions. We stress the importance of putting quit line numbers on the package. As underlined in the Sambrook research (p46), providing a telephone number on the pack is more effective than telling smokers to seek advice from a doctor or pharmacist. P46 Health warnings on water pipes: There is a growing body of evidence to show that water



pipes are at least as hazardous, if not more so, than other forms of tobacco use. Warnings should also be included on the packaging of tobacco used in water pipes.

### **additional comments**

Under Article 5.3 of the TPD 2001, Member States have the option to adopt pictorial warnings. This situation emphasised the right of Member States to go further than the Directive to protect public health as set out in Article 30 of the Treaty of the Union (now article 36). Ten years after the entering into force of the TPD, four countries (the UK, Belgium, Romania and Malta) have adopted the option. More countries such as Spain and France are planning to adopt mandatory pictorial warnings. Such measures are in compliance with the current TPD and are welcomed by the tobacco control community. However, their adoption by some Member States necessarily creates growing discrepancies between Member States. As stated above, there is clear evidence that pictorial warnings are much more powerful than written health warnings. Extending the information and protection to all EU Member States would be in harmony with Article 168 of the TFEU and consistent with the objectives of the internal market stated in Article 114.3 of the TFEU and reiterated in Recital 19 of the Directive. A revision of the TPD should, therefore, aim at making pictorial health warnings of tobacco products subject to common rules. Note: Legislation on labelling, advertising and product regulation put forward by the Commission in the field of tobacco control, has been based on the internal market legislation (Articles 26 and 114 of the TFEU). Article 26 of the TFEU establishes the internal market. Article 114 gives EU institutions the competence to regulate and set rules for the functioning of the internal market. More specifically, article 114.3 also states that when establishing rules for the functioning of the internal market in the context of health, safety, environmental protection and consumer protection, the Commission “will take as a base a high level of protection, taking account in particular of any new development based on scientific facts.” The European Court of Justice (the “ECJ”) made an extensive analysis of Article 95 EC (now Article 114) throughout the years. In *Spain v. Council*, the Court observed that “recourse to Article 100a (now Article 114) as a legal basis is possible if the aim is to prevent the emergence of future obstacles to trade resulting from multifarious development of national laws.” The TPD was adopted on the basis of Article 114 TFEU (ex Article 95). As a result, Recital 19 of the TPD states that “[t]he presentation of warning labels and yields has continued to remain variable in the different Member States. As a consequence, consumers in one Member State may be better informed as to the risks of tobacco products than in another. Such differences are unacceptable and are liable to constitute a barrier to trade and to impede the operation of the internal market in tobacco products, and should therefore be eliminated.”

### **questions on reporting**

#### **problem definition**

Yes

#### **which option**

Establish a common compulsory reporting format; Introduce fees and sanctions

### **additional comments**

The current situation which allows different formats and reporting mechanisms is unsatisfactory, making it difficult for authorities to compare and analyse the data. All tobacco manufacturers and importers should be subject to the same reporting requirements. The SFP believes that tobacco products, which are highly harmful, should be subject to an effective reporting system that allows the gathering and analysis of relevant data, including comparison

as appropriate, in order to ensure high levels of consumer safety and information. The format already exists (based on the voluntary reporting format developed by the Commission in May 2007) and it would therefore be very easy to adopt this measure and to implement it. We welcome the introduction of yearly registration fees in order to finance the data collection on ingredients by the national authorities and their analysis work on ingredients. The payment of penalties in case of non-compliance with the requirements of delivery of data on tobacco product ingredients also seems adequate and would contribute to fund the tests conducted on these products. It is crucial that the appropriate toxicological and addictiveness tests are properly conducted. Such tests would allow policy-makers to make more informed decisions in this field, as there would be more scientific evidence. It would enhance the scientific knowledge of the dangers of tobacco products and would contribute to a high protection of health, as stated in Article 95.3 TFEU. Besides, such measures would also have an indirect impact on illicit trade, since only registered products would be allowed on the market.

### **regulation of ingredients**

#### **problem definition**

Yes

#### **which option**

Establish a common list of tobacco ingredients

#### **which one**

Establish a positive common list of tobacco ingredients

#### **additional comments**

We support the adoption of a positive common list of tobacco ingredients. We believe that tobacco products are highly toxic and addictive, and that their content should therefore be closely regulated, in order to achieve high standards of health protection, as stated under article 114.3. There is a need for such a list at EU level since at the moment, consumers in the internal market are not subject to the same level of protection. Some citizens may be using substances that are banned in other Member States. Apart from creating unequal health protection across the EU, this may constitute an obstacle to free movement of goods within the internal market: some countries can refuse access to their markets of cigarettes from Member States that do not comply with the importing Member State's national requirements. Regulation of Flavours and Ingredients: Flavourings are an increasingly important part of tobacco industry marketing, particularly to young people. Flavourings enhance attractiveness, encourage youth initiation, and discourage cessation. The prohibition of ingredients that may be used to increase attractiveness, such as sugars and sweeteners, flavouring substances, and spices and herbs, in cigarettes and cigarette-like tobacco products should be introduced. The prohibition of ingredients that may create the impression of a health benefit (e.g. vitamins), ingredients associated with energy and vitality (e.g. caffeine), and ingredients with colouring properties (e.g. pink cigarette paper) should also be banned. Tobacco manufacturers and importers should report sales volume information by brand. This information is essential to help governments ensure that product regulation is effective. The above measures should be compliant with the Guidelines on Art. 9/10, adopted unanimously at the Fourth Conference of the Parties in Uruguay on the 20th November 2010.

### **access to tobacco products**

#### **problem definition**

Yes

**which option**

Ban

**which one2**

Cross-border retail sales of tobacco to be banned over the Internet; Vending machines to be banned; Promotion and displays in retail stores to be banned

**additional option**

We urge the Commission to call for a ban on the promotion of tobacco products at point of sale and a ban on vending machines as described in the Art 13 Guidelines of the FCTC.

**additional comments**

Internet. The principle of preventing cross-border promotion of tobacco products in order to protect public health was enshrined in the Tobacco Advertising directive (2001/0119). It is logical, therefore, to extend that principle to the sale of tobacco products between member states via the Internet. We support the prohibition of tobacco sales via the Internet. Vending machines. The majority of member states (22 out of 27) already prohibit the sale of tobacco products from vending machines in order to deter young people accessing cigarettes from this source. We support this measure. Point of Sale. Evidence shows that a coordinated cross border marketing strategy on the part of the tobacco companies is reflected at point of sale (i.e. point of sale marketing is similar in most EU countries (i.e.: a brand is advertised at point of sale in the same way in Germany and Belgium). There is a growing body of evidence to show that putting tobacco products out of sight in retail outlets can reduce youth smoking. To date, this measure has been adopted by Ireland and Finland (as well as Iceland and Norway). This measure is also official government policy in Scotland, Wales and Northern Ireland and a decision is awaited in England. We strongly support an EU-wide adoption of a ban on the display of tobacco products at the point of sale.

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NGO

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**questions scope****problem definition**

Yes

**which option**

No change

**questions smokeless  
problem definition**

Yes

**which option**

No change

**questions consumer  
problem definition**

Yes

**which option**

No change

**questions on reporting  
problem definition**

Yes

**which option**

No change; Establish a common compulsory reporting format

**regulation of ingredients  
problem definition**

Yes

**which option**

Establish a common list of tobacco ingredients

**access to tobacco products  
problem definition**

Yes

**which option**

No change

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**NGO submission**

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affiliation**

NGO

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**questions scope**

**problem definition**

Yes

**which option**

No change

**questions smokeless**

**problem definition**

Yes

**which option**

Ban on all types of smokeless tobacco products

**questions consumer**

**problem definition**

Yes

**which option**

Improve consumer information; Introduce generic or plain packaging

**which improvement**

Picture warnings to become mandatory; Health warnings to be put on water pipes

**questions on reporting**

**problem definition**

Yes

**which option**

Establish a common compulsory reporting format

**regulation of ingredients**

**problem definition**

Yes

**which option**

Establish a common list of tobacco ingredients

**which one**

Establish a negative common list of tobacco ingredients

**access to tobacco products**

**problem definition**

Yes

**which option**

Controlled supply and access

**which supply and access**

Age verification of buyers and other legal conditions to be set for cross-border retail sale;  
Access to vending machines to be restricted to adults

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**NGO submission****identification****affiliation**

NGO

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Germany

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42

**gender**

male

**questions scope****problem definition**

Yes

**which option**

No change

**questions smokeless****problem definition**

Yes

**which option**

No change

**questions consumer****problem definition**

Yes

**which option**

No change

**questions on reporting**

**problem definition**

Yes

**which option**

No change

**regulation of ingredients**

**problem definition**

Yes

**which option**

No Change

**access to tobacco products**

**problem definition**

Yes

**which option**

No change

---

**NGO submission**

**identification**

**affiliation**

NGO

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**questions scope**

**problem definition**

Yes

**which option**

No change

**questions smokeless**

**problem definition**

Yes

**which option**

Lifting the ban on snus

**questions consumer****problem definition**

No

**explanations**

Non si concorda con l'opinione della Commissione europea per cui le avvertenze sanitarie illustrate siano uno strumento efficace per informare maggiormente le persone sui danni del fumo. Fumatori e non fumatori sono ampiamente consapevoli dei rischi per la salute derivanti dal fumo. L'aggiunta delle immagini difficilmente farà aumentare questa consapevolezza. E' anche arbitrario ritenere - come fa la Commissione - che elementi del design del pacchetto generino immagini evocative che distraggono il consumatore dalle avvertenze per la sua salute.

**which option**

No change

**questions on reporting****problem definition**

No

**explanations**

Gli Stati membri possono già introdurre imposte di registrazione e sanzioni per il mancato rispetto delle norme della Direttiva del 2001. sarebbe importante, tuttavia, stabilire un formato comune europeo per la comunicazione degli ingredienti presenti nelle sigarette, per uniformare il sistema tra i diversi paesi membri della UE.

**which option**

Establish a common compulsory reporting format

**regulation of ingredients****problem definition**

No

**explanations**

La proposta di vietare l'utilizzo di alcuni ingredienti nella produzione delle sigarette è contestabile, soprattutto perchè si basa su criteri soggettivi e arbitrari come l'attrattiva. Una regolamentazione del settore, invece, dovrebbe piuttosto basarsi su criteri di carattere scientifico: ad esempio, bisognerebbe vietare l'uso di quegli ingredienti la cui aggiunta determini un aumento della tossicità del fumo di tabacco. Se la misura fosse invece adottata senza una base scientifica, si rischia solo di creare danni irrimediabili alla filiera tabacchicola. In particolare, i coltivatori di tabacco Burley sarebbero fortemente pregiudicati da una proibizione dell'uso di ingredienti. Il Burley infatti ha bisogno dell'aggiunta di alcuni additivi nel processo di lavorazione. Il pregiudizio non sarebbe giustificabile da ragioni di salute pubblica, perché non vi è prova scientifica che le sigarette senza ingredienti (o "Virginia blend") siano meno nocive di quelle con ingredienti ("American blend"), come ha ricordato la stessa Organizzazione Mondiale della Salute. Solo nel nostro paese 60.000 tabaccoltori sarebbero ingiustamente messi in seria difficoltà dall'adozione di una misura del genere.



**which option**

No Change

**access to tobacco products****problem definition**

No

**explanations**

Il divieto totale di vendita via internet e attraverso i distributori automatici, come pure il divieto di esposizione dei prodotti di tabacco al punto vendita, non è la strada più efficace per affrontare i problemi dell'accesso dei prodotti di tabacco ai minori. Piuttosto, misure del genere rischiano di creare vantaggio alle organizzazioni criminali che alimentano i mercati con prodotti contraffatti e di contrabbando. Questa prospettiva rischia di creare serie ripercussioni sull'intera filiera del tabacco italiano. La legislazione italiana e il monopolio di vendita al dettaglio dei prodotti di tabacco basato sul sistema di concessione delle licenze assicurano efficaci controlli all'accesso. Sarebbe meglio potenziare tale sistema, piuttosto che accrescere misure restrittive che limiterebbero indiscriminatamente l'accesso e quindi la libera scelta dei fumatori adulti.

**which option**

No change

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**NGO submission****identification****affiliation**

NGO

**name**

Niezależny Samorządny Związek Zawodowy Solidarność pracowników British American Tobacco Polska S.A. zrzeszający 369 członków. Jesteśmy największą organizacją związkową działającą na terenie fabryki BAT Polska S.A. i jednocześnie jesteśmy członkiem Krajowej Sekcji Przemysłu Spożywczego NSZZ Solidarność oraz organizacji zrzeszającej wszystkie ZZ Solidarność działające w fabrykach przemysłu tytoniowego na terenie Polski. Jesteśmy partnerem dla zarządu firmy przy podejmowaniu decyzji szczególnie dotyczących spraw pracowniczych

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Polska

**questions scope****problem definition**

No

**explanations**

Naszym zdaniem problem jest zdefiniowany niewłaściwie i niejasno. Są tu pomieszane zagadnienia wyrobów tytoniowych i wyrobów netytoniowych zawierających nikotynę, co dowodzi braku rozumienia sektora tytoniowego. Definicja problemu nie przedstawia naukowych i sprawdzonych podstaw dla różnych opcji rozważanych w tej ankiecie. Regulacje każdej z kategorii powinny się opierać na obiektywnych i specyficznych dla danej kategorii produktu przesłankach czego niestety nie ma w definicji problemu

**which option**

No change

**questions smokeless****problem definition**

No

**comments**

Naszym zdaniem snus jest jednym z dostępnych na niektórych rynkach europejskich legalnym produktem który może stanowić alternatywę dla tradycyjnych papierosów. Zakaz produkcji i sprzedaży snusa w Unii Europejskiej powinien być zniesiony

**which option**

Lifting the ban on snus

**questions consumer****problem definition**

No

**explanations**

Naszym zdaniem część propozycji jak np. plain packaging oraz zwiększone napisy zdrowotno ostrzegawcze, które w praktyce uniemożliwiają umieszczenie znaków towarowych producentów – narusza obowiązujące w Polsce przepisy prawa dot. ochrony własności przemysłowej oraz konstytucyjną zasadę wolności działalności gospodarczej. Stąd to będzie również w sprzeczności z międzynarodowymi konwencjami z zakresu ochrony własności intelektualnej, których stroną jest Polska

**which option**

No change

**questions on reporting****problem definition**

No

**explanations**

Naszym zdaniem wskazane jest ujednoczenie sposobu i zakresu raportowania tzw. składników do wyrobów tytoniowych. Sankcje za niewłaściwe raportowanie powinny jednak pozostać w gestii państw członkowskich UE.

**which option**

Establish a common compulsory reporting format

**regulation of ingredients****problem definition**

No

**explanations**

Naszym zdaniem regulacje dotyczace skladnikow uzywanych w produkcji wyrobow tytoniowych powinny byc oparte tylko i wyklaczenie na obiektywnych i potwierdzonych naukowo przeslankach . Powolywanie sie na blizej niezdefiniowane pojecie „atrakcyjności „, moze spowodowac iz zostana wyeliminowane skladniki niezbedne do procesu produkcyjnego, co nie bedzie mialo wplywu na efekt zdrowotny . Ale negatywna konsekwencja bedzie wyeliminowanie prawie polowy upraw tytoniu w Polsce a co za tym idzie 7 tys rodzin plantatorskich straci jedyne zrodlo utrzymania . Cieszac sie beda przemyslownicy . Straci budzet panstwa , legalni producenci , dostawcy , kooperanci .

**which option**

No Change

**access to tobacco products****problem definition**

No

**explanations**

Naszym zdaniem mozliwosc pokazywania produktow jest bardzo wazna dla normalnego dzialania gospodarki rynkowej. Pozwala konsumentowi przede wszystkim dokonywac swiadomego wyboru. Wprowadzenie zakazu ekspozycji narusza wolnosc dzialalnosci gospodarczej oraz prawo konsumenta do informacji o produkcie Propozycja mialaby rowniez negatywny wplyw na zapewnienie rownych warunkow konkurowania na rynku dla 120 tys podmiotow zajmujacych sie sprzedaza detaliczna wyrobow tytoniowych.

**which option**

No change

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**NGO submission****identification****affiliation**

NGO

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**age**

**gender**

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**questions scope**

**problem definition**

Yes

**which option**

Extend the scope of the Directive

**questions smokeless**

**problem definition**

Yes

**which option**

Ban on all types of smokeless tobacco products

**questions consumer**

**problem definition**

Yes

**which option**

Improve consumer information; Introduce generic or plain packaging

**which improvement**

Picture warnings to become mandatory; Tar, nicotine and carbon monoxide levels to be replaced with general information on harmful substances in tobacco products; Information on harmful substances in tobacco products that cannot be placed on the package would be placed inside the package; Health warnings to be put on water pipes

**questions on reporting**

**problem definition**

Yes

**which option**

Establish a common compulsory reporting format; Introduce fees and sanctions

**regulation of ingredients**

**problem definition**

Yes

**which option**

Establish a common list of tobacco ingredients

**access to tobacco products**

**problem definition**

Yes

**which option**

Ban

**which one2**

Cross-border retail sales of tobacco to be banned over the Internet; Vending machines to be banned; Promotion and displays in retail stores to be banned

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**NGO submission**

**identification**

**affiliation**

NGO

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**questions scope**

**problem definition**

Yes

**which option**

Extend the scope of the Directive

**questions smokeless**

**problem definition**

Yes

**which option**

Ban on all types of smokeless tobacco products

**questions consumer**

**problem definition**

Yes

**which option**

Improve consumer information; Introduce generic or plain packaging

**which improvement**

Picture warnings to become mandatory; Tar, nicotine and carbon monoxide levels to be replaced with general information on harmful substances in tobacco products; Information on harmful substances in tobacco products that cannot be placed on the package would be placed inside the package; Health warnings to be put on water pipes

**questions on reporting****problem definition**

Yes

**which option**

Establish a common compulsory reporting format; Introduce fees and sanctions

**regulation of ingredients****problem definition**

Yes

**which option**

Establish a common list of tobacco ingredients

**access to tobacco products****problem definition**

Yes

**which option**

Ban

**which one2**

Cross-border retail sales of tobacco to be banned over the Internet; Vending machines to be banned; Promotion and displays in retail stores to be banned

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**NGO submission****identification****affiliation**

NGO

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Österreich

**questions scope**

**problem definition**

Yes

**which option**

Extend the scope of the Directive

**additional comments**

Der Umfang und Rahmen der Richtlinie sollte auf alle bisher nicht durch die EU-Gesetzgebung geregelten, nikotinhaltigen Waren und Produkte ausgedehnt werden (z.B. elektronische Zigaretten). Im Sinne von umfassenden Maßnahmen zur Einschränkung des Tabakkonsums, sollen alle nikotinhaltigen Produkte und Waren, die durch die EU-Gesetzgebung für Nahrungsmittel und Pharmazeutika nicht bereits in anderer Form geregelt werden, ebenfalls in der EU-Tabakprodukttrichtlinie erfasst werden.

**questions smokeless****problem definition**

Yes

**which option**

Ban on all types of smokeless tobacco products

**additional comments**

Das Rauchertelefon befürwortet die Ausweitung des Verbots von "Snus" auf alle weiteren rauchlosen Tabakprodukte.

**questions consumer****problem definition**

Yes

**which option**

Improve consumer information

**which improvement**

Picture warnings to become mandatory; Tar, nicotine and carbon monoxide levels to be replaced with general information on harmful substances in tobacco products; Information on harmful substances in tobacco products that cannot be placed on the package would be placed inside the package; Health warnings to be put on water pipes

**additional comments**

Das Rauchertelefon unterstützt die Forderung, Zigarettenpackungen mit bildlichen Warnhinweisen zu bedrucken. Zudem soll die Mindestgröße für kombinierte Warnhinweise in Bild- und Textform (derzeit 30% auf der Vorderseite und 40% auf der Rückseite) auf 80% auf Vorder- und Rückseite erhöht werden. Auf jeder Packung von Tabakprodukten soll die verpflichtende Angabe von Informationen zur Hilfestellung und Unterstützung bei der Raucherentwöhnung – einschließlich der Nennung von Rauchstopp-Linien aufgedruckt sein. Weiters unterstützt das Rauchertelefon die zusätzliche Einführung von Packungsbeilagen mit Informationen zu den schädlichen Inhaltsstoffen einschließlich der gesundheitlichen Auswirkungen des Tabakkonsums und zu den Möglichkeiten einer Raucherentwöhnung. Die Schädlichkeit des Konsums von Wasserpfeifen soll ebenfalls verstärkt kommuniziert werden. Viele Konsumenten - unter ihnen auch viele Jugendliche - leben im Glauben, die

Wasserpfeife würde weniger gesundheitsschädlich sein als andere Tabakprodukte. Zur Aufklärung sollen die gesundheitlichen Warnungen auch auf Wasserpfeifen platziert werden und die Informationen zur Schädlichkeit zusätzlich in der „Gebrauchsanweisung“ aufscheinen.

**questions on reporting**

**problem definition**

Yes

**which option**

Introduce fees and sanctions

**additional comments**

Das Rauchertelefon unterstützt die Meldung und Registrierung von Inhaltsstoffen in Tabakprodukten in Verbindung mit der Einführung entsprechender Gebühren und Sanktionen.

**regulation of ingredients**

**problem definition**

Yes

**which option**

Establish a common list of tobacco ingredients

**which one**

Establish a positive common list of tobacco ingredients

**additional comments**

Das Rauchertelefon befürwortet die Erstellung einer gemeinsamen Liste von Tabakinhaltsstoffen anhand einheitlicher Kriterien. Auf dieser „Positiv“-Liste werde nur jene Inhaltsstoffe angeführt, die bei der Herstellung von Tabakprodukten erlaubt sind, jene, die nicht auf der Liste geführt werden, sind somit verboten.

**access to tobacco products**

**problem definition**

Yes

**which option**

Ban

**which one2**

Cross-border retail sales of tobacco to be banned over the Internet; Vending machines to be banned; Promotion and displays in retail stores to be banned

**additional comments**

Das Rauchertelefon unterstützt ein uneingeschränktes Verbot aller Formen der Werbung, Bewerbung und des Sponsorings für Tabakprodukte in der EU. Weiters soll ein grenzüberschreitendes Online-Verkaufsverbot im Einzelhandel sowie ein Verbot von Verkaufsautomaten sowie von Werbung und Plakaten umgesetzt werden.

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## **NGO submission**

### **identification**

#### **affiliation**

NGO

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#### **country**

United Kingdom

### **questions scope**

#### **problem definition**

Yes

#### **which option**

Extend the scope of the Directive

### **recommend option**

All tobacco products are hazardous to health – there is no safe level of usage. Therefore the National Heart Forum recommends that the scope of the Directive includes the regulation of any smoked tobacco products (such as low emission or nicotine-free cigarettes), while the prohibition of any form of oral tobacco, including snus, should be maintained. As it is the combustion process and inhalation of smoke that causes most of the harm from smoking, it is appropriate that herbal cigarettes, which are used in a similar way to tobacco cigarettes, are regulated in the same way as smoked tobacco products, and should therefore be included in the scope of the Directive. Novel nicotine-based products (that is, products containing nicotine but not tobacco products) have the potential to offer a less hazardous alternative to cigarettes. Currently these include e-cigarettes and nicotine gel. However, as such products are generally marketed as alternatives to cigarettes and in some cases as an aid to quitting smoking, the NHF believes that it is appropriate for them to be brought under the same regulatory framework as pharmaceutical products rather than under the scope of the tobacco products Directive. The question of how nicotine-containing products should be controlled is currently under consideration by the UK's Medicines and Healthcare Regulatory Authority (MHRA) following a recent public consultation on whether to extend its remit on the regulation of nicotine replacement therapies to other nicotine-containing products (1). The outcome of this consultation may assist the Commission in developing its policy on these products. (1) Medicines and Healthcare Regulatory Authority. Public consultation (MLX 364): The regulation of nicotine containing products (NCPs). June 2010  
<http://www.mhra.gov.uk/Publications/Consultations/Medicinesconsultations/MLXs/CON065617>

### **additional comments**

The NHF believes that the scope of the Directive should be extended to include smoking paraphernalia such as filters, cigarette paper, pipes, water pipes as well as the tobacco leaf.

Smokers of roll-your-own cigarettes (RYO), pipes and water pipes often believe that these products are less harmful than manufactured cigarettes when in fact there is evidence to the contrary(2)(3). (2)Young, D., R. Borland, D. Hammond, K. M. Cummings, E. Devlin, H. H. Yong and R. J. O’Connor, ‘Prevalence and Attributes of Roll-your-own Smokers in the International Tobacco Control (ITC) Four Country Survey,’ Tobacco Control, Vol. 15, Suppl., 3 Jun 2006, pp. iii 76–82.3 (3)Richter, P. A., L. L. Pederson and M. M. O’Hegarty, ‘Young Adult Smoker Risk Perceptions of Traditional Cigarettes and Nontraditional Tobacco Products’, American Journal of Health Behaviour, Vol. 30, No. 3, May–Jun 2006, pp. 302–312.

### **questions smokeless**

#### **problem definition**

Yes

#### **which option**

No change

#### **additional option**

The NHF believes that it is a high priority that the current ban on snus is definitely maintained. Indeed we believe that there is no legitimate reason to introduce a dangerous product on the market, particularly as, from an internal market point of view, we have no idea how snus would be perceived or used in other countries. The SCENIHR report (4) notes the difficulties of extrapolating to new markets from experience in existing markets, pointing out different patterns for smoking prevalence and snus use in Sweden and Norway for example. The switching behaviour reported in Swedish men is not reflected in Norway where smoking cessation rates have been similar in Norwegian men and women during the last decade, but increased use of smokeless tobacco is observed only in young men. Further, there is little evidence that smokers in EU countries other than Sweden would find snus to be an acceptable alternative to cigarettes, were it to be legalised. The NHF believes that, if the ban on snus were to be lifted, it could encourage dual use of cigarettes and smokeless tobacco and discourage total abstinence from tobacco, thus weakening any potential health gains (5). Therefore, there is no legitimate reason to justify bringing a new hazardous product onto the market. With regard to other smokeless tobacco products, particularly those used by ethnic minority populations, the NHF believes that they should not be “marketed” in all Member States. We therefore recommend that all tobacco containing products are more tightly regulated – but we do not support a total ban on such products. The NHF fears that a total ban would likely be counter-productive by facilitating the use of smokeless tobacco products underground and creating an unnecessary illegal market. This would make it more difficult to engage with users and to offer help in quitting. (4) Health Effects of Smokeless Tobacco Products. A report by the Scientific Committee on Emerging and Newly Identified Health Risks (SCENIHR) for the European Commission (February 2008). At: [http://ec.europa.eu/health/ph\\_risk/committees/04\\_scenihr/docs/scenihr\\_q\\_004.pdf](http://ec.europa.eu/health/ph_risk/committees/04_scenihr/docs/scenihr_q_004.pdf) (accessed 29 November 2010) (5) Broadstock M.: Systematic review of the health effects of modified smokeless tobacco products. New Zealand Health Technology Assessment. Christchurch School of Medicine and Health Sciences. NZHTA Report 2007 Volume 10 Number 1.

#### **additional comments**

N/A

#### **questions consumer**

**problem definition**

Yes

**which option**

Improve consumer information; Introduce generic or plain packaging

**which improvement**

Picture warnings to become mandatory; Tar, nicotine and carbon monoxide levels to be replaced with general information on harmful substances in tobacco products; Information on harmful substances in tobacco products that cannot be placed on the package would be placed inside the package; Health warnings to be put on water pipes

**additional option**

Picture Warnings The NHF highly recommends that picture warnings should be mandatory in all Member States and that they should occupy a minimum of 80% of the front and back surfaces of all tobacco packaging (i.e not just cigarettes) including products imported from outside the EU The warnings should be placed on the upper portion of the packs for maximum visibility. Considering the proven weak effects of written health warnings only, it is essential that pictorial warnings are displayed on both sides of the pack. Evidence clearly supports the need for large pictorial health warnings (80%) showing that increasing the size of warning messages (text only and combined text and picture) increases the effectiveness of the warning amongst both young and adult smokers/non-smokers (6). Research carried out in Canada by Createc (7) on behalf of Health Canada in 2007 showed that young and adult smokers/non-smokers are sensitive to the size of health warning messages. Results showed that warning messages that cover 100% of the pack are significantly more effective across all measured effectiveness indicators compared with warning messages that cover only 50% of the pack. There is further evidence to show that health warnings are effective in conveying the dangers of smoking and helping smokers to quit (8),(9). They also help deter young people from starting to smoke. Picture warnings are more effective than written warnings. Further, we believe that all warnings should be displayed in rotation so that each message is given equal display to reach its target audience. (6) Wardle H, Pickup D, Lee L, Hall J, Pickering K, Grieg K, Moodie C and MacKintosh AM, 2010; 'Evaluating the impact of Picture Health Warnings on Cigarette Packets'; Public Health Research Consortium Executive Summary 12 (7) Createc report prepared for Health Canada (2008). Effects of modified packaging through increasing the size of warnings on cigarette packs. Quantitative study of Canadian adult smokers. (8) Borland R, Wilson N, Fong GT. et al. Impact of graphic and text warnings on cigarette packs: findings from four countries over five years. *Tob Control* 2009;18:358–64. doi:10.1136/tc.2008.028043 PMID:19561362 (9) Borland R, Yong HH, Wilson N. et al. How reactions to cigarette packet health warnings influence quitting: findings from the ITC Four-Country survey. *Addiction* 2009;104:669–75. doi:10.1111/j.1360-0443.2009.02508.x PMID:19215595 Information on tar, nicotine & carbon monoxide (TNCO) Concerning option 2b, to replace levels of tar, nicotine and carbon monoxide (TNCO) with general information on harmful substances in tobacco products, the NHF believes that instead of removing information on the levels of TNCO, they should be completed with qualitative information about the hazardous content and “stop smoking” help lines. Further it should be insured that the data on the quantities of TNCO are accurate. Additional information on harmful substances in tobacco products The NHF supports the proposal to include additional information on the health effects of tobacco consumption on inserts inside the packaging. This should include advice on quitting smoking (see answer above). Health warnings on water pipes There is a growing body of evidence to show that water pipes are at least as hazardous,

if not more so, than other forms of tobacco use. However, there is a common perception that tobacco smoke is 'cleansed' by the water and therefore not as dangerous and some users believe flavoured shisha is not in fact tobacco. It is important that these myths are countered by the inclusion of a health warning on water pipes. Warnings should also be included on the packaging of tobacco used in water pipes.

### **additional comments**

**Generic or plain packaging** The NHF strongly recommends the introduction of plain or generic packaging. This should include not only the removal of all branding from the packaging but the size and shape of the packaging should also be standardised. Not only would this prevent the promotion of smoking through branding as occurs presently but it would reinforce the health warning messages. Although the Australian Federal Government has recently announced that it will introduce plain packaging by 2012 (10), no other jurisdiction has yet implemented a law requiring plain packaging. Research suggests that it would help deter young people from taking up smoking because smoking would lose its appeal (11). Tobacco companies invest considerable resources in making tobacco packaging alluring and eye-catching, as this is now one of the few methods currently available to the industry to market its products to new and existing smokers (12). The NHF therefore believes that tobacco packaging provides a direct link between consumers and manufacturers and is the main marketing channel, particularly in jurisdictions with tobacco advertising bans. Branding gives the misleading impression some cigarettes are safer than others. (10) Government to demand no frills cigarette packs. ABC News 29 April 2010

<http://www.abc.net.au/news/stories/2010/04/28/2885166.htm> (accessed 03 December 2010)

(11) Cunnigham, R. & Kyle K. The case for plain packaging. *Tobacco Control* 1995; 4: 80-86

(12) Wakefield, M. The cigarette pack as image: new evidence from tobacco industry documents. *Tobacco Control* 2002; 11:i73-i80

[http://tobaccocontrol.bmj.com/cgi/content/full/11/suppl\\_1/i73](http://tobaccocontrol.bmj.com/cgi/content/full/11/suppl_1/i73) There is evidence from around the world to show that the tobacco industry uses branding in general and pack design in particular to: • Target young people • Maximise display space (some members of brand families are virtually indistinguishable on taste alone yet the number of variants has increased dramatically in recent years). • Communicate misleading messages (it would be illegal for manufacturers to claim products were "low tar," "light" or less harmful – yet all these are communicated by the colour of sub-brand packaging) (13) (14) (15). The NHF is aware of the tobacco industry claims that plain packaging would contravene intellectual property law. However, legal analysis concludes that this is incorrect and there are no international legal impediments to the implementation of generic packaging (16). (13) Hammond D, Dockrell M, Arnott D, Lee A, McNeill A. Cigarette pack design and perceptions of risk among UK adults and youth *Eur J Public Health*. 2009 Dec;19(6):631-7. (14) Hammond D, Parkinson C. The impact of cigarette package design on perceptions of risk *J Public Health (Oxf)*. 2009 Sep;31(3):345-53 (15) Hastings G, Galopel-Morvan K, Rey JM. The plain truth about tobacco packaging *Tob Control* 2008;17:361-362 (16) Davison M. Plain packaging of cigarettes: Would it be lawful? *Australian Intellectual Property Law Bulletin* October 2010; 105-108

### **questions on reporting**

#### **problem definition**

Yes

#### **which option**

Establish a common compulsory reporting format; Introduce fees and sanctions

**additional options**

While this is outside the expertise of the NHF we agree with the Smoke Free Partnership's view that the current situation which allows different formats and reporting mechanisms is unsatisfactory, making it difficult for authorities to compare and analyse the data. Tobacco companies should be required to use a standardised reporting format. Additionally the companies should be required to pay a yearly registration fee to cover the costs of administering this data collection. Further, the NHF believes that above measures should be compliant with Articles 9 & 10 of the Framework Convention on Tobacco Control (FCTC).

**additional comments**

N/A

**regulation of ingredients****problem definition**

Yes

**which option**

Establish a common list of tobacco ingredients

**which one**

Establish a positive common list of tobacco ingredients

**additional option**

The NHF believes that a combination of Option 3, to establish a common list of tobacco ingredients and option 3a, to establish a positive common list of tobacco products ingredients should be chosen. The NHF supports the response by Smoke Free Partnership Europe of adopting a positive common list of tobacco ingredients. We believe that tobacco products are highly toxic and addictive, and that their content should therefore be closely regulated, in order to achieve high standards of health protection, as stated under article 95.3. There is a need for such a list at EU level since at the moment, consumers in the internal market are not subject to the same level of protection. Some citizens may be using substances that are banned in other Member States. This constitute an obstacle to free movement of goods within the internal market since some countries may be reluctant to import cigarettes from other Member States that do not comply with the national requirements. Regulation of Flavours and Ingredients: Flavourings are an increasingly important part of tobacco industry marketing, particularly to young people. Flavourings enhance attractiveness, encourage youth initiation, and discourage cessation. The prohibition of ingredients that may be used to increase attractiveness, such as sugars and sweeteners, flavouring substances, and spices and herbs, in cigarettes and cigarette-like tobacco products should be introduced. The prohibition of ingredients that may create the impression of a health benefit (e.g. vitamins), ingredients associated with energy and vitality (e.g. caffeine), and ingredients with colouring properties (e.g. pink cigarette paper) should also be banned. Tobacco manufacturers and importers should report sales volume information by brand. This information is essential to help governments ensure that product regulation is effective. In addition, the NHF believes that the above measures should be compliant with the Guidelines on Art. 9/10, adopted unanimously at the Fourth Conference of the Parties in Uruguay on the 20th November 2010.

**additional comments**

N/A

## **access to tobacco products**

### **problem definition**

Yes

### **which option**

Ban

### **which one2**

Cross-border retail sales of tobacco to be banned over the Internet; Vending machines to be banned; Promotion and displays in retail stores to be banned

### **additional option**

Whilst the NHF urges the Commission to call for a ban on the promotion of tobacco products at point of sale and a ban on vending machines, we are aware that these issues do not have cross-border effects. The legal basis for such measures at an EU level is weak. However, these measures are important for health protection and we call on the Commission to include them as non-mandatory measures as part of the Tobacco Products Directive. The NHF believes that the Directive should also remind national governments that they should adopt a comprehensive ban on all forms of tobacco advertising, promotion and sponsorship in accordance with Article 13 of the FCTC. Further, we recommend that the EU Directive follows the lead set by Finland which, as part of its recently passed Tobacco Act, has set limits on the amount of tobacco that can be imported into Finland where the labelling differs from that of tobacco products sold in Finland. We recommend that similar limits should be set at EU level, that is, that for each Member State the amount of tobacco that may be imported for personal use which does not conform to domestic labelling requirements should be limited to a maximum of 200 cigarettes, 50 cigars, 100 cigarillos and 250 grams of pipe or cigarette tobacco.

### **additional comments**

Internet: The principle of preventing cross-border promotion of tobacco products in order to protect public health was enshrined in the Tobacco Advertising Directive (2001/0119). It is logical, therefore, to extend that principle to the sale of tobacco products between member states via the Internet. The NHF supports the prohibition of tobacco sales via the Internet. Vending machines: The majority of member states (22 out of 27) already prohibit the sale of tobacco products from vending machines in order to deter young people accessing cigarettes from this source. The NHF supports this measure. However, as this does not have cross-border effects, we urge the Commission to make the prohibition of tobacco vending machines a non-mandatory measure as part of the product directive. Point of Sale: Similarly, there is a growing body of evidence to show that putting tobacco products out of sight in retail outlets can reduce youth smoking. To date, this measure has been adopted by Ireland, the UK and Finland. We support an EU-wide adoption of a ban on the display of tobacco products at the point of sale. As with vending machines, the NHF urges the Commission to make the prohibition of tobacco vending machines a non-mandatory measure as part of the product directive.

---

## **NGO submission**

### **identification**

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**questions scope****problem definition**

Yes

**which option**

Extend the scope of the Directive

**additional comments**

Der Umfang und Rahmen der Richtlinie sollte auf alle bisher nicht durch die EU-Gesetzgebung geregelten, nikotinhaltigen Waren und Produkte ausgedehnt werden (z.B. elektronische Zigaretten). Im Sinne von umfassenden Maßnahmen zur Einschränkung des Tabakkonsums, sollen alle nikotinhaltigen Produkte und Waren, die durch die EU-Gesetzgebung für Nahrungsmittel und Pharmazeutika nicht bereits in anderer Form geregelt werden, ebenfalls in der EU-Tabakprodukttrichtlinie erfasst werden.

**questions smokeless****problem definition**

Yes

**which option**

Ban on all types of smokeless tobacco products

**additional comments**

Das Verbot von "Snus" sollte auf alle weiteren rauchlosen Tabakprodukte ausgeweitet werden.

**questions consumer****problem definition**

Yes

**which option**

Improve consumer information

**which improvement**

Picture warnings to become mandatory; Tar, nicotine and carbon monoxide levels to be replaced with general information on harmful substances in tobacco products; Information on harmful substances in tobacco products that cannot be placed on the package would be placed inside the package; Health warnings to be put on water pipes

**additional comments**

Die NÖGKK unterstützt die Forderung, Zigarettenpackungen mit bildlichen Warnhinweisen zu bedrucken. Zudem soll die Mindestgröße für kombinierte Warnhinweise in Bild- und Textform (derzeit 30% auf der Vorderseite und 40% auf der Rückseite) auf 80% auf Vorder- und Rückseite erhöht werden. Auf jeder Packung von Tabakprodukten soll die verpflichtende Angabe von Informationen zur Hilfestellung und Unterstützung bei der Raucherentwöhnung – einschließlich der Nennung von Rauchstopp-Linien aufgedruckt sein. Weiters unterstützt die NÖGKK die zusätzliche Einführung von Packungsbeilagen mit Informationen zu den schädlichen Inhaltsstoffen einschließlich der gesundheitlichen Auswirkungen des Tabakkonsums und zu den Möglichkeiten einer Raucherentwöhnung. Die Schädlichkeit des Konsums von Wasserpfeifen soll ebenfalls verstärkt kommuniziert werden. Viele Konsumenten - unter ihnen auch viele Jugendliche - leben im Glauben, die Wasserpfeife würde weniger gesundheitsschädlich sein als andere Tabakprodukte. Zur Aufklärung sollen die gesundheitlichen Warnungen auch auf Wasserpfeifen platziert werden und die Informationen zur Schädlichkeit zusätzlich in der „Gebrauchsanweisung“ aufscheinen.

**questions on reporting****problem definition**

Yes

**which option**

Introduce fees and sanctions

**additional comments**

Die NÖGKK unterstützt die Meldung und Registrierung von Inhaltsstoffen in Tabakprodukten in Verbindung mit der Einführung entsprechender Gebühren und Sanktionen.

**regulation of ingredients****problem definition**

Yes

**which option**

Establish a common list of tobacco ingredients

**which one**

Establish a positive common list of tobacco ingredients

**additional comments**

Die NÖGKK befürwortet die Erstellung einer gemeinsamen Liste von Tabakinhaltsstoffen anhand einheitlicher Kriterien. Auf dieser „Positiv“-Liste werde nur jene Inhaltsstoffe angeführt, die bei der Herstellung von Tabakprodukten erlaubt sind. Jene, die nicht auf der Liste geführt werden, sind somit verboten.

**access to tobacco products****problem definition**

Yes

**which option**

Ban



**which one2**

Cross-border retail sales of tobacco to be banned over the Internet; Vending machines to be banned; Promotion and displays in retail stores to be banned

**additional comments**

Die NÖGKK unterstützt ein uneingeschränktes Verbot aller Formen der Werbung, Bewerbung und des Sponsorings für Tabakprodukte in der EU. Weiters soll ein grenzüberschreitendes Online-Verkaufsverbot im Einzelhandel sowie ein Verbot von Verkaufsautomaten sowie von Werbung und Plakaten umgesetzt werden. Als letzter wichtiger Punkt ist anzumerken, dass die NÖ Gebietskrankenkasse eine EU-weite Umsetzung des Arbeitnehmerschutzes in Bezug auf die Passivrauchbelastung unterstützt und ein generelles Rauchverbot in allen öffentlichen Gebäuden inkl. aller Gastronomie- und Tourismusbetrieben fordert.

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**NGO submission****identification****affiliation**

NGO

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**questions scope****problem definition**

Yes

**which option**

No change

**questions smokeless****problem definition**

No

**comments**

No scientific evidence concerning the risks related to smokeless tobacco products consumption.

**which option**

Lifting the ban on snus

**questions consumer  
problem definition**

No

**explanations**

No scientific evidence proving that bigger warnings determine a better knowledge of the suggested messages; no scientific evidence on the relation between the use of a particular graphic and the impact on consumers.

**which option**

No change

**additional comments**

The knowledge of how harmful tobacco would be is already of a high level, also on the basis of the existing warnings; no value added by the increase of information; negative impact on the fulfilments of sector's operators and of tobacco retailers; full aversion to plain packaging because of the confusion on manufacturers identification brands, with a consequent proliferation of illegal trade of counterfeited as well as smuggled products.

**questions on reporting  
problem definition**

Yes

**which option**

Establish a common compulsory reporting format

**regulation of ingredients**

**problem definition**

No

**explanations**

It is not possible to prove in advance which is the possible impact of an ingredient in terms of toxicity; targeting lists in advance, positively or negatively, would be in contrast with this statement; risk of product standardisation with a consequent reduction of the principle of free market and the risk of increase of counterfeited products.

**which option**

No Change

**access to tobacco products**

**problem definition**

Yes

**which option**

Controlled supply and access

**which supply and access**

Age verification of buyers and other legal conditions to be set for cross-border retail sale;  
Access to vending machines to be restricted to adults

**additional option**

Sale to be carried out only within a network of specialized shops, provided with an appropriate license, which main activity is tobacco sale.

**additional comments**

There is no evidence of the correlation between display ban and consumption bent. In other experiences – see Canada – important loss have been recorded for the tobacco retailers: structural reorganization of the shop, higher management costs and important reduction of the profitability with the consequent risk of giving up the business. Also increasing of illegal products sale (counterfeited and smuggled).

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**NGO submission****identification****affiliation**

NGO

**name**

PRACODAWCY Rzeczypospolitej Polskiej Pracodawcy Rzeczypospolitej Polskiej (wcześniej Konfederacja Pracodawców Polskich) - jest największą i najstarszą organizacją pracodawców w Polsce. Powstała w listopadzie 1989 roku, reprezentuje ponad 7000 firm: od małych przedsiębiorstw, po największe w skali kraju – te, które skutecznie konkurują na światowych rynkach. Przedsiębiorstwa zrzeszone w Pracodawcach RP zatrudniają ok. 3 mln pracowników. Zdecydowana większość z nich – 85 proc. – to firmy prywatne. Jesteśmy uznanym partnerem społecznym w Polsce i w Europie. Siłą Pracodawców Rzeczypospolitej Polskiej są racje i argumenty prezentowane politycznym i ekonomicznym decydentom oraz liczba i różnorodność naszych członków: związków, federacji i firm. O naszym potencjale stanowi wieloletnie doświadczenie i sukcesy, które osiągnęliśmy, realizując naszą naczelną ideę – tworzenia państwa przyjaznego pracodawcom. Naszą pozycję budujemy także hołdując – w każdym podejmowanym działaniu – zasadom profesjonalizmu obiektywizmu, rzetelności i skuteczności. Pracodawcy Rzeczypospolitej Polskiej jednakową troską otacza wszystkich polskich przedsiębiorców. Nie dzielimy ich na lepszych i gorszych – dla nas nie jest ważne jaką branżą reprezentują, czy są prywatni, czy państwowi, duzi czy mali – interesy wszystkich są dla nas tak samo istotne, gdyż tylko razem możemy wpływać na otoczenie gospodarki, czyniąc je bardziej praktycznym i racjonalnym. Aktywnie wspierając przedsiębiorczość, pamiętamy, że gospodarka musi rozwijać się w sposób zrównoważony, a względy ekonomiczne nigdy nie mogą znacznie dominować nad społecznymi. Dążymy do stworzenia harmonii na linii pracodawca – pracownik, wiedząc, że sprawnie funkcjonująca firma otwiera przed pracownikami możliwość partycypacji w płynących z tego faktu profitach. Przedsiębiorcom zrzeszonym w organizacji Pracodawcy Rzeczypospolitej Polskiej zapewniamy – oprócz oczywistego prestiżu – także konkretne wsparcie merytoryczne ich działań. Pracodawcy Rzeczypospolitej Polskiej są wszędzie tam, gdzie dzieje się coś ważnego dla biznesu i pracodawców: podczas obrad sejmowych i senackich komisji, przy pracach decyzyjnych i doradczych gremiów różnych szczebli administracji państwowej oraz komitetów sterujących i monitorujących wykorzystywanie funduszy Unii Europejskiej. Udział w Trójstronnej Komisji do Spraw Społeczno – Gospodarczych zapewnia Pracodawcom RP możliwość wypowiedzenia się i współdecydowania w najważniejszych

kwestiach. Rekrutujący się spośród grona najznamienitszych specjalistów i autorytetów, eksperci Pracodawców Rzeczypospolitej Polskiej wydają obszernie publikacje naukowe, doradzają politycznym decydom i komentują gospodarczą rzeczywistość. Organizowane przez Pracodawców RP konferencje – oprócz znamienitych prelegentów – stanowią także istotny wkład w debatach publicznych i konsultacjach społecznych. \* Pracodawcy Rzeczypospolitej Polskiej działają na rzecz wspólnych interesów pracodawców zrzeszonych w organizacjach członkowskich Konfederacji, przedsiębiorstw nierzadko konkurujących ze sobą na rynku, lecz świadomych potrzeby wspólnego działania dla dobra środowiska pracodawców i przedsiębiorców. \* Pracodawcy Rzeczypospolitej Polskiej wspierają wszelkie inicjatywy zmierzające do wzmocnienia roli polskich pracodawców oraz współpracuje dla realizacji wspólnych interesów środowiska biznesu ze wszystkimi organizacjami pracodawców i przedsiębiorców. \* Pracodawcy Rzeczypospolitej Polskiej współpracują z partnerami społecznymi - organizacjami pracobiorców - dla osiągnięcia wspólnych korzyści pracodawców i pracowników wynikających z rozwoju gospodarczego, sprawiedliwych i stabilnych warunków zatrudnienia, bezpieczeństwa w pracy i spokoju społecznego. \* Pracodawcy Rzeczypospolitej Polskiej wywierają wpływ na władze publiczne wszystkich szczebli, by wspólny interes społeczeństwa, przedsiębiorców i rządzących - dobro Polski - mógł być realizowany, a głos pracodawców miał znaczenie przy podejmowaniu decyzji o przyszłości naszego kraju. \* Pracodawcy Rzeczypospolitej Polskiej kształtują i promuje wizerunek pracodawców i przedsiębiorców jako podmiotów tworzących dochód narodowy, dających innym pracę i - poprzez rozwój swoich przedsiębiorstw - przyczyniających się do rozwoju naszego kraju i realizacji indywidualnych aspiracji jego mieszkańców. tel. (22) 518 87 00, (22) 828 84 31 fax. (22) 828 84 37 ul. Brukselska 7 03 - 973 Warszawa

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Polska

**questions scope****problem definition**

No

**explanations**

Zdaniem Pracodawców Rzeczypospolitej Polskiej problem został zdefiniowany niejasno i niewłaściwie. Należy zaznaczyć, że proponowany zakres wskazuje na brak dogłębnej analizy dotyczącej dostępnych na rynku produktów tytoniowych i nietytoniowych. Co więcej definicja problemu nie została oparta na zweryfikowanych i potwierdzonych naukowo dowodach. Regulacje każdej z kategorii powinny opierać się na obiektywnych i specyficznych dla danej kategorii produktu przesłankach, czego zabrakło w definicji problemu.

**which option**

No change

**questions smokeless****problem definition**

No

**comments**

Zdaniem Pracodawców RP SNUS jest jednym z dostępnych na niektórych rynkach europejskich legalnym produktem, który może stanowić alternatywę dla tradycyjnych papierosów. Badania naukowe wskazują, że używanie SNUS wiąże się z mniejszym ryzykiem wystąpienia niektórych chorób oddytniowych, co pokazuje przykład Szwecji, w której ten produkt jest dostępny. Zakaz produkcji i wprowadzenia do obrotu SNUS w Unii Europejskiej powinien być zniesiony.

**which option**

Lifting the ban on snus

**questions consumer****problem definition**

No

**explanations**

Zdaniem Pracodawców RP część zaproponowanych rozwiązań - w tym plain packaging oraz drastycznie zwiększone tzw. ostrzeżenia zdrowotne, które w praktyce uniemożliwią umieszczanie znaków towarowych legalnych producentów - narusza obowiązujące w Polsce przepisy prawa dotyczące ochrony własności przemysłowej oraz konstytucyjną zasadę wolności działalności gospodarczej, jak również stoi w sprzeczności z międzynarodowymi konwencjami z zakresu ochrony własności intelektualnej, których stroną jest Polska. Takie rozwiązania są dyskusyjne również z punktu widzenia dorobku porządku prawnego UE, w tym zasad subsydiarności i proporcjonalności.

**which option**

No change

**questions on reporting****problem definition**

No

**explanations**

Zdaniem Pracodawców RP wskazane jest ujednoclenie sposobu i zakresu raportowania tzw. składników wyrobów tytoniowych. Sankcje za niewłaściwie raportowanie powinny jednak pozostać w gestii państw członkowskich.

**which option**

Establish a common compulsory reporting format

**regulation of ingredients****problem definition**

No

**explanations**

Zdaniem Pracodawców RP regulacje składu wyrobów tytoniowych (tj. regulacje składników używanych w procesie produkcji) powinny być oparte tylko i wyłącznie na obiektywnych i potwierdzonych naukowo przesłankach. Powoływanie się na bliżej niezdefiniowane pojęcie "atrakcyjności" może doprowadzić do sytuacji, w której wyeliminowane zostaną składniki niezbędne do procesu produkcyjnego, co nie będzie miało wpływu na efekt zdrowotny.

Negatywną konsekwencją będzie natomiast wyeliminowanie części upraw tytoniu, w tym np. blisko połowy upraw obecnych na polskim rynku (ok. z 14 tys. rodzin plantatorskich). Taka sytuacja prowadziłaby do wzrostu nielegalnego rynku i negatywnych konsekwencji dla całej gospodarki.

**which option**

No Change

**access to tobacco products**

**problem definition**

No

**explanations**

Zdaniem Pracodawców RP propozycja wprowadzenia zakazu ekspozycji wyrobów tytoniowych w punktach sprzedaży detalicznej narusza wolność działalności gospodarczej oraz prawo konsumenta do informacji o legalnym produkcie. Propozycja miałaby również negatywny wpływ na zapewnienie równych warunków konkurencji na rynku, a także wiązałaby się z negatywnymi skutkami finansowymi dla ok. 120 tys. podmiotów zajmujących się sprzedażą detaliczną tych produktów. Definicja problemu nie wskazuje na skuteczność takiego rozwiązania w ograniczaniu dostępności do wyrobów tytoniowych dla osób nieletnich, co w naszej ocenie jest niezgodne z zasadą proporcjonalności.

**which option**

No change

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**NGO submission**

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**questions scope**

**problem definition**

Yes

**which option**

No change

**questions smokeless**

**problem definition**

Yes

**which option**

Lifting the ban on snus

**questions consumer****problem definition**

No

**explanations**

Non concordo che "l'evidenza mostra che, se adeguatamente dimensionate e ben collocate, le avvertenze illustrate costituiscono una misura efficace per informare il pubblico in merito ai pericoli del fumo" e che "maggiore è la dimensione dell'avvertenza illustrata, maggiore ne è l'efficacia". Talvolta le immagini illustrate introdotte in alcuni paesi per sostituire le avvertenze sanitarie scritte, più che informare il consumatore sembrano essere state introdotte per suscitare stupore e shock. Non sembra questa la strada migliore per proteggere la salute dei consumatori, che già sono molto consapevoli dei pericoli e della dannosità delle sigarette. Sono anche totalmente contrari all'introduzione del cosiddetto "pacchetto generico", che rischia di favorire il business delle organizzazioni criminali e di danneggiare le aziende serie che tradizionalmente forniscono solo società manifatturiere di altrettanta serietà ed operanti solo sul mercato legale, che si vedrebbero gravemente danneggiate per la distruzione del valore dei marchi. Tra l'altro il "plain packaging" spingerebbe ad una concorrenza basata sul prezzo e non sulla qualità, così danneggiando il tabacco europeo che della qualità superiore ha l'unica arma possibile, ora che i sostegni diretti ai produttori, per compensarne i costi più alti, sono stati smantellati

**which option**

No change

**questions on reporting****problem definition**

No

**explanations**

Sono d'accordo sulla creazione di un formato comune di reporting ma non concordo con la creazione di un nuovo livello di imposizione fiscale che andrebbe a sovrapporsi a quello dello stato membro, creando confusione e andando contro i principi di uniformità dell'Unione.

**which option**

Establish a common compulsory reporting format

**regulation of ingredients****problem definition**

No

**explanations**

Sono in totale disaccordo con l'ipotesi di vietare l'impiego di ingredienti nella produzione di sigarette. Questa ipotesi finirebbe per avere serie conseguenze per le produzioni di "Burley", in Italia e in tutta Europa. Questa qualità di tabacco, utilizzata principalmente per il cosiddetto

“American blend”, rispetto ad altre varietà di tabacco, necessita di un certo numero di ingredienti in fase di lavorazione. D’altra parte, come chiarito anche dall’OMS e dallo SCENIHR non esiste alcuna prova scientifica del fatto che le sigarette realizzate senza ingredienti (come quelle che utilizzano la varietà di tabacco "Virginia") siano meno dannose di quelle che necessitano di ingredienti. Questa, pertanto, appare una chiara discriminazione, che avrebbe il solo effetto di pregiudicare significativamente gli oltre 60. 000 addetti alla coltivazione di tabacco in Italia e circa 400.000 in tutta Europa.

**which option**

No Change

**access to tobacco products**

**problem definition**

No

**explanations**

Le enunciazioni del documento di consultazione, in realtà non definiscono il problema, ma fotografano unicamente il quadro normativo di riferimento, seppure in modo parziale. Sono infatti elencati nel documento solo i paesi in cui esistono misure estreme per regolamentare l’accesso ai prodotti: paesi, ad esempio, in cui i distributori automatici sono vietati o dove è vietata l’esposizione dei prodotti nei punti vendita. Ritengo che non si debba arrivare tanto lontano per ottenere gli obiettivi prefissati di salvaguardia dei minori. Il sistema italiano di monopolio e di controlli sull’accesso, se applicato con determinazione e con le giuste risorse a disposizione degli organismi di controllo, costituisce un’ottima soluzione per limitare l’accesso dei minori al tabacco.

**which option**

No change

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LATVIA

**questions scope**

**problem definition**

Yes



**which option**

Extend the scope of the Directive

**recommend option**

All tobacco products are hazardous to health – there is no safe level of usage. Therefore we recommend that the scope of the Directive includes the regulation of any new smoked tobacco products (such as low emission or nicotine-free cigarettes), while the prohibition of any novel forms of oral tobacco, including snus, should be maintained. Herbal cigarettes are also harmful because it is the combustion and inhalation of smoke that causes most of the harm from smoking. Therefore, herbal cigarettes should be included in the scope Tobacco Products Directive and be also subject to health warnings requirements. Finally, all forms of nicotine based products (that is, products containing nicotine but not tobacco product such as electronic cigarettes, nicotine gel, drinks, and sweets) are often marketed as alternatives to cigarettes and in some cases as an aid to quitting smoking. Therefore, they should only be sold as quitting aids and comply with specific safety and quality requirements under the same regulatory framework as pharmaceutical products rather than under the scope of the Tobacco Products Directive.

**additional comments**

This is not a high priority

**questions smokeless****problem definition**

Yes

**which option**

Ban on all types of smokeless tobacco products

**additional option**

The ban on snus should definitely be maintained. This is high priority. Indeed, there is no legitimate reason to introduce a dangerous product on the market, particularly as from an internal market point of view, we have no idea how snus would be perceived or used in other countries. A small study conducted by the University of Nottingham by Professor Ann McNeil showed that, in the UK, people could not see the point of snus unless it was as a cessation aid. For internal market purposes, it really does not make sense to lift the ban. Furthermore, if the ban on snus were to be lifted, it could encourage dual use of cigarettes and smokeless tobacco and discourage total abstinence from tobacco, thus weakening any potential health gains. The only concession we would support is if the EC sanctioned the use of snus in randomised controlled trials (RCTs), i.e. provided a special license to overcome the illegality of snus for research purposes only. Indeed, it is a matter of public health interest that RCTs on snus as a cessation aid are undertaken. Cancer Research UK was considering such a trial but due to the dual difficulties of snus a) being a tobacco product and b) illegal, the trial proposal has not as yet gone to peer review. Finally, we would like to stress that there are already available effective treatments for nicotine addiction, including medicinal or 'clean' nicotine (NRT), that do not carry the risks associated with the use of snus. These should be promoted first and foremost. It is clear that public health interest can be served even more by encouraging a) greater use of these treatments and b) the development of more effective cessation aids, especially those that mimic more closely the nicotine 'hit' delivered by cigarettes. The SFP supports the ban on all types of smokeless tobacco products in principle, since there is evidence that such products are addictive and can cause cancer, as stated in the

Opinion of the Scientific Committee on Emerging and Newly Identified Health Risks (SCENIHR). The SFP also recognises that the use of smokeless tobacco products has not been proved to be an effective quitting aid. Therefore the SFP supports a ban on all types of smokeless tobacco products, provided that such ban would be practical in its implementation and that the European Commission can establish that it has the legal competence to do so from an internal market perspective.

**questions consumer  
problem definition**

No

**explanations**

The problem definition could be improved. We agree with the Commission that the current situation, whereby some Member States have made graphic warnings compulsory and others not, has led to a disparity in labelling throughout the EU. Consequently, this has an impact on the functioning of the internal market, on consumers' awareness and as a result, on their smoking behaviour. We also agree that packaging as an advertising tool is not covered by the current Directive. Finally, we welcome the acknowledgement that tobacco packaging and product features are increasingly used to attract consumers, to promote products and brand image. In this context, it would have been wise to highlight the fact that, in the Eurobarometer survey released in 2010, the policy that received the most positive response is that of putting health warnings on all packages of tobacco products (on average, 75% of EU citizens are in favour of mandatory pictorial warnings, and over 54% support plain packaging measures).

**which option**

Improve consumer information; Introduce generic or plain packaging

**which improvement**

Picture warnings to become mandatory; Tar, nicotine and carbon monoxide levels to be replaced with general information on harmful substances in tobacco products; Information on harmful substances in tobacco products that cannot be placed on the package would be placed inside the package; Health warnings to be put on water pipes

**additional option**

Crucial importance of Graphic health warnings: Evidence clearly shows that text only warning messages are not very effective because many consumers don't bother to read them. Pictures, especially fear inducing pictures, are proven to be effective in getting consumers more engaged with the warning message. Pictures are able to immediately provoke a reaction and prompt people to read the associated text message. The need for graphic health warnings on both sides of the pack: There is also evidence that pictures on both sides of the packaging would have a greater impact than on one side only. Considering the proven weak effects of written health warnings only, it is essential that pictorial warnings are displayed on both sides of the pack. The need for LARGE pictorial health warnings (80%): Evidence clearly shows that increasing the size of warning messages (text only and combined text and picture) increases the effectiveness of the warning amongst both young and adult smokers / non smokers. Research carried out in Canada by Createc on behalf of Health Canada in 2007 showed that young and adult smokers/non smokers are sensitive to the size of health warning messages. Results showed that warning messages that cover 100% of the pack are significantly more effective across all measured effectiveness indicators compared with warning messages that cover only 50% of the pack. The importance of Rotation: Warning

texts and pictures should be displayed on a rotating basis, so that each message is given equal display and can reach its target audience. The proved effectiveness of shocking health warnings & targeted messages: as specified in the Sambrook Research International report, fear inducing warnings (using strong “shocking” related to health risks (such as rotten teeth or throat cancer) and strong emotion inducing warnings (especially involving children and unborn babies) are the most effective way to educate consumers on the health risks of tobacco use and to achieve changes in attitudes and behaviour. These warnings’ effectiveness is enhanced if they are used in conjunction with quit line. Generic or plain packaging: We strongly recommend the introduction of standardised/plain packaging. This should include not only the removal of all branding from the packaging but the size and shape of the packaging should also be standardised. Not only would this prevent the promotion of smoking through branding as occurs presently but it would reinforce the health warning messages. Tobacco packaging provides a direct link between consumers and manufacturers and is the main marketing channel, particularly in jurisdictions with tobacco advertising bans. Branding gives the misleading impression some cigarettes are safer than others. The tobacco industry claims that plain packaging would contravene intellectual property law. However, legal analysis concludes that this is incorrect and there are no international legal impediments to the implementation of generic packaging. Replace TNCO quantitative labelling with qualitative information on contents, emissions and quit-lines: The inclusion of machine-based tar, nicotine and carbon monoxide yields on cigarette packs promotes the mistaken belief that some cigarette brands are less harmful than others . We support the proposal to replace numerical measurements with descriptive information on the hazardous effects of tobacco constituents and emissions. We stress the importance of putting quit line numbers on the package. As underlined in the Sambrook research (p46), providing a telephone number on the pack is more effective than telling smokers to seek advice from a doctor or pharmacist. P46 Health warnings on water pipes: There is a growing body of evidence to show that water pipes are at least as hazardous, if not more so, than other forms of tobacco use. Warnings should also be included on the packaging of tobacco used in water pipes.

### **additional comments**

Under Article 5.3 of the TPD 2001, Member States only have the option to adopt pictorial warnings. As a result, some Member States have mandatory pictorial warnings and other don’t, which creates a disparity in labelling throughout the EU. This situation is not consistent with the legal basis of the TPD, Article 95 (internal market). So far, all the legislation on labelling, advertising and product regulation put forward by the Commission in the field of tobacco control, has been based on the internal market legislation (Article 26 and 114 of the TFEU). Article 26 of the TFEU establishes the internal market. Article 114 gives EU institutions the competence to regulate and set rules for the functioning of the internal market. More specifically, article 95.3 also states that when establishing rules for the functioning of the internal market in the context of health, safety, environmental protection and consumer protection, the Commission “will take as a base a high level of protection, taking account in particular of any new development based on scientific facts.” The European Court of Justice (the “ECJ”) made an extensive analysis of Article 95 EC (now Article 114) throughout the years. In Spain v. Council, the Court observed that “recourse to Article 100a (now Article 114) as a legal basis is possible if the aim is to prevent the emergence of future obstacles to trade resulting from multifarious development of national laws.” The TPD was adopted on the basis of Article 114 TFEU (ex Article 95). As a result, Recital 19 of the TPD states that “[t]he presentation of warning labels and yields has continued to remain variable in the different Member States. As a consequence, consumers in one Member State may be better informed as to the risks of tobacco products than in another. Such differences are unacceptable and are

liable to constitute a barrier to trade and to impede the operation of the internal market in tobacco products, and should therefore be eliminated.” In the present case, Article 5.3 of the TPD and the Commission Decision on the use of colour photographs or other illustrations as health warnings (the “Commission Decision”) give Member States the option to adopt pictorial warnings in the form of colour photographs or other illustrations. Almost ten years later, four countries (the UK, Belgium, Romania and Malta) have adopted the option. More countries such as Spain and France are planning to adopt mandatory pictorial warnings. Although such measures are in compliance with the current TPD and are welcome by the tobacco control community, their adoption by some Member States necessarily creates growing discrepancies between Member States. As stated above, there is clear evidence that pictorial warnings are much more powerful than written health warnings. As a result, consumers in the UK are better informed about the risks of tobacco products than consumers in Germany (for example). This is inconsistent with the objectives of the internal market stated under Article 114.3 of the TFEU and reiterated in Recital 19 of the Directive. The disparity of laws in Member States results in the unequal information of consumers on the risks of tobacco products, and therefore, an uneven protection of health throughout the European Union, which are both contrary to the principles and objectives of the internal market. From an internal market point of view, these differences in the rules regarding pictorial warnings are likely to constitute barriers to trade and to impede the smooth operation of the internal market. These obstacles and discrepancies should accordingly be eliminated and to that end, pictorial health warnings of tobacco products should be made subject to common rules. This is why mandatory pictorial warnings are not only welcome, but necessary in order to comply with the legal grounds on which the TPD was adopted.

### **questions on reporting**

#### **problem definition**

Yes

#### **which option**

Establish a common compulsory reporting format; Introduce fees and sanctions

#### **additional options**

The current situation which allows different formats and reporting mechanisms is unsatisfactory, making it difficult for authorities to compare and analyse the data. All tobacco manufacturers and importers should be subject to the same reporting requirements. The SFP believes that tobacco products, which are highly harmful, should be subject to an effective reporting system that allows the gathering and analysis of relevant data, including comparison as appropriate, in order to ensure high levels of consumer safety and information. The format already exists (based on the voluntary reporting format developed by the Commission in May 2007) and it would therefore be very easy to adopt this measure and to implement it.

#### **additional comments**

We welcome the introduction of yearly registration fees in order to finance the data collection on ingredients by the national authorities and their analysis work on ingredients. The payment of penalties in case of non-compliance with the requirements of delivery of data on tobacco products ingredients also seems adequate and would contribute to fund the tests conducted on these products. It is crucial that the appropriate toxicological and addictiveness tests are properly conducted. Such tests would allow policy-makers to make more informed decisions in this field, as there would be more scientific evidence. It would enhance the scientific knowledge of the dangers of tobacco products and would contribute to a high protection of

health, as stated in Article 95.3 TFEU. Besides, such measures would also have an indirect impact on illicit trade, since only registered products would be allowed on the market.

### **regulation of ingredients**

#### **problem definition**

Yes

#### **which option**

Establish a common list of tobacco ingredients

#### **which one**

Establish a positive common list of tobacco ingredients

### **additional comments**

We support the adoption of a positive common list of tobacco ingredients. We believe that for tobacco products are highly toxic and addictive, and that their content should therefore be closely regulated, in order to achieve high standards of health protection, as stated under article 95.3. There is a need for such a list at EU level since at the moment, consumers in the internal market are not subject to the same level of protection. Some citizens may be using substances that are banned in other member states. This constitute an obstacle to free movement of goods within the internal market since some countries may be reluctant to import cigarettes from other Member States that do not comply with the national requirements. Regulation of Flavours and Ingredients: Flavourings are an increasingly important part of tobacco industry marketing, particularly to young people. Flavourings enhance attractiveness, encourage youth initiation, and discourage cessation. The prohibition of ingredients that may be used to increase attractiveness, such as sugars and sweeteners, flavouring substances, and spices and herbs, in cigarettes and cigarette-like tobacco products should be introduced. The prohibition of ingredients that may create the impression of a health benefit (e.g. vitamins), ingredients associated with energy and vitality (e.g. caffeine), and ingredients with colouring properties (e.g. pink cigarette paper) should also be banned. Tobacco manufacturers and importers should report sales volume information by brand. This information is essential to help governments ensure that product regulation is effective. The above measures should be compliant with Articles 9 & 10 of the Framework Convention on Tobacco Control (FCTC).

### **access to tobacco products**

#### **problem definition**

Yes

#### **which option**

Ban

#### **which one2**

Cross-border retail sales of tobacco to be banned over the Internet; Vending machines to be banned; Promotion and displays in retail stores to be banned

### **additional option**

Whilst we urge the Commission to call for a ban on the promotion of tobacco products at point of sale and a ban on vending machines, we are aware that these issues do not have cross-border effects. The legal basis for such measures at an EU level is weak. However, these

measures are important for health protection and we call on the Commission to include them as non-mandatory measures as part of the product directive. The Directive should also remind national governments that they should adopt a comprehensive ban on all forms of tobacco advertising, promotion and sponsorship in accordance with Article 13 of the FCTC which calls on Parties to.

**additional comments**

Internet. The principle of preventing cross-border promotion of tobacco products in order to protect public health was enshrined in the Tobacco Advertising directive (2001/0119). It is logical, therefore, to extend that principle to the sale of tobacco products between member states via the Internet. We support the prohibition of tobacco sales via the Internet. Vending machines. The majority of member states (22 out of 27) already prohibit the sale of tobacco products from vending machines in order to deter young people accessing cigarettes from this source. We support this measure. However, as this does not have cross-border effects, we urge the Commission to make the prohibition of tobacco vending machines a non-mandatory measure as part of the product directive. Point of Sale. Similarly, there is a growing body of evidence to show that putting tobacco products out of sight in retail outlets can reduce youth smoking. To date, this measure has been adopted by Ireland, the UK and Finland. We support an EU-wide adoption of a ban on the display of tobacco products at the point of sale. As with vending machines, we urge the Commission to make the prohibition of tobacco vending machines a non-mandatory measure as part of the product directive.

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**NGO submission**

**identification**

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NGO

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Belgium

**questions scope**

**problem definition**

Yes

**which option**

Extend the scope of the Directive

**additional comments**

All tobacco products are hazardous to health – there is no safe level of usage. Therefore we recommend that the scope of the Directive includes the regulation of any new smoked tobacco products (such as low emission or nicotine-free cigarettes), while the prohibition of any novel

forms of oral tobacco, including snus, should be maintained. Herbal cigarettes are also harmful because it is the combustion and inhalation of smoke that causes most of the harm from smoking. Therefore, herbal cigarettes should be included in the scope Tobacco Products Directive and should also be subject to health warnings requirements. Finally, all forms of nicotine based products (that is, products containing nicotine but which are not tobacco products, such as electronic cigarettes, nicotine gel, drinks, and sweets) are often marketed as alternatives to cigarettes and in some cases as an aid to quitting smoking. Therefore, they should only be sold as quitting aids and comply with specific safety and quality requirements under the same regulatory framework as pharmaceutical products rather than under the scope of the Tobacco Products Directive.

#### **questions smokeless**

##### **problem definition**

Yes

##### **which option**

No change

##### **additional option**

The ban on snus should definitely be maintained. This is high priority. Indeed, there is no legitimate reason to reintroduce a carcinogenic and addictive product onto the EU market. Furthermore, if the ban on snus were to be lifted, it could encourage dual use of cigarettes and smokeless tobacco and discourage total abstinence from tobacco, thus weakening any potential health gains. In this context, we stress that there are already available effective treatments for nicotine addiction, including medicinal or 'clean' nicotine (NRT), that do not carry the risks associated with the use of snus. These should be promoted first and foremost. It is clear that the public health interest can be served even more by encouraging a) greater use of these treatments and b) the development of more effective cessation aids, especially those that mimic more closely the nicotine 'hit' delivered by cigarettes. Regarding other forms of smokeless tobacco products, ECL does not believe that they should be "marketed" in all Member States. We recognise that they are as addictive and dangerous as smoked tobacco. As stated in the Opinion of the Scientific Committee on Emerging and Newly Identified Health Risks (SCENIHR), many forms of smokeless tobacco increase the risk of mouth, esophageal, pancreatic and liver cancer, and other conditions including gum and heart disease. However, we also know that these products are mostly consumed in the UK and used by South Asian communities; introducing an EU-wide ban on these products now could lead to the creation of an unnecessary illegal market, pushing consumption underground. This is why we do not recommend an immediate ban on all types of smokeless tobacco products; we do recommend that they should be regulated in the same way as tobacco products.

#### **questions consumer**

##### **problem definition**

No

##### **explanations**

The problem definition could be improved. We agree with the Commission that the current situation, whereby some Member States have made graphic warnings compulsory and others not, has led to a disparity in labelling throughout the EU. Consequently, this has an impact on the functioning of the internal market, on consumers' awareness and as a result, on their smoking behaviour. We also agree that packaging as an advertising tool is not covered by the

current Directive. Finally, we welcome the acknowledgement that tobacco packaging and product features are increasingly used to attract consumers, to promote products and brand image. In this context, it would have been judicious to highlight the fact that, in the Eurobarometer survey released in 2010, the policy that received the most positive response is that of putting health warnings on all packages of tobacco products (on average, 75% of EU citizens are in favour of mandatory pictorial warnings, and over 54% support plain packaging measures).

#### **which option**

Improve consumer information; Introduce generic or plain packaging

#### **which improvement**

Picture warnings to become mandatory; Tar, nicotine and carbon monoxide levels to be replaced with general information on harmful substances in tobacco products; Information on harmful substances in tobacco products that cannot be placed on the package would be placed inside the package; Health warnings to be put on water pipes

#### **additional option**

Crucial importance of Graphic health warnings: Evidence shows that text only warning messages are not as effective as graphic warnings. Pictures, especially fear-inducing pictures, are proven to be effective in getting consumers more engaged with the warning message. Pictures are able to immediately provoke a reaction and prompt people to read the associated text message. The need for graphic health warnings on both sides of the pack: There is also evidence that pictures on both sides of the packaging have a greater impact. The need for LARGE pictorial health warnings (80%): The global trend is towards larger health warnings. Uruguay, for instance, has implemented legislation to make pictorial health warnings obligatory, covering 80% of the front and the back of cigarette packs. Evidence clearly shows that increasing the size of warning messages (text only and combined text and picture) increases the effectiveness of the warning amongst both young and adult smokers / non smokers. Research carried out in Canada by Createc on behalf of Health Canada in 2007 showed that young and adult smokers/non smokers are sensitive to the size of health warning messages. Results showed that warning messages that cover 100% of the pack are significantly more effective across all measured effectiveness indicators compared with warning messages that cover only 50% of the pack. The importance of Rotation: Warning texts and pictures should be displayed on a rotating basis, so that each message is given equal display and can reach its target audience. The proved effectiveness of shocking health warnings & targeted messages: as specified in the Sambrook Research International report, fear inducing warnings (using strong “shocking” images related to health risks such as rotten teeth or throat cancer) and strong emotion inducing warnings (especially involving children and unborn babies) are the most effective way to educate consumers on the health risks of tobacco use and to achieve changes in attitudes and behaviour. These warnings’ effectiveness is enhanced if they are used in conjunction with a quit line. Generic or plain packaging: We strongly recommend the introduction of standardised/plain packaging. This should include not only the removal of all branding from the packaging but the size and shape of the packaging should also be standardised. Not only would this prevent the promotion of smoking through branding as occurs presently but it would reinforce the health warning messages. Tobacco packaging provides a direct link between consumers and manufacturers and is the main marketing channel, particularly in jurisdictions with tobacco advertising bans. Branding gives the misleading impression some cigarettes are safer than others. The tobacco industry claims that plain packaging would contravene intellectual property law. However, legal analysis



concludes that this is incorrect and there are no international legal impediments to the implementation of generic packaging. Replace TNCO quantitative labelling with qualitative information on contents, emissions and quit-lines: The inclusion of machine-based tar, nicotine and carbon monoxide yields on cigarette packs promotes the mistaken belief that some cigarette brands are less harmful than others. We support the proposal to replace numerical measurements with descriptive information on the hazardous effects of tobacco constituents and emissions. We stress the importance of putting quit line numbers on the package. As underlined in the Sambrook research (p46), providing a telephone number on the pack is more effective than telling smokers to seek advice from a doctor or pharmacist. P46 Health warnings on water pipes: There is a growing body of evidence to show that water pipes are at least as hazardous, if not more so, than other forms of tobacco use. Warnings should also be included on the packaging of tobacco used in water pipes.

### **additional comments**

Under Article 5.3 of the TPD 2001, Member States have the option to adopt pictorial warnings. This situation emphasised the right of Member States to go further than the Directive to protect public health as set out in Article 30 of the Treaty of the Union (now article 36). Five years after the adoption of the library of 42 pictorial health warnings by the European commission, seven Member States have adopted legislation to introduce pictorial health warnings (Belgium, Romania, United Kingdom, Latvia, Malta, France and Spain). Such measures are in compliance with the current TPD and are welcomed by the tobacco control community. However, their adoption by some Member States necessarily creates growing discrepancies between Member States. As stated above, there is clear evidence that pictorial warnings are much more powerful than written health warnings. Extending the information and protection to all EU Member States would be in harmony with Article 168 of the TFEU and consistent with the objectives of the internal market stated in Article 114.3 of the TFEU and reiterated in Recital 19 of the Directive. A revision of the TPD should, therefore, aim at making pictorial health warnings of tobacco products subject to common rules. Note: Legislation on labelling, advertising and product regulation put forward by the Commission in the field of tobacco control, has been based on the internal market legislation (Articles 26 and 114 of the TFEU). Article 26 of the TFEU establishes the internal market. Article 114 gives EU institutions the competence to regulate and set rules for the functioning of the internal market. More specifically, article 114.3 also states that when establishing rules for the functioning of the internal market in the context of health, safety, environmental protection and consumer protection, the Commission “will take as a base a high level of protection, taking account in particular of any new development based on scientific facts.” The European Court of Justice (the “ECJ”) made an extensive analysis of Article 95 EC (now Article 114) throughout the years. In Spain v. Council, the Court observed that “recourse to Article 100a (now Article 114) as a legal basis is possible if the aim is to prevent the emergence of future obstacles to trade resulting from multifarious development of national laws.” The TPD was adopted on the basis of Article 114 TFEU (ex Article 95). As a result, Recital 19 of the TPD states that “[t]he presentation of warning labels and yields has continued to remain variable in the different Member States. As a consequence, consumers in one Member State may be better informed as to the risks of tobacco products than in another. Such differences are unacceptable and are liable to constitute a barrier to trade and to impede the operation of the internal market in tobacco products, and should therefore be eliminated.”

### **questions on reporting problem definition**

Yes

**which option**

Establish a common compulsory reporting format; Introduce fees and sanctions

**additional comments**

The current situation which allows different formats and reporting mechanisms is unsatisfactory, making it difficult for authorities to compare and analyse the data. All tobacco manufacturers and importers should be subject to the same reporting requirements. ECL believes that tobacco products, which are highly harmful, should be subject to an effective reporting system that allows the gathering and analysis of relevant data, including comparison as appropriate, in order to ensure high levels of consumer safety and information. The format already exists (based on the voluntary reporting format developed by the Commission in May 2007) and it would therefore be very easy to adopt this measure and to implement it. We welcome the introduction of yearly registration fees in order to finance the data collection on ingredients by the national authorities and their analysis work on ingredients. The payment of penalties in case of non-compliance with the requirements of delivery of data on tobacco product ingredients also seems adequate and would contribute to fund the tests conducted on these products. It is crucial that the appropriate toxicological and addictiveness tests are properly conducted. Such tests would allow policy-makers to make more informed decisions in this field, as there would be more scientific evidence. It would enhance the scientific knowledge of the dangers of tobacco products and would contribute to a high protection of health, as stated in Article 95.3 TFEU. Besides, such measures would also have an indirect impact on illicit trade, since only registered products would be allowed on the market.

**regulation of ingredients****problem definition**

Yes

**which option**

Establish a common list of tobacco ingredients

**which one**

Establish a positive common list of tobacco ingredients

**additional comments**

We support the adoption of a positive common list of tobacco ingredients. We believe that tobacco products are highly toxic and addictive, and that their content should therefore be closely regulated, in order to achieve high standards of health protection, as stated under article 114.3. There is a need for such a list at EU level since at the moment, consumers in the internal market are not subject to the same level of protection. Some citizens may be using substances that are banned in other Member States. Apart from creating unequal health protection across the EU, this may constitute an obstacle to free movement of goods within the internal market: some countries can refuse access to their markets of cigarettes from Member States that do not comply with the importing Member State's national requirements. Regulation of Flavours and Ingredients: Flavourings are an increasingly important part of tobacco industry marketing, particularly to young people. Flavourings enhance attractiveness, encourage youth initiation, and discourage cessation. The prohibition of ingredients that may be used to increase attractiveness, such as sugars and sweeteners, flavouring substances, and spices and herbs, in cigarettes and cigarette-like tobacco products should be introduced. The prohibition of ingredients that may create the impression of a health benefit (e.g. vitamins),

ingredients associated with energy and vitality (e.g. caffeine), and ingredients with colouring properties (e.g. pink cigarette paper) should also be banned. Tobacco manufacturers and importers should report sales volume information by brand. This information is essential to help governments ensure that product regulation is effective. The above measures should be compliant with the Guidelines on Art. 9/10, adopted unanimously at the Fourth Conference of the Parties in Uruguay on the 20th November 2010.

### **access to tobacco products**

#### **problem definition**

Yes

#### **which option**

Ban

#### **which one2**

Cross-border retail sales of tobacco to be banned over the Internet; Vending machines to be banned; Promotion and displays in retail stores to be banned

#### **additional option**

We urge the Commission to call for a ban on the promotion of tobacco products at point of sale and a ban on vending machines as described in the Art 13 Guidelines of the FCTC.

#### **additional comments**

Internet. The principle of preventing cross-border promotion of tobacco products in order to protect public health was enshrined in the Tobacco Advertising directive (2001/0119). It is logical, therefore, to extend that principle to the sale of tobacco products between member states via the Internet. We support the prohibition of tobacco sales via the Internet. Vending machines. Considering that only 2 Member States have no legislation on vending machines, we support harmonisation of the legislation on the basis of a prohibition of the sale of tobacco from vending machines . Point of Sale. Evidence shows that a coordinated cross border marketing strategy on the part of the tobacco companies is reflected at point of sale (i.e. point of sale marketing is similar in most EU countries (i.e.: a brand is advertised at point of sale in the same way in Germany and Belgium). There is a growing body of evidence to show that putting tobacco products out of sight in retail outlets can reduce youth smoking. To date, this measure has been adopted by Ireland and Finland (as well as Iceland and Norway). This measure is also official government policy in Scotland, Wales and Northern Ireland and a decision is awaited in England. We strongly support an EU-wide adoption of a ban on the display of tobacco products at the point of sale.

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**questions scope****problem definition**

No

**explanations**

kein kommentar

**which option**

No change

**questions smokeless****problem definition**

No

**comments**

kein kommentar

**which option**

No change

**questions consumer****problem definition**

No

**explanations**

kein kommentar

**which option**

No change

**questions on reporting****problem definition**

No

**explanations**

kein kommentar

**which option**

No change

**regulation of ingredients**

**problem definition**

No

**explanations**

kein kommentar

**which option**

No Change

**access to tobacco products**

**problem definition**

No

**explanations**

kein kommentar

**which option**

No change

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**questions scope**

**problem definition**

No

**explanations**

kein Kommentar

**which option**

No change

**questions smokeless**

**problem definition**

No

**comments**

kein Kommentar

**which option**

Lifting the ban on snus

**questions consumer**

**problem definition**

No

**explanations**

kein Kommentar

**which option**

No change

**questions on reporting**

**problem definition**

No

**explanations**

kein Kommentar

**which option**

No change

**regulation of ingredients**

**problem definition**

No

**explanations**

kein Kommenat

**which option**

No Change

**access to tobacco products**

**problem definition**

No

**explanations**

kein Kommentar

**which option**

No change

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ESPAÑA

**questions scope**

**problem definition**

Yes

**which option**

No change

**additional comments**

Esta Organización muestra su acuerdo en una posible ampliación del ámbito de la Directiva en lo que se refiere a autorizar el uso de productos de tabaco oral (SNUS) en todo el ámbito europeo. Sin embargo, en cuanto al resto de productos mencionados, cigarrillos electrónicos (ENDS), bebidas o caramelos con nicotina e incluso cigarrillos que no contengan tabaco como es el caso de los cigarrillos de hierbas, estimamos según el contenido de la propia Directiva y de la Ley 28/2005, de 26 de diciembre de medidas sanitarias frente al tabaquismo, artículo 2.a), que los mismos no pueden ser considerados productos del tabaco e incluidos, por tanto, en el ámbito de aplicación de la presente Directiva. Entendemos que este tipo de productos debe seguir siendo regulado en el ámbito comunitario y en los respectivos Estados miembro por legislaciones de carácter alimentario o farmacéuticas.

**questions smokeless**

**problem definition**

No

**comments**

No hay evidencia científica sobre los riesgos relacionados con el consumo de productos de tabaco sin humo.

**which option**

Lifting the ban on snus

**questions consumer**

**problem definition**

No

**explanations**

Nuestra Organización podría llegar a compartir los intereses de la Unión Europea en pretender que el consumidor final cuente con información más exhaustiva del contenido de estos productos, pero no existen resultados contundentes que relacionen que el uso de imágenes de advertencia sobre el hábito del tabaco implique un mejor conocimiento del consumidor sobre los posibles efectos para la salud de este tipo de productos. La introducción de paquetes genéricos atentaría contra los principios de libre empresa y competencia estipulados en la Constitución Española. Las recomendaciones sobre empaquetado y etiquetado genéricos harán peligrar la correcta identificación de la gama de productos vendidos. Se restringirá la capacidad de elección del consumidor, con el consiguiente perjuicio para el comercio. El consumidor tenderá a buscar el precio más bajo. El empaquetado genérico hará más sencilla la falsificación y el contrabando. El empaquetado genérico supone una invitación para que el consumidor tenga en cuenta como criterio principal el precio y se incline por las marcas más baratas.

**which option**

No change

**additional comments**

Nuestra Organización entiende que la adopción de este tipo de medidas, como la adopción del paquete genérico, lejos de conseguir efectos positivos desde un punto de vista sanitario, fomentará que sea más difícil diferenciar los distintos productos existentes en el mercado y la consecuencia final que ello traerá consigo, tal y como sucede con los mercados de materias primas, es que las empresas compitan únicamente con el precio. Tal escenario de caída generalizada de los precios no beneficiará ni a los objetivos de Salud Pública (dada la correlación entre tabaco barato y mayor consumo) ni a la Hacienda Pública, perjudicando seriamente los ingresos de todos los sectores de este mercado. Como conclusión, estamos seguros que la adopción de este tipo de medidas, que buscan hacer del tabaco un producto indiferenciado producirán únicamente nuevas guerras de precios entre los fabricantes, con el consiguiente perjuicio para los objetivos del Estado, en materia de recaudación y de salud pública, y además reducirá aún más si cabe, los ingresos de un sector industrial y comercial europeo que da trabajo a aproximadamente 200.000 personas en Europa (67.000 empresas operando en la fabricación, alrededor de 65.000 expendedurías y 150.000 asalariados). Este tipo de propuestas de hacer del tabaco un producto indiferenciado, bien a través de un empaquetado genérico o bien a través del aumento del tamaño de las advertencias sanitarias son un grave error, que lo único que provocará es un crecimiento exponencial del contrabando y de las falsificaciones. No debemos olvidar que en España el 99 % del tabaco de contrabando es falsificado y procede en un porcentaje similar en un 98 o 99 % de China y, en general, de los países del sudeste asiático. Aunque en nuestro país los índices de contrabando para consumo interno están en un porcentaje que es un mínimo histórico (según los últimos datos disponibles es de un 0.55 %) no ocurre lo mismo en cuanto al contrabando que pasa por España para terceros países.

**questions on reporting**



**problem definition**

Yes

**which option**

Establish a common compulsory reporting format

**additional comments**

Nuestra Organización podría mostrar su acuerdo en que se regulara a nivel europeo un formato de información común obligatorio, pudiendo basarse en la plantilla de información voluntaria desarrollada por la Comisión en mayo de 2007 para que la industria informe a los Estados miembros. Establecer un formato común de notificación obligatoria. No obstante lo anterior, entendemos que en España existe una estricta regulación de este particular ya que el artículo del Real Decreto 1079/2002, de 18 de octubre, por el que se regulan los contenidos máximos de nicotina, alquitrán y monóxido de carbono de los cigarrillos, el etiquetado de los productos del tabaco, así como las medidas relativas a ingredientes y denominaciones de los productos del tabaco. El artículo 6 establece que el Ministerio de Sanidad y Consumo exigirá a todos los fabricantes, importadores y marquistas de productos del tabaco la lista de todos los ingredientes del tabaco, así como las cantidades de dichos ingredientes, utilizados en la fabricación de dichos productos del tabaco, especificados por marcas y tipos individuales.

**regulation of ingredients****problem definition**

No

**explanations**

La adopción de medidas como una prohibición de ingredientes en los cigarrillos, podrían tener un efecto indeseado sobre el contrabando de este tipo de productos. Como conocedores de primera mano de las preferencias del consumidor español, podemos anticipar que en caso de que existiese una prohibición de ingredientes de forma que se llegase a un “cigarrillo genérico” contaríamos con un factor añadido para la proliferación del comercio ilegal de tabaco que escaparía a los controles sanitarios respecto de los ingredientes

**which option**

No Change

**access to tobacco products****problem definition**

No

**which option**

Controlled supply and access

**which supply and access**

Age verification of buyers and other legal conditions to be set for cross-border retail sale;  
Access to vending machines to be restricted to adults

**additional comments**

La prohibición de la exhibición de los productos del tabaco en los puntos de venta supone un ataque a la libertad de comercio de un producto legal cuyo último reducto es el punto de venta, donde los adultos con intención de comprar pueden informarse de la variedad ofertada.

Ataque a la libre competencia. Supone también una invitación para que el consumidor tenga en cuenta como criterio principal el precio y se incline por las marcas más baratas, con la consecuencia de la pérdida de ingresos de los puntos de venta, en un periodo de crisis económica. Posible aumento del comercio ilícito, al desconocer las características de los productos genuinos. Imposibilidad de los expendedores de diferenciar o hacer conocer productos a través de promociones (ya suficientemente controladas). El sistema de distribución de tabaco en España, a través de la red de distribución minorista ya prevé una plataforma efectiva para el control del acceso de los menores al tabaco. Los adultos que entran en un estanco son fumadores responsables que deben tener la posibilidad de elegir el producto legal que más les guste. Una de las consecuencias para los expendedores es la gran inversión económica que tendrían que realizar en sus establecimientos para ocultar las cajetillas a los consumidores. En relación con el acceso al tabaco, en especial por los menores, la red de estancos existente en España ha demostrado a día de hoy ser la mejor garantía para la venta responsable de los productos del tabaco. Teniendo en cuenta el modelo de estanco, donde la actividad principal y casi exclusiva es la venta de tabaco, pensamos que las propuestas de regular aún más la actividad en el punto de venta, y en especial, de prohibir la exhibición del producto y restringir la comunicación con el consumidor adulto son desproporcionadas. Cabe recordar que en nuestro país, la venta de tabaco a menores de edad ya está prohibida por Ley, tanto en las expendedurías como en las máquinas expendedoras ubicadas en los puntos de venta autorizados para la venta de tabaco con recargo, con sanciones de hasta 10.000 euros por incumplimiento. Entendemos que mantener una comunicación mínima con el consumidor adulto como hasta ahora, es vital para mantener el sistema actual de distribución minorista. Además defendemos la dignidad de la actividad que realizamos con alto grado de profesionalidad. Mostramos nuestro mayor rechazo a medidas populistas, como tener que esconder los productos legales que comercializamos, sin que por ello medie ningún beneficio de Salud Pública. La actividad de distribución complementaria a través de las máquinas y de acuerdo con la estricta regulación existente al respecto, que incluye mecanismos de control de acceso a la máquina para impedir que los menores puedan comprar tabaco, impide la proliferación de canales alternativos de venta ilegal de tabaco con los perjuicios que el contrabando y la falsificación suponen para todos. PARA MAYOR ABUNDAMIENTO, HACEMOS REFERENCIA A LOS CONTENIDOS DE LA LEY 13/98 DE 4 DE MAYO, DE ORDENACIÓN DEL MERCADO DE TABACOS Y NORMATIVA TRIBUTARIA Y LEY 28/2005, DE 26 DE DICIEMBRE, DE MEDIDAS SANITARIAS FRENTE AL TABAQUISMO

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**questions scope**

**problem definition**

No

**explanations**

no

**which option**

No change

**questions smokeless**

**problem definition**

No

**comments**

no

**which option**

No change

**questions consumer**

**problem definition**

No

**explanations**

no

**which option**

No change

**questions on reporting**

**problem definition**

No

**explanations**

no

**which option**

No change

**regulation of ingredients**

**problem definition**

No

**explanations**

no

**which option**

No Change

**access to tobacco products**

**problem definition**

No

**explanations**

no

**which option**

No change

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**questions scope**

**problem definition**

No

**explanations**

no

**which option**

No change

**recommend option**

no

**questions smokeless**

**problem definition**

No

**comments**

no

**which option**

No change

**questions consumer  
problem definition**

No

**explanations**

no

**which option**

No change

**questions on reporting  
problem definition**

No

**explanations**

no

**which option**

No change

**regulation of ingredients  
problem definition**

No

**explanations**

no

**which option**

No Change

**access to tobacco products  
problem definition**

No

**explanations**

nö

**which option**

No change

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## **NGO submission**

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### **questions scope**

#### **problem definition**

Yes

#### **which option**

No change

### **questions smokeless**

#### **problem definition**

No

#### **comments**

Il n'y a pas d'études scientifiques efficaces prouvant les risques concernant les produits du tabac sans fumée.

#### **which option**

Lifting the ban on snus

### **questions consumer**

#### **problem definition**

No

### **explanations**

Aucune étude ne prouve l'efficacité des paquets neutres. Aucune étude ne prouve l'efficacité des photos chocs, ni même de plus grands avertissements sanitaires sur les paquets. La mise en place de paquets neutres risque d'entraîner une guerre des prix du tabac (puisque cela restera le seul moyen pour les fabricants de se différencier). La mise en place de photos chocs sur les 2 faces des paquets ou de paquets génériques va pousser les consommateurs français à aller s'approvisionner sur les marchés parallèles du tabac (achats à l'étranger ou de contrebande, ou sur internet. De telles mesures risquent de déstabiliser et pénaliser économiquement le réseau des 28 000 buralistes français organisés dans un réseau réglementé et sous tutelle de l'Etat.

#### **which option**

No change

**questions on reporting  
problem definition**

Yes

**which option**

Establish a common compulsory reporting format

**regulation of ingredients  
problem definition**

No

**explanations**

Cela risque d'entraîner une standardisation de la production avec comme conséquence une diminution de l'offre au fumeur adulte et responsable, et le risque de voire apparaitre une augmentation des produits du tabac contrefaits.

**which option**

No Change

**access to tobacco products  
problem definition**

Yes

**which option**

Controlled supply and access; Ban

**which supply and access**

Age verification of buyers and other legal conditions to be set for cross-border retail sale

**which one2**

Cross-border retail sales of tobacco to be banned over the Internet; Vending machines to be banned

**additional comments**

Il n'y a pas de corrélation prouvée entre la disparition des linéaires tabac et la lutte contre le tabagisme. La France dispose d'un réseau de 28 000 buralistes, préposés de l'administration responsables et professionnels, seuls habilités à vendre du tabac. Ce réseau est fortement réglementé par l' Etat ce qui permet déjà de contrôler efficacement l'accès au produit tabac.

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**questions scope**

**problem definition**

No

**explanations**

kein Kommenteer

**which option**

No change

**questions smokeless**

**problem definition**

No

**comments**

kein Kommentar

**which option**

Lifting the ban on snus

**questions consumer**

**problem definition**

No

**explanations**

kein Kommentar

**which option**

No change

**questions on reporting**

**problem definition**

No

**explanations**

kein Kommentar

**which option**

No change

**regulation of ingredients**

**problem definition**



No

**explanations**

kein Kommentar

**which option**

No Change

**access to tobacco products**

**problem definition**

No

**explanations**

kein Kommentar

**which option**

No change

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**questions scope**

**problem definition**

Yes

**which option**

Extend the scope of the Directive

**recommend option**

All tobacco products are hazardous to health – there is no safe level of usage. We recommend that the scope of the Directive includes the regulation of any new smoked tobacco products (such as low emission or nicotine-free cigarettes), while the prohibition of any novel forms of oral tobacco, including snus, should be maintained. As it is the combustion process and inhalation of smoke that causes most of the harm from smoking, it is appropriate that herbal cigarettes, which are used in a similar way as nicotine cigarettes, are regulated in the same

way as smoked tobacco products, and should therefore be included in the scope of the Directive. Nicotine containing products (NCPs) such as electronic cigarettes, gels and some oral products have the potential to offer a less hazardous alternative to cigarettes, but are currently under-regulated. Concerns have been expressed about the quality, efficacy and safety of these products. INWAT Europe believes that it is appropriate for them to be brought under the same regulatory framework as pharmaceutical products rather than under the scope of the tobacco products directive.

**additional comments**

INWAT Europe believes that the scope of the Directive should be extended to include smoking paraphernalia such as filters, cigarette paper, pipes, water pipes as well as the tobacco leaf. INWAT Europe agrees with the impact assessment study conducted by RAND Europe stating that the primary benefit of extending the scope of the directive to paraphernalia and other non-tobacco nicotine products would be to increase consumers' awareness of the risks of these products. Smokers of roll-your-own cigarettes (RYO), pipes and water pipes often believe that these products are less harmful than manufactured cigarettes when in fact there is evidence to the contrary.

**questions smokeless**

**problem definition**

Yes

**which option**

No change

**additional option**

With regard to other smokeless tobacco products than snus, particularly those used by ethnic minority populations, INWAT Europe recommends that they should be more tightly regulated (in the same way as tobacco products) but we do not support a total ban on such products.

**additional comments**

INWAT Europe believes that it is a high priority that the current ban on snus is maintained. There is no legitimate reason to introduce a dangerous product on the European market, particularly as we have no idea how snus would be perceived or used in new markets. There is little evidence that smokers in EU countries other than Sweden would find snus to be an acceptable alternative to cigarettes, were it to be legalised. It is also important to note that the smoking prevalence of women has decreased substantially in Sweden without replacing smoking with snus although the manufactures of snus have worked hard in their product development to make snus more attractive among women with among all new packet design and adding several flavours. Moreover, a lifting of the ban might encourage dual use of cigarettes and snus, as has happened in Sweden. This could have the effect of discouraging complete smoking cessation . The SCENIHR report also notes the difficulties of extrapolating to new markets from experience in existing markets, pointing out different patterns for smoking prevalence and snus use in Sweden and Norway for example. The switching behaviour reported in Swedish men is not reflected in Norway where smoking cessation rates have been similar in Norwegian men and women during the last decade, but increased use of smokeless tobacco is observed only in young men. INWAT Europe rejects the argument that snus can be used for harm reduction and as an aid to stopping smoking. Proven, safe medicinal products (NRT) are widely available in the EU and these should be used to aid smoking cessation. Even more effective products, subject to pharmaceutical regulation,

should be developed. Therefore, there is no legitimate reason to justify bringing a new hazardous product onto the market.

**questions consumer  
problem definition**

Yes

**which option**

Improve consumer information; Introduce generic or plain packaging

**which improvement**

Picture warnings to become mandatory; Information on harmful substances in tobacco products that cannot be placed on the package would be placed inside the package; Health warnings to be put on water pipes

**additional option**

Picture Warnings INWAT Europe strongly recommends that picture warnings should be mandatory in all Member States and that they should occupy a minimum of 80% of the front and back surfaces of all tobacco packaging. The warnings should be placed on the upper portion of the packs for maximum visibility. Evidence clearly supports the need for large pictorial health warnings (80%) showing that increasing the size of warning messages (text only and combined text and picture) increases the effectiveness of the warning amongst both young and adult smokers / non smokers. Research carried out in Canada by Createc on behalf of Health Canada in 2007 showed that young and adult smokers/non smokers are sensitive to the size of health warning messages. Results showed that warning messages that cover 100% of the pack are significantly more effective across all measured effectiveness indicators compared with warning messages that cover only 50% of the pack. There is further evidence to show that health warnings are effective in conveying the dangers of smoking and helping smokers to quit. , They also help deter young people from starting to smoke. Picture warnings are more effective than written warnings. Further, we believe that all warnings should be displayed in rotation . Last but not least, in accordance with the gender-sensitive standard outlined in the WHO/FCTC Articles 4.2da and 11, pre-testing should be undertaken to assess the effectiveness of the warnings on all target groups including women. For example, it is not effective to exclusively address women's smoking by only selecting images of the dangers of smoking during pregnancy. This severely limits the audience and can increase the chances of a woman resuming smoking after giving birth by giving a message that the only time a woman has to worry about her smoking is during pregnancy. Generic or plain packaging There is now evidence, even from the tobacco industry's own documents, of the importance of the cigarette pack as a means to promote cigarette brand images and smoking, especially in jurisdictions where other means of promotion are restricted . The WHO Regional Office for Europe has highlighted the way pack and product design has been a particularly important element in promoting cigarettes to girls and women . Designer packs, some of them resembling a perfume or lipstick case, are especially pitched to girls and young women. The challenge of placing a prominent health warning on such packs is obvious. Therefore, INWAT Europe strongly recommends the introduction of plain or generic packaging. This should include not only the removal of all branding from the packaging but also standardisation of the size and shape of the packaging. Although the Australian Federal Government has recently announced its intention to introduce plain packaging in 2012 , no other jurisdiction has yet implemented a law requiring plain packaging. Research suggests that it would help deter young people from taking up smoking because smoking would lose its appeal. Information on Tar, nicotine &

carbon monoxide (TNCO) Concerning option 2b, to replace levels of tar, nicotine and carbon monoxide (TNCO) with general information on harmful substances in tobacco products, the NHF believes that instead of removing information on the levels of TNCO, they should be completed with qualitative information about the hazardous content and “stop smoking” help lines. Further it should be insured that the data on the quantities of TNCO are accurate. Additional information on harmful substances in tobacco products INWAT Europe supports the proposal to include additional information on the health effects of tobacco consumption on inserts inside the packaging. This should include advice on quitting smoking (see above).

### **additional comments**

Health warnings should also appear on water pipes There is a growing body of evidence to show that water pipes are at least as hazardous, than other forms of tobacco use. However, there is a common perception that tobacco smoke is ‘cleansed’ by the water and therefore not as dangerous and some users believe flavoured shisha is not in fact tobacco. It is important that these myths are countered by the inclusion of a health warning on water pipes. Warnings should also be included on the packaging of tobacco used in water pipes. There is evidence from around the world to show that the tobacco industry uses branding in general and pack design in particular to: • Target young people • Maximise display space (some members of brand families are virtually indistinguishable on taste alone yet the number of variants has increased dramatically in recent years). • Communicate misleading messages (it would be illegal for manufacturers to claim products were “low tar” “light” or less harmful yet all these are communicated by the colour of sub-brand packaging). , , Claims that plain packaging would contravene intellectual property law are not correct, as legal analysis prepared in Australia has concluded. There are no impediments in international law to plain packaging .

### **questions on reporting problem definition**

Yes

### **which option**

Establish a common compulsory reporting format; Introduce fees and sanctions

### **additional options**

INWAT Europe agrees with the Smoke Free Partnership’s view that the current situation which allows different formats and reporting mechanisms is unsatisfactory, making it difficult for authorities to compare and analyse the data. Tobacco companies should be required to use a standardised reporting format. The companies should be required to pay a yearly registration fee to cover the costs of administering this data collection. These measures should be compliant with Articles 9 & 10 of the Framework Convention on Tobacco Control (FCTC).

### **regulation of ingredients**

#### **problem definition**

Yes

### **which option**

Establish a common list of tobacco ingredients

### **which one**

Establish a positive common list of tobacco ingredients

**additional option**

INWAT Europe supports the response by Smoke Free Partnership Europe of adopting a positive common list of tobacco ingredients. We agree that tobacco products are highly toxic and addictive, and that their content should therefore be closely regulated in order to achieve high standards of health protection, as stated under Article 95.3 of the Treaty on the Functioning of the European Union (TFEU). There is a need for such a list at EU level since at the moment, consumers in the internal market are not subject to the same level of protection. Some citizens may be using substances that are banned in other Member States. This constitutes an obstacle to free movement of goods within the internal market since some countries may be reluctant to import cigarettes from other Member States that do not comply with the national requirements. Regulation of Flavours and Ingredients: Flavourings, such as vanilla, chocolate, mint and fruit flavours are an increasingly important part of tobacco industry marketing in Europe, particularly to young people. The prohibition of ingredients that may be used to increase attractiveness, such as sugars and sweeteners, flavouring substances, and spices and herbs, in cigarettes and cigarette-like tobacco products should be introduced. The prohibition of ingredients that may create the impression of a health benefit (e.g. vitamins), ingredients associated with energy and vitality (e.g. caffeine), and ingredients with colouring properties (e.g. pink cigarette paper) should also be banned. Tobacco manufacturers and importers should report sales volume information by brand. This information is essential to help governments ensure that product regulation is effective. These measures should be compliant with the Guidelines on Art. 9/10, adopted unanimously at the Fourth Conference of the Parties in Uruguay on the 20th November 2010.

**access to tobacco products****problem definition**

Yes

**which option**

Ban

**which one2**

Cross-border retail sales of tobacco to be banned over the Internet; Vending machines to be banned; Promotion and displays in retail stores to be banned

**additional option**

The Commission should call for a ban on the promotion of tobacco products at point of sale and a ban on vending machines, although we are aware that these issues do not have cross-border effects. The legal basis for such measures at an EU level is weak. However, these measures are important for health protection and we call on the Commission to include them as non-mandatory measures as part of the Tobacco Products Directive. The Directive should also remind national governments that they should adopt a comprehensive ban on all forms of tobacco advertising, promotion and sponsorship in accordance with Article 13 of the FCTC. Further, we recommend that the EU Directive follows the lead set by Finland which, as part of its recently passed Tobacco Act, has set limits on the amount of tobacco that can be imported into Finland where the labelling differs from that of tobacco products sold in Finland. We recommend that similar limits should be set at EU level, that is, that for each Member State the amount of tobacco that may be imported for personal use which does not conform to domestic labelling requirements, should be limited to a maximum of 200 cigarettes, 50 cigars, 100 cigarillos and 250 grams of pipe or cigarette tobacco.

**additional comments**

Internet: The principle of preventing cross-border promotion of tobacco products in order to protect public health was enshrined in the Tobacco Advertising directive (2001/0119). It is logical, therefore, to extend that principle to the sale of tobacco products between member states via the Internet. INWAT Europe supports the prohibition of tobacco sales via the Internet. Vending machines: The majority of member states (22 out of 27) already prohibit the sale of tobacco products from vending machines in order to deter young people accessing cigarettes from this source. INWAT Europe supports this measure. Point of Sale. Similarly, there is a growing body of evidence to show that putting tobacco products out of sight in retail outlets can reduce youth smoking. To date, this measure has been adopted by Ireland, the UK and Finland. We support an EU-wide adoption of a ban on the display of tobacco products at the point of sale.

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**NGO submission****identification****affiliation**

NGO

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Sweden

**questions scope****problem definition**

Yes

**which option**

Extend the scope of the Directive

**questions smokeless****problem definition**

Yes

**which option**

Ban on all types of smokeless tobacco products

**questions consumer****problem definition**

Yes

**which option**

Improve consumer information

**which improvement**

Picture warnings to become mandatory; Health warnings to be put on water pipes

**questions on reporting****problem definition**

Yes

**which option**

Establish a common compulsory reporting format

**regulation of ingredients****problem definition**

Yes

**which option**

Establish a common list of tobacco ingredients

**which one**

Establish a positive common list of tobacco ingredients

**access to tobacco products****problem definition**

Yes

**which option**

Ban

**which one2**

Cross-border retail sales of tobacco to be banned over the Internet; Vending machines to be banned; Promotion and displays in retail stores to be banned

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**NGO submission****identification****affiliation**

NGO

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**country**

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**age**

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**gender**

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**questions scope**

**problem definition**

No

**explanations**

no comment

**which option**

No change

**questions smokeless**

**problem definition**

No

**comments**

no comment

**which option**

No change

**additional option**

no comment

**questions consumer**

**problem definition**

No

**explanations**

no comment

**which option**

No change

**additional option**

no comment

**questions on reporting**

**problem definition**

No

**explanations**

no comment

**which option**

No change



**additional options**

no comment

**regulation of ingredients**

**problem definition**

No

**explanations**

no comment

**which option**

No Change

**additional option**

no comment

**access to tobacco products**

**problem definition**

No

**explanations**

no comment

**which option**

No change

**additional option**

no comment

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**NGO submission**

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**questions scope****problem definition**

Yes

**which option**

No change

**questions smokeless****problem definition**

Yes

**which option**

Lifting the ban on snus

**questions consumer****problem definition**

No

**explanations**

There is no evidence that bigger warnings are more effective. There is no evidence that plain packaging would lead to decreased smoking.

**which option**

No change

**additional option**

Consumers are already fully aware of the dangers of smoking; if anything they overestimate those dangers. Generic or plain packaging would do nothing to decrease smoking. It would lead to increased counterfeiting, decreases in government revenues, and violations of intellectual property rights.

**questions on reporting****problem definition**

No

**explanations**

There is no reason that enforcement cannot be addressed individually by each Member State

**which option**

Establish a common compulsory reporting format

**regulation of ingredients****problem definition**

No

**explanations**

The only "problem" is whether an ingredient increases health risks.

**which option**

No Change

**access to tobacco products****problem definition**

No

**explanations**

The Directive has not identified any specific problem related to the display and promotion at point of sale.

**which option**

No change

**additional option**

Before any consideration is given to speech restrictions (such as restrictions on display and promotion at point of sale), the EC ought to try all non-speech methods of preventing sales to underage consumers (which presumably is the "problem" that is being addressed). For example, consideration ought to be given to imposing stiffer fines on retailers shown to have made sales to underage consumers.

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**NGO submission****identification****affiliation**

NGO

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France

**questions scope****problem definition**

Yes

**which option**

Extend the scope of the Directive

**recommend option**

Tous les produits du tabac sont toxiques pour la santé et il n'existe pas de seuil de risque. La portée de cette directive doit inclure l'interdiction de toute nouvelle forme de tabac à usage oral. Le champ d'application de la directive doit dès lors concerner l'ensemble de ces produits

et veiller à ce qu'en l'état, de nouvelles formes de produits, tels que le SNUS ou autres catégories de tabacs non fumés, ne soient pas introduits sur le marché, afin de ne pas accroître davantage la consommation. Par ailleurs, l'élargissement du champ d'application est nécessaire dès lors que l'apparition d'une catégorie de nouveaux produits et de nouvelles formes de consommation peut avoir une incidence sur l'application d'autres dispositions en matière de réglementation du tabac. (cf. La cigarette électronique et l'utilisation de pipes à eau/narguilé mettent à mal l'application de l'interdiction de fumer dans les lieux à usage collectif). En France, a été constaté que les mesures visant à assurer l'application de l'interdiction de fumer dans les lieux à usage collectif peuvent être compromises par l'utilisation de ces produits : certaines cigarettes électroniques sont équipées de diodes électroluminescentes rouges qui s'allument à l'inhalation, elles produisent également, à l'inhalation et à l'expiration, un halo parfaitement identique à la fumée de tabac. La consommation de ces produits dans les lieux concernés par l'interdiction de fumer devrait être interdite, afin d'éviter d'entraver les actions de contrôles des agents chargés de faire respecter la législation et des personnes responsables de lieux dans lesquels il est interdit de fumer. Les cigarettes et autre produits destinés à être fumés mais qui ne contiennent pas de tabac (cf. cigarettes aux herbes) sont également nuisibles, même s'ils ne contiennent pas de tabac car les gaz et particules dégagées par la combustion sont nocifs tant pour le fumeur que pour son environnement et particulièrement pour le non-fumeur qui côtoie cet environnement. Ainsi, les cigarettes et produits destinés à être fumés, même sans tabac, devraient être inclus dans la directive. Il serait nécessaire de prévoir que ces produits, si leur mise sur le marché est autorisée, comportent des avertissements sanitaires. Tous les produits qui contiennent de la nicotine (des produits ne contenant pas du tabac ou des produits du tabac, mais de la nicotine, tels que les cigarettes électroniques, le gel à la nicotine, les boissons à la nicotine et les bonbons à la nicotine) sont souvent vendus comme des solutions de substitution au tabac et, dans certains cas, comme un produit d'aide à l'arrêt. Cependant, la plupart de ces produits ne respectent pas les conditions de mise sur le marché exigées pour les produits de substitution nicotinique : ils devraient être exclusivement vendus sous l'appellation « produits de substitution ». Il serait nécessaire de préciser dans la directive qu'en matière de SEDN, c'est la réglementation des produits pharmaceutiques, avec ses exigences particulières en matière de sécurité et de qualité qui devrait être appliquée. Dans cette perspective, il incombe de renforcer considérablement le contrôle sur la composition de ces produits ainsi que l'information sur le caractère toxique, addictif et nuisible sur le plan sanitaire mais aussi économique, social et environnemental des produits du tabac.

### **questions smokeless**

#### **problem definition**

Yes

#### **which option**

No change

#### **additional option**

L'interdiction concernant le snus doit être en l'état maintenue. Il s'agit d'une priorité essentielle. La libre commercialisation des produits du tabac sans fumée tel que le snus pourrait au contraire favoriser une augmentation de la consommation du tabac (orale et à fumer) et mettre à mal les efforts menés par les Etats pour diminuer la demande de tabac, et, en conséquence, jouer un rôle néfaste dans les objectifs visant à promouvoir la santé de la population. L'interdiction de ce type de produit est d'autant plus pertinente qu'il existe déjà des traitements de substitution nicotinique (TSN) et des thérapies cognitives d'aide à l'arrêt,

qui ne présentent pas les risques associés à l'utilisation des produits du tabac sans fumée . Si le but est de diminuer la consommation des produits du tabac, il est plutôt nécessaire d'encourager l'utilisation de traitements et de thérapies reconnues pour faciliter l'arrêt, au lieu de permettre l'utilisation des produits du tabac sans fumée, dont l'efficacité en termes d'aide à l'arrêt n'est pas démontrée. Enfin, l'hypothèse de l'introduction du tabac oral porte le risque d'effets négatifs pour la santé des plus jeunes, qui pourraient considérer le Snus comme un produit moins dangereux que la tabac à fumer, ou l'utiliser comme « porte d'entrée » dans la consommation d'autres produits du tabac. Par ailleurs, les conditions d'introduction du snus dans une optique de réduction de risques, à la fois pour l'individu et pour la société, ne sont pas réunies. En l'absence d'un consensus au sein de la communauté de santé publique et d'études expérimentales réalisées à son initiative en vue de déterminer si le snus pourrait s'inscrire dans une optique de protocole de prise en charge des fumeurs qui ne parviennent pas à arrêter de fumer, la demande de snus aujourd'hui, dans l'hypothèse d'une levée de son interdiction, serait uniquement développée à l'initiative des opérations de marketing des fabricants de tabac. En revanche, il serait nécessaire que la communauté scientifique et de santé publique se saisisse sereinement de cette problématique de la réduction de risques. Des études prospectives devraient être réalisées visant à une possible introduction du snus, dans la seule perspective de faire diminuer les risques pour des fumeurs qui ne parviennent pas à arrêter de fumer des cigarettes, tout en veillant à ce qu'aucune promotion ne vienne inciter à consommer ce produit au moment de l'initiation au tabagisme. Une telle démarche s'inscrit dans un contrôle nécessaire de l'ensemble des produits du tabac et de la nicotine, dans le cadre d'une agence européenne de réglementation, réunissant des représentants des autorités sanitaires, des scientifiques, des représentants de la société civile impliqués dans le contrôle du tabac et le sevrage tabagique. Cela devrait exclure très clairement toute représentation des fabricants de tabac dont les intérêts ont été démontrés comme inconciliables avec ceux de la santé publique. Cette disposition serait une application des engagements pris par la Commission Européenne et la quasi-totalité des Etats membres, qui ont ratifié la Convention Cadre de l'OMS pour la Lutte Anti-tabac (CCLAT), notamment son article 5.3.

### **questions consumer**

#### **problem definition**

No

#### **explanations**

La définition du problème pourrait être améliorée. Nous partageons l'analyse de la Commission selon laquelle la situation actuelle induit des différences majeures entre les Etats Membres selon qu'ils ont adopté, ou pas, l'apposition d'avertissements graphiques sur les emballages des produits du tabac. Cette différence signifie une distorsion de qualité d'information en direction des consommateurs et citoyens européens, les avertissements graphiques ayant également une vertu préventive majeure. Par ailleurs, les dispositions de la directive sont sensiblement en deçà aujourd'hui des recommandations internationales fondées sur les évidences scientifiques qui préconisent une surface beaucoup plus importante dédiée aux avertissements sanitaires (lignes directrices de l'article 11 de la CCLAT). Ces dispositions ont été adoptées, notamment par la Commission Européenne et la quasi-totalité des Etats Membres en novembre 2008, lors de la troisième Conférence des Parties. Les Etats membres qui souhaitent apposer des avertissements sanitaires, comme la France à partir de 2011, ont ainsi été contraints de limiter la surface dédiée à ces avertissements graphiques en raison du caractère obsolète de la directive européenne. Il est indispensable que la directive soit donc modifiée pour se mettre en conformité avec les prescriptions adoptées dans le cadre de la CCLAT. Nous partageons également l'analyse que l'utilisation des packagings des

produits du tabac, en tant que supports publicitaires, n'est pas couverte par la présente directive européenne relative aux produits. Cependant, il apparaît bien que les produits du tabac et leur conditionnement sont inextricablement liés et conçus pour attirer les consommateurs, notamment les plus jeunes. En France, les fabricants de tabac sont condamnés chaque année par les Tribunaux pour violation des législations en vigueur ; et il a été constaté, au cours de cette dernière décennie, une envolée de l'utilisation d'arômes et de parfums, associés à des packagings évocateurs visant à faire oublier la dangerosité des produits et à assimiler les produits du tabac à des confiseries, parfums, accessoires ... Dans cette perspective, il est important d'envisager, de manière concomitante, l'obligation d'apposer des avertissements graphiques et l'instauration de paquets neutres standardisés (ou paquets génériques). Par ailleurs, des études scientifiques ont montré l'efficacité des paquets neutres standardisés pour dénormaliser le tabac, inciter à ne pas commencer à fumer et à arrêter .

### **which option**

Improve consumer information; Introduce generic or plain packaging

### **which improvement**

Picture warnings to become mandatory; Tar, nicotine and carbon monoxide levels to be replaced with general information on harmful substances in tobacco products; Information on harmful substances in tobacco products that cannot be placed on the package would be placed inside the package; Health warnings to be put on water pipes

### **additional option**

L'industrie a développé au fil des décennies toute une imagerie glamour, ludique, rebelle, et séduisante autour du packaging de ses produits. Afin de casser ce marketing et de montrer aux consommateurs la réelle dangerosité du tabac, il faut apposer sur les paquets des produits du tabac des avertissements graphiques illustrant les dégâts causés par le tabagisme actif et passif. • Il est nécessaire de rendre obligatoires les avertissements sanitaires graphiques. Les études démontrent que les avertissements seulement composés d'un texte ne sont pas suffisamment efficaces, notamment parce que de nombreux consommateurs ne les lisent pas. Les photos, surtout celles induisant la peur, se sont révélées être efficaces pour captiver davantage les consommateurs. Les photos sont en mesure de provoquer une réaction rapide et d'amener les gens à lire le message texte associé. Les avertissements sanitaires : - améliore le niveau de connaissance sur les méfaits; - a un impact sur l'envie d'arrêter de fumer; - motive les non fumeurs et ex fumeurs à le rester ; - dissuade les jeunes d'entrer dans le tabagisme ; - renforce la lisibilité, visibilité et compréhension des messages sanitaires, en particulier sur les populations défavorisées ; - réduit significativement l'attractivité du paquet de cigarettes (et donc incite moins les jeunes à commencer à fumer). • Sur un plan pratique, les avertissements sanitaires doivent-être segmentés : c'est-à-dire qu'ils doivent présenter des informations de natures diverses pour toucher l'ensemble des populations cibles ; fumeurs, non fumeurs, hommes, femmes, jeunes, adultes, etc. Ainsi différents messages doivent être présentés : information sur les risques sur la santé, sur les coûts financiers, sur la dégradation physique, les méfaits esthétiques, les aides à l'arrêt, etc. • Il est fondamental d'introduire des avertissements graphiques en couleur , sur les deux côtés du paquet . Il est également prouvé que les images des deux côtés de l'emballage, en haut du paquet , couvrant au moins 60% de la surface (Maurice 60 % de la surface du paquet, 80 % pour les avertissements en Uruguay ), auraient un impact plus important que sur un seul côté. L'augmentation de la taille des avertissements augmente l'efficacité de l'avertissement à la fois parmi les adultes et les jeunes fumeurs. Enfin, cela a des effets sur les non-fumeurs, en particulier l'incitation de ne pas

commencer à fumer. Les avertissements devront être imprimés de manière alternée, de sorte que chaque message soit montré autant de fois qu'un autre et qu'il puisse atteindre à un moment son public cible. • Il faut également prendre en compte l'efficacité des avertissements sanitaires choquants : la peur liée à des risques pour la santé (images telles que membres gangrénés ou cancer de la gorge) et à l'émotion (images impliquant des enfants et les bébés à naître) sont des moyens efficaces pour sensibiliser les consommateurs sur les risques liés à l'usage du tabac et pour obtenir des changements dans leurs comportements. L'efficacité de ces messages est renforcée par une proposition d'aide à l'arrêt, par exemple le numéro à 4 chiffres d'une ligne téléphonique dédiée à l'assistance pour arrêter de fumer, ou à des fiches d'information qui peuvent être glissés à l'intérieur du paquet de cigarettes comme au Canada, afin de rassurer les fumeurs sur leur capacité à arrêter de fumer. • Il existe un nombre croissant de preuves montrant que les pipes à eau ou narguilé constituent des formes de consommation du tabac également dangereuses (cf. rapport OMS). Des avertissements devraient donc figurer sur l'emballage de tabac utilisé dans les pipes à eau.

### **additional comments**

- Instauration de paquets neutres standardisés ou paquets génériques : L'Alliance soutient fortement l'introduction de paquets neutres standardisés pour l'ensemble des produits du tabac par la suppression de toute référence à l'univers publicitaire de la marque et l'apposition du nom de celle-ci de manière générique. La définition d'une taille et d'une forme standardisée du paquet est également requise. L'objectif est de supprimer les packagings comme supports publicitaires mais également de parvenir à une meilleure mise en exergue des avertissements apposés sur les conditionnements et enfin de mettre un terme aux pratiques actuelles de détournement des dispositions de la directive en vigueur qui interdit l'apposition de descriptifs mensongers tels que douce, légères ... et qui sont remplacées par les cigarettiers par des codes couleurs. Il faut insister sur la nécessité de réglementer de manière positive les packagings des produits du tabac en raison notamment de la permanence d'une fraude à la loi de la part de l'ensemble des fabricants de tabac. Le CNCT, l'un des membres fondateurs de l'Alliance, à l'instar d'autres organisations internationales, a réalisé plusieurs études sur l'opportunité et la faisabilité juridique et pratique des paquets neutres concluent clairement à l'intérêt de cette mesure et à sa faisabilité juridique. - Remplacer les informations quantitatives relatives aux goudrons, nicotine et monoxyde de carbone par des informations qualitatives sur les ingrédients, les teneurs et apposer un numéro de téléphone pour les lignes téléphoniques d'aide à l'arrêt. Nous recommandons de remplacer les informations numériques sur les taux de goudron, nicotine et CO, qui peuvent induire en erreur quant à la dangerosité des différents produits. L'introduction d'informations descriptives des effets dangereux des constituants du tabac et de la fumée serait plus appropriée. Les rendements indiqués sur les packagings sont ceux définis par des machines à fumer et ne sont pas fidèles de la manière de fumer des fumeurs. Les données quantitatives n'apportent aucune information aux consommateurs, elles sont même susceptibles de les induire en erreur en leur laissant croire que certaines cigarettes sont moins dangereuses que d'autres. La France a banni l'utilisation des descriptifs tels que légers. Pourtant une étude révèle que près d'un Français sur 2 croit prendre moins de risque pour sa santé avec des cigarettes moins « chargée » en nicotine. Le dispositif d'information qualitative sur les ingrédients en substitution des données quantitatives était très apprécié de même que l'instauration d'un dispositif complémentaire d'information notamment au travers de l'insertion de vignette à l'intérieur des paquets.

### **questions on reporting problem definition**

Yes

**which option**

Establish a common compulsory reporting format; Introduce fees and sanctions

**additional options**

La situation actuelle qui autorise différents formats et mécanismes de rapport rend difficile l'analyse et la comparaison des données par les autorités. Tous les fabricants et les importateurs devraient être soumis aux mêmes exigences en termes de déclaration des composants et ingrédients et des effets en termes de toxicité et de dépendance. Etant donné la nocivité des produits du tabac, le rapport fourni par les fabricants aux autorités doit permettre la collecte et l'analyse de données pertinentes, le but étant d'assurer un niveau élevé de sécurité des consommateurs par une amélioration de l'information. Un format commun existe déjà (basé sur le format des rapports volontaires mis au point par la Commission en mai 2007) et il serait donc très facile d'adopter cette mesure.

**additional comments**

La situation actuelle qui se caractérise par l'existence de différents formats et mécanismes de notification, induit des difficultés majeures pour les autorités publiques en vue d'analyser et de comparer ces données. Elle est préjudiciable au bon fonctionnement du marché intérieur et elle va à l'encontre de la nécessaire transparence requise dans le cadre des articles 9 et 10 du traité de la CCLAT pour communiquer et définir une réglementation des produits du tabac, particulièrement toxiques, mais aujourd'hui très peu réglementés. Tous les fabricants et importateurs doivent être soumis aux mêmes exigences de notification. Compte tenu du caractère extrêmement toxique des produits du tabac, ces derniers devraient être soumis à une obligation de diffusion des données la plus complète possible, en vue d'accroître la connaissance scientifique des produits, dans un objectif sanitaire et de réduction de la consommation, et de permettre d'élaborer des éléments comparatifs. Cette démarche s'inscrit également dans une optique de lutte contre le commerce illicite des produits du tabac, au travers un contrôle de l'offre plus efficace, dans la mesure où seuls les produits homologués seraient autorisés sur le marché. Un tel format de notification existe déjà, développé par la Commission Européenne en mai 2007, et devrait donc être généralisé. Cette généralisation apparaît en effet aisée et peu coûteuse à mettre en œuvre. L'introduction des redevances annuelles pour financer la collecte de données sur les composants et faciliter ainsi les travaux de comparaison et d'analyse des ingrédients par les autorités compétentes est une bonne disposition. Le paiement des amendes en cas de non-conformité avec les exigences de communication de données sur les ingrédients des produits du tabac semble également indispensable et pourrait contribuer à financer les tests effectués sur ces produits. Il est fondamental d'introduire des évaluations toxicologique et de dépendance de ces produits par des essais cliniques appropriés. Ces tests permettraient aux décideurs de prendre des dispositions plus élaborées dans ce domaine, en donnant accès à des preuves scientifiques supplémentaires. Il importe que la valeur du montant soit déterminée et révisée de telle manière que cette activité n'induisse pas de prélèvement sur les budgets de financements du contrôle du tabac, qui sont très limités, et sont indispensables à la mise en œuvre d'autres politiques publiques de réduction de la consommation de tabac.

**regulation of ingredients****problem definition**

Yes

**which option**



Establish a common list of tobacco ingredients

**which one**

Establish a positive common list of tobacco ingredients

**additional option**

/

**additional comments**

Les produits du tabac sont très toxiques, ainsi leur composition doit être étroitement réglementée afin d'atteindre des normes élevées de protection de la santé. Il est nécessaire d'établir une liste commune au niveau de l'UE afin que les consommateurs puissent profiter du même niveau de protection dans le marché intérieur. Actuellement, certains citoyens européens encourent le risque de consommer des substances interdites dans d'autres Etats membres. De plus, l'inégalité en termes de protection de la santé et d'information des consommateurs constitue aussi un obstacle à la libre circulation des marchandises dans le marché intérieur, car certains pays pourraient être réticents à importer des cigarettes d'autres États membres lorsque celles-ci ne sont pas conformes aux exigences nationales. L'utilisation des arômes n'est pas une nouveauté ainsi que l'attestent les documents internes de l'industrie du tabac. Le fabricant RJ Reynolds (JTI) indiquait ainsi en 1972 dans une note à propos de l'utilisation des arômes que «Le goût des fraises connaît une forte acceptabilité parmi le marché des jeunes». L'élément nouveau dans nombre de marchés, et notamment celui de la France, est le développement exponentiel de l'utilisation des arômes au cours S'agissant des arômes les plus acidulés, les objectifs poursuivis par les fabricants de tabac sont de masquer l'âcreté du produit pour les plus jeunes, de proposer ainsi un produit d'initiation permettant de capter l'intérêt des enfants et de les faire évoluer vers d'autres produits de la gamme au fur et à mesure qu'ils grandissent. Globalement l'utilisation de ces arômes conduit à une banalisation et à une altération de la perception des produits du tabac comme des produits dangereux. L'acte de fumer est assimilé à un simple geste de gourmandise ou encore à un accessoire de type parfum pour les produits aux arômes de fleurs ... alors que ces produits sont tout aussi dangereux que les autres. Par ailleurs, le produit en tant que tel est de plus en plus conçu de manière attractive via notamment l'utilisation de papier de couleur ou de papier à cigarettes illustrées par de grands designers. (ex paquets Vogue jour, Vogue Nuit ou Pink Elephant ...) Les arômes et additifs de goût sont des outils de marketing de l'industrie du tabac et sont mis en place à l'attention particulière des jeunes. Les arômes permettent de renforcer l'attractivité, d'encourager l'initiation des jeunes et de décourager l'arrêt. L'interdiction des ingrédients qui peuvent être utilisés pour augmenter l'attractivité - comme les sucres et les édulcorants, les substances aromatisées, les épices et les herbes- devrait être introduite. L'interdiction des ingrédients qui peuvent donner l'impression d'être bon pour la santé (vitamines par exemple), des ingrédients associés au regain d'énergie et à la vitalité (par exemple, la caféine), et des ingrédients avec des propriétés colorantes (par exemple le papier à cigarette coloré) devrait également être introduite. Enfin, les fabricants de tabac et les importateurs doivent communiquer des informations sur le volume des ventes par marque. Cette information est essentielle pour permettre aux gouvernements de s'assurer que la réglementation des produits est respectée et efficace. Les mesures ci-dessus doivent prendre en compte les dispositions des articles 9 et 10 de la Convention-cadre pour la lutte antitabac (CCLAT) et de ses lignes directrices, adoptées en novembre dernier à l'occasion de la 4<sup>e</sup> Conférence des Parties en Uruguay.

**access to tobacco products**

**problem definition**

Yes

**which option**

Ban

**which one2**

Cross-border retail sales of tobacco to be banned over the Internet; Vending machines to be banned; Promotion and displays in retail stores to be banned

**additional option**

L'interdiction de la promotion des produits du tabac sur le point de vente et l'interdiction des distributeurs automatiques ont une finalité différente des contrôles des ventes transfrontalières. L'interdiction de la vente sur Internet est une disposition additionnelle permettant de lutter contre la contrebande et la contrefaçon des produits du tabac, mais aussi contre la vente de tabac aux mineurs. La directive devrait également rappeler aux gouvernements nationaux qu'ils doivent adopter une interdiction globale de toutes les formes de publicité pour le tabac, la promotion et le parrainage des produits du tabac conformément à l'article 13 de la CCLAT . Nous demandons à la Commission l'instauration d'une interdiction de toute publicité et promotion sur les lieux de vente, conformément aux engagements pris à Durban, lors de la 3ème Conférence des Parties à la CCLAT en novembre 2008 (adoption des lignes directrices de l'article 13).

**additional comments**

- Internet : Afin de protéger la santé publique, le principe du contrôle de la promotion et la publicité transfrontalière de produits du tabac a été inscrit dans la directive publicité pour le tabac (2001/0119). Il est donc logique d'étendre ce principe à la vente des produits du tabac entre les États membres via Internet. La France, quant à elle, prévoit un dispositif d'interdiction d'achat des produits du tabac sur internet ou à distance : "Les débiteurs ne peuvent vendre du tabac qu'aux clients présents dans l'enceinte du débit. Il leur est interdit de vendre du tabac par correspondance ou par réseaux informatiques" . En l'absence d'harmonisation des législations, en particulier au niveau des différents Etats Membres de l'Union Européenne, cette disposition protectrice trouve néanmoins son efficacité réduite. En limitant les possibilités d'accès aux produits, on restreint non seulement l'offre et également la demande, et par ailleurs, on est davantage en mesure de contrôler cette offre et de lutter contre toute forme de commerce illicite des produits du tabac. - Réglementation sur les lieux de ventes : Un nombre croissant de preuves montre que la mise des produits du tabac hors de la vue des consommateurs chez les détaillants est une mesure permettant de réduire le tabagisme chez les jeunes. À ce jour, cette mesure a été adoptée par l'Irlande, le Royaume-Uni et la Finlande. L'adoption à l'échelle européenne d'une interdiction de l'étalage des produits du tabac au point de vente permettrait de renforcer le dispositif de protection de la santé au bénéfice de l'ensemble des citoyens européens. En France, les produits du tabac sont vendus dans les débits de tabac et il existe une exception au principe d'interdiction de toute publicité dans ces lieux, cette exception est cependant strictement encadrée et était initialement justifiée par un souci d'information en direction des consommateurs. Ainsi la publicité : - ne doit pas être visible de l'extérieur du débit ; - doit être exclusivement sous la forme d'une affichette d'un format maximal de 60 x 80 cm ; - cette affichette ne peut comporter d'autres mentions que la dénomination du produit, sa composition, ses caractéristiques et conditions de vente, à l'exception du prix, le nom et l'adresse du fabricant et, le cas échéant, du distributeur ; - cette affichette ne doit avoir aucune autre représentation graphique ou photographique que celle du

produit, de son emballage et de l'emblème de la marque ; - l'affichette doit également comporter un avertissement sanitaire, lui-même apposé selon des règles de taille, emplacement, formulation, bien précises. Une évaluation de cette réglementation vient d'être rendue publique et met en exergue que plus de 80 % des débits de tabac violent la réglementation en vigueur. Sur l'ensemble des PLV recensées, 88 % des publicités étaient illicites sur la forme (format affichette non respecté) ou sur le contenu (présence d'un slogan publicitaire, mention du prix, visuel autre que le produit du tabac etc..). De plus, il apparaît que ces supports sont conçus pour faire oublier la nature dangereuse du tabac en utilisant les codes publicitaires d'autres produits inoffensifs (bonbons, musique, jeux, produits high-tech...) souvent consommés par les jeunes. L'exception conçue à des fins d'information se trouve totalement détournée et a conduit les fabricants à développer toute une désinformation et une promotion de leurs produits. Cette évaluation met clairement en exergue la nécessité d'interdire strictement toute publicité sur le lieu de vente y compris au niveau de l'étal en raison de la permanence des détournements et des violations qui sont systématiquement faits dans le cas d'exception.

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## **NGO submission**

### **identification**

#### **affiliation**

NGO

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#### **country**

Finland

### **questions scope**

#### **problem definition**

Yes

#### **which option**

Extend the scope of the Directive

### **additional comments**

The aim of European tobacco policy should be in long run totally to eradicate smoking within EU and its Member States like Finland has decided. Because of this, the definition of tobacco and nicotine products is needed. The base of definition should be FCTC (see: preamble) and the final sentence of definition should: The tobacco and nicotine products are no ordinary commodities.

### **questions smokeless**

#### **problem definition**

Yes

**which option**

Ban on all types of smokeless tobacco products

**additional option**

EU and its Member States don't need novel tobacco products in the market, when the aim of tobacco policy is either to limit or stop smoking in EU.

**questions consumer****problem definition**

Yes

**which option**

Introduce generic or plain packaging

**additional option**

When introducing generic or plain packaging we should use only written warnings instead of pictorial warnings, when the aim is plain package (no colors, no pictures)

**questions on reporting****problem definition**

No

**explanations**

it is no sense to collect the information of all ingredients, because we very well know the high toxicity of tobacco products and because the aim of EU and Member States is to limit or to stop smoking. The aim is not to develop less toxic products, which is the aim of tobacco industry. The less toxic products are however toxic.

**which option**

Introduce fees and sanctions

**additional options**

Instead of collection of information of ingredients EU should ban the use of ingredient, which change the taste of tobacco products or are anesthetic etc. Information of tar, nicotine and CO contents are enough

**regulation of ingredients****problem definition**

Yes

**which option**

Introducing the basic criteria on the EU level without a common list

**access to tobacco products****problem definition**

Yes

**which option**

Ban

**which one2**

Cross-border retail sales of tobacco to be banned over the Internet; Vending machines to be banned; Promotion and displays in retail stores to be banned

**additional option**

If we have the definition of tobacco and nicotine products, which says, that the products are not ordinary commodities. EU and its Member States are easier to able to ban all cross border retail sales and even to limit supply of products or ban products etc

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**NGO submission****identification****affiliation**

NGO

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**country**

Finland

**questions scope****problem definition**

Yes

**which option**

No change

**recommend option**

While the scope of the directive could address also other products, it is important that any extension of the directive and consequent regulation is based on scientific studies and evidence.

**questions smokeless****problem definition**

Yes

**which option**

Lifting the ban on snus

**questions consumer****problem definition**

No

**explanations**

Regulation and restrictions should be based on definite evidence of their benefits for the public. This is not the case with bigger health warnings or plain packaging.

**which option**

No change

**questions on reporting****problem definition**

No

**explanations**

Enforcement of the directive including fees and sanctions should remain in the hands of the member states.

**which option**

Establish a common compulsory reporting format

**regulation of ingredients****problem definition**

No

**explanations**

Any regulation should be based on scientific evidence and the focus on ingredients should be in the toxicity of the smoke.

**which option**

No Change

**access to tobacco products****problem definition**

No

**explanations**

Regulation and restrictions should be based on definite evidence of their benefits for the public. This is not the case with age controlled vending machines or the display ban.

**which option**

No change

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**NGO submission****identification****affiliation**

NGO

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**country**

Portugal

**questions scope****problem definition**

Yes

**which option**

No change

**recommend option**

The scope of the Directive can be extended to cover these other products, but this should not include an automatic ban on one category of product (novel form of oral tobacco). Any bans should be based on scientific assessments.

**questions smokeless****problem definition**

Yes

**which option**

Lifting the ban on snus

**questions consumer****problem definition**

No

**explanations**

There is no evidence that warnings are more effective. There is no evidence that plain packaging would improve the functioning of the internet market or have any public health benefits. It would make it easier for criminals to copy legitimate brands and would lead to an increase in illegal sales of cigarettes.

**which option**

No change

**questions on reporting****problem definition**

No

**explanations**

Member States can already introduce fees and sanctions. Enforcement of the provisions of the Directive should remain the responsibility of the Member States.

**which option**

Establish a common compulsory reporting format

**regulation of ingredients****problem definition**

No

**explanations**

The focus of ingredients testing should be on whether the ingredients result in increased toxicity of tobacco smoke.

**which option**

No Change

**access to tobacco products****problem definition**

No

**explanations**

There is no clear problem stated as regards either vending machines or POSO. There is no evidence provided as to why bans would improve the functionality of the internet market or advance any public health objectives.

**which option**

No change

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**NGO submission****identification****affiliation**

NGO

**name**

ASOCIACION PROVINCIAL DE ESTANQUEROS DE GUADALAJARA

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**country**

España

**questions scope****problem definition**

Yes

**which option**

No change

**additional comments**

Nuestra asociación se muestra de acuerdo en una posible ampliación del ámbito de la Directiva en lo que se refiere a autorizar el uso de productos de tabaco oral (SNUS) en todo el



ámbito europeo.

**questions smokeless**

**problem definition**

No

**comments**

No hay evidencia científica sobre los riesgos relacionados con el consumo de productos de tabaco sin humo.

**which option**

Lifting the ban on snus

**questions consumer**

**problem definition**

No

**explanations**

Nuestra asociación podría llegar a compartir los intereses de la Unión Europea en pretender que el consumidor final cuente con información más exhaustiva del contenido de esos productos, pero no existen resultados contundentes que relacionen que el uso de imágenes de advertencia sobre el hábito del tabaco implique un mejor conocimiento del consumidor sobre los posibles efectos para la salud de ese tipo de productos.

**which option**

No change

**additional comments**

Nuestra Asociación entiende que la adopción de este tipo de medidas, como la adopción del paquete genérico, lejos de conseguir efectos positivos desde un punto de vista sanitario, fomentará que sea más difícil diferenciar los distintos productos existentes en el mercado y la consecuencia final que ello traerá consigo, tal y como sucede con los mercados de materias primas, es que las empresas competirán únicamente con el precio.

**questions on reporting**

**problem definition**

Yes

**which option**

Establish a common compulsory reporting format

**additional comments**

Nuestra Asociación podría mostrar su acuerdo en que se regulara a nivel europeo un formato de información común obligatorio, pudiendo basarse en la plantilla de información voluntaria desarrollada por la Comisión en mayo de 2007 para que la industria informe a los Estados miembros.

**regulation of ingredients**

**problem definition**

No

**explanations**

La adopción de medidas como una prohibición de ingredientes en los cigarrillos, podrían tener un efecto indeseado sobre el contrabando de este tipo de productos. Como conocedores de primera mano de las preferencias del consumidor español, podemos anticipar que en caso de que existiese una prohibición de ingredientes de forma que se llegase a un "cigarrillo genérico" contaríamos con un factor añadido para la proliferación del comercio ilegal de tabaco que escaparía a los controles sanitarios respecto de los ingredientes.

**which option**

No Change

**access to tobacco products****problem definition**

No

**which option**

Controlled supply and access

**which supply and access**

Age verification of buyers and other legal conditions to be set for cross-border retail sale;  
Access to vending machines to be restricted to adults

**additional comments**

La prohibición de la exhibición de los productos del tabaco en los puntos de venta supone un ataque a la libertad de comercio de un producto legal cuyo último reducto es el punto de venta, donde los adultos con intención de comprar pueden informarse de la variedad ofertada.

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**NGO submission****identification****affiliation**

NGO

**name**

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**country**

FRANCE

**questions scope****problem definition**

No

**explanations**

Pas d'accord car le problème, dans sa définition-même, exclut des produits ou segments de marchés qui sont précisément des façons pour l'industrie du tabac de prolonger, directement ou indirectement, son influence. Je pense ici, à titre d'exemple, aux « nicotine drinks », ou à l'« emerging market of nicotine sweets world »

**which option**

Extend the scope of the Directive

**recommend option**

L'option 2 qui envisage d'élargir le champs de la Directive

**additional comments**

Élargir le champs de la Directive (ou alors envisager une autre Directive) pour s'attaquer aux problématiques ayant un impact économique ou financier direct sur toute la filière des tabaculteurs : taxation des profits, mettre fin à la règle de non affectation des recettes fiscales qui est en vigueur dans certains États-Membres afin de pouvoir affecter une taxation des profits ou du chiffre d'affaires au budget de la sécurité sociale.

**questions smokeless**

**problem definition**

No

**comments**

Pas d'accord : nombre de médecins mettent sévèrement en cause l'effet positif des produits alternatifs (gommes, patch, etc). On répond à une addiction par la création d'une autre addiction...

**which option**

No change

**additional option**

Il ne s'agit pas d'interdire les produits dérivés (patch etc) mais de s'attaquer frontalement à la nicotine délivrée sous forme de cigarette

**questions consumer**

**problem definition**

Yes

**which option**

Improve consumer information

**which improvement**

Picture warnings to become mandatory; Information on harmful substances in tobacco products that cannot be placed on the package would be placed inside the package; Health warnings to be put on water pipes

**additional option**

Les informations qui figurent sur le paquet ne fournissent aucune information opérationnelle pour les fumeurs. Par ailleurs, plus le packaging sera « générique » et neutre, plus la notion de marque, de sensibilité, de préférence disparaîtra et plus, parallèlement, la notion d'addiction et

d'accoutumance sera présente dans l'esprit du consommateur. Sur l'option 2a « picture warning »: bien que l'on trouve toujours des études qui démontrent ce que l'on souhaite, il paraît (cf Royaume-Uni et Canada) que les pays ayant opté pour des photos chocs sur les paquets ont réussi à marquer les esprits. C'est d'ailleurs la même situation pour les questions de sécurité routière : la France a longtemps refusé de mettre en scène des accidents et vient de le faire car elle a dû se rendre à l'évidence à savoir que ces spots chocs sont efficaces.

### **questions on reporting**

#### **problem definition**

No

#### **explanations**

La question du secret de fabrication est une question ancienne et probablement sur-estimée. Les fabricants ont des secrets différents et pourtant un produit qui a le même effet néfaste (blondes ou des brunes, des menthol ou des « full flavour »). Cette question n'est sans doute pas à sur-estimer. Sauf, et c'est un grand sauf : sauf pour les secrets qui sont communs comme l'ajout de substance ayant pour effet d'améliorer la « prégnance » de la nicotine sur les poumons

#### **which option**

Establish a common compulsory reporting format; Introduce fees and sanctions

#### **additional options**

Forcer les fabricants à révéler les secrets génériques, contraires à la notion de santé publique. En clair : tout le monde sait que la nicotine est mauvaise pour la santé. Mais personne ne sait ce que la cigarette contient d'autres produits qui renforcent l'effet négatif. Il faut donc que l'industrie fasse preuve de transparence sur les composants.

### **regulation of ingredients**

#### **problem definition**

No

#### **explanations**

La notion même de light est une invention marketing stupide

#### **which option**

Establish a common list of tobacco ingredients

#### **which one**

Establish a negative common list of tobacco ingredients

#### **additional option**

Interdire les appellations mensongères telles que light, qui laissent penser qu'il y aurait une version moins nocive de la cigarette

### **access to tobacco products**

#### **problem definition**

Yes

#### **which option**

Controlled supply and access

**which supply and access**

Age verification of buyers and other legal conditions to be set for cross-border retail sale;  
Access to vending machines to be restricted to adults; Tobacco display and promotion at  
points of sales to be restricted

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**NGO submission**

**identification**

**affiliation**

NGO

**name**

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**country**

France

**questions scope**

**problem definition**

Yes

**which option**

No change

**questions smokeless**

**problem definition**

No

**comments**

Aucune expérience scientifique n'est en mesure de prouver que les tabacs sans fumée sont nocifs.

**which option**

Lifting the ban on snus

**questions consumer**

**problem definition**

No

**explanations**

Rien ne prouve que les paquets neutres inciteront les gens à moins fumer. Les photos chocs, c'est comme les mentions sanitaires, les fumeurs s'amuse à les collectionner, dans un premier temps, puis cela devient complètement banal. Le fait d'imposer des paquets neutres

amènera les fabricants à user de nouveaux stratégies pour garder leurs parts de marché, comme la guerre des prix. A force de vouloir ridiculiser les paquets de cigarettes, les consommateurs iront s'approvisionner sur des marchés parallèles, sur internet sur le marché chinois par exemple où ils achèteront de la cochonnerie qui les empoisonnera 2 fois plus. Et les buralistes Français, que deviendront-ils? eux qui assurent des missions de service public sur l'ensemble du territoire pour le compte de l'Etat? C'est le naufrage programmé de toute une profession, à savoir 150 000 emplois directs et indirects

**which option**

No change

**questions on reporting**

**problem definition**

No

**explanations**

Celà risque d'entraîner une standardisation de la production avec comme conséquence une diminution de l'offre au fumeur adulte et responsable et le risque de voire apparaître une augmentation des produits du tabac contrefaits.

**which option**

No change

**regulation of ingredients**

**problem definition**

Yes

**which option**

Establish a common list of tobacco ingredients

**which one**

Establish a positive common list of tobacco ingredients

**access to tobacco products**

**problem definition**

Yes

**which option**

Controlled supply and access; Ban

**which supply and access**

Age verification of buyers and other legal conditions to be set for cross-border retail sale

**which one2**

Cross-border retail sales of tobacco to be banned over the Internet; Vending machines to be banned

**additional comments**

Il n'y a pas de corrélation prouvée entre la disparition des linéaires tabac et la lutte contre le tabagisme. Les 28 000 buralistes Français sont tous des préposés de l'administration et sont

des gens responsables capables de mettre en oeuvre des actions de bon sens et ce au quotidien. Leur professionnalisme n'est plus à démontrer. Leur réseau fortement structuré et encadré, assure efficacement la distribution pour le compte de l'Etat d'un produit légal et générateur d'importantes recettes fiscales; le tabac, mais qui surtout répond à un cahier des charges précis sur le plan sanitaire. Il est regrettable que cette consultation européenne soit proposée dans la langue d'un pays qui n'a toujours pas adopté la monnaie unique. Cela limite l'accès à un grand nombre de personnes qui n'ont pu s'exprimer.

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## **NGO submission**

### **identification**

#### **affiliation**

NGO

#### **name**

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Sweden

#### **gender**

female

### **questions scope**

#### **problem definition**

Yes

#### **which option**

Extend the scope of the Directive

### **additional comments**

Alla tobaksprodukter är hälsofarliga. Vi menar därför att direktivet ska inkludera alla nya tobaksprodukter avsedda för rökning, samtidigt som förbud mot alla nya former av oral tobak, inkluderande snus, bibehålls. All inandning av förbränningsprodukter vid rökning är skadlig varför också örtcigaretter bör inkluderas i direktivet. Alla produkter som innehåller nikotin och som nu inte är klassade som tobaksprodukter, t ex elektroniska cigaretter, nikotingel, nikotindrinkar och nikotingodis, och marknadsförs som stöd vid rökavvänjning bör vara underställda samma säkerhets- och kvalitetskrav som gäller för farmaceutiska produkter.

### **questions smokeless**

#### **problem definition**

Yes

#### **which option**

No change

### **additional option**

Det är av högsta prioritet att behålla försäljningsförbudet för snus. Det finns ingen anledning att introducera ytterligare en hälsofarlig produkt. Erfarenheter från Sverige visar att snusbruk uppmuntrar till samtidig användning av cigaretter och snus och därigenom riskerar att minska benägenheten att komma ur nikotinberoendet. Fyra av tio dagligbrukare av snus är också rökare. Snus attraherar ungdomar till tobaksbruk. Fyra av tio dagligbrukare av snus har aldrig rökt. Det finns på marknaden i dag effektiva produkter inkluderande rena nikotinläkemedel som stöd för att sluta röka. Dessa ska i första hand användas som stöd och forskning intensifieras för att få fram ännu bättre läkemedel. Rökproblemet kan inte lösas genom att en ny tobaksprodukt introduceras av tobaksindustrin. Det är också värt att notera att andra rökfria produkter än snus marknadsförs i unionen. Eftersom användningen av dessa är marginell – mest framträdande i Storbritannien av invandrargrupper – kan man, å ena sidan, anse att ett försäljningsförbud för alla orala produkter inte är särskilt relevant. Å andra sidan kan man hävda att också dessa mindre befolkningsgrupper har rätt till det skydd för hälsan som ett försäljningsförbud avser att ge. I vilket fall bör dessa produkter regleras som tobaksprodukter.

### **questions consumer problem definition**

No

### **explanations**

Olikheten i märkning av tobaksprodukter på den inre marknaden är otillfredsställande – några länder har infört obligatoriska varningsbilder men de flesta har det inte. I dessa senare länder saknas den konsumentmedvetenhet och påverkan på konsumtionen som varningsbilder visat sig medföra. I Sverige är enligt Eurobarometern 2010 69 procent av befolkningen positiva till införande av bildvarningar. Vi välkomnar också insikten att tobaksförpackningar i sig alltmer utnyttjas som reklampelare för att öka konsumtionen. Fyrtioen procent av befolkningen i Sverige välkomnar införande av neutrala tobaksförpackningar enligt Eurobarometern 2010.

### **which option**

Improve consumer information; Introduce generic or plain packaging

### **which improvement**

Picture warnings to become mandatory; Tar, nicotine and carbon monoxide levels to be replaced with general information on harmful substances in tobacco products; Information on harmful substances in tobacco products that cannot be placed on the package would be placed inside the package; Health warnings to be put on water pipes

### **additional option**

Bildvarningar är överlägsna textvarningar. Det finns evidens för att bildvarningar är mer effektiva än textvarningar. Bilder ger en mer omedelbar reaktion och leder till att textvarningen uppmärksammas bättre. Det är underförstått att bildvarningar ska finnas på alla typer av tobaksprodukter, inte bara cigaretter.. Bildvarningar ska finnas på förpackningens två största sidor. Varningsbudskapets (text + bild) storlek har betydelse – ju större desto mer effektiva. Varningsbudskapen ska även växlas på förpackningarna i ett roterande system. Bilder av hälsoskador orsakade av rökning har, tillsammans med ”känslösa” bilder på barn och foster, visat sig vara mest effektiva. Effektiviteten ökar ytterligare om bilderna kombineras med telefonnummer till Sluta Röka-linje och om de i större utsträckning gendranpassas i enlighet med Tobakskonventionens artikel 4.2.d. Det är av högsta prioritet



att neutrala tobaksförpackningar införs! Detta innebär en standardisering av storlek och form och frånvaro av märkesspecifika kännetecken. Juridisk analys i samband med pågående införande i Australien visar att det inte finns några internationella juridiska hinder för införande av neutrala paket så som tobaksindustrin hävdar. Det är av högsta prioritet att numeriska uppgifter om nivå på nikotin och kolmonoxid ersätts med kvalitativ beskrivning av skadlig inverkan av innehållet i tobak och tobaksrök. De nu förekommande numeriska värdena har erhållits vid maskinrökta tester och är vilseledande. Hälsovarningar ska också finnas på vattenpipor och tobak som röks i dessa.

**questions on reporting**  
**problem definition**

Yes

**which option**

Establish a common compulsory reporting format; Introduce fees and sanctions

**additional comments**

Den nuvarande situationen med olika format och rapporteringssystem är helt otillfredsställande för alla parter. Ett nytt system – baserat på det Kommissionen utarbetat 2007 – är det minsta man kan kräva för tobaksprodukter som ju dödar i förtid varannan av sina långtidsanvändare. Årliga avgifter bör också tas ut för att bekosta hantering, analys, och bedömning av detta material samt kommunikering av resultatet till medborgarna.

**regulation of ingredients**  
**problem definition**

Yes

**which option**

Establish a common list of tobacco ingredients

**which one**

Establish a positive common list of tobacco ingredients

**additional comments**

Skapa en gemensam lista över ingredienser i tobaksprodukter Skapa en positiv gemensam lista över ingredienser i tobaksprodukter En gemensam lista som tillåter ett antal ingredienser bör skapas med avsikt att konsumenter i alla medlemsländer ska ha tillgång till samma nivå av hälsoskydd. Reglering av smaktillsatser är högt prioriterad eftersom sådana har ökat markant i produktionen för att öka attraktionen, särskilt hos unga, och minska benägenheten att sluta. Även ingredienser som ger sken av att ha hälsoeffekt, t ex vitamin, ge energi, t ex koffein, eller färgämnen bör regleras. Riktlinjerna till Tobakskonventionens artiklar 9/10, nyligen antagna vid COP 4, ska beaktas.

**access to tobacco products**  
**problem definition**

Yes

**which option**

Ban

**which one2**

Cross-border retail sales of tobacco to be banned over the Internet; Vending machines to be banned; Promotion and displays in retail stores to be banned

**additional option**

Riktlinjerna till Tobakskonventionens artikel 13 innehåller krav på dolda tobaksprodukter på säljstället och förbud mot försäljning genom tobaksautomater. Dessa riktlinjer måste respekteras.

**additional comments**

Principen att förbjuda gränsöverskridande reklam för tobaksprodukter för att skydda folkhälsan slås fast i Tobacco Advertising Directive (2001/01 19). Det är därför logiskt att också förbjuda försäljningen av tobaksvaror mellan länder via Internet. Tobaksautomater är redan förbjudna i 22 av 27 medlemsländer för att försvåra tillgängligheten för unga. Det är konsekvent att införa samma reglering i alla medlemsländer. Det finns en ökande grad av evidens för att dolda tobaksförpackningar på säljställen kan minska ungas rökning. Denna ordning bör därför införas i alla medlemsländer.

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**NGO submission****identification****affiliation**

NGO

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**country**

PORTUGAL

**age**

48

**gender**

female

**questions scope****problem definition**

Yes

**which option**

No change

**questions smokeless****problem definition**

Yes

**which option**

Lifting the ban on snus

**questions consumer**

**problem definition**

No

**explanations**

SAUDE

**which option**

No change

**questions on reporting**

**problem definition**

No

**explanations**

SIM

**which option**

Establish a common compulsory reporting format

**regulation of ingredients**

**problem definition**

No

**explanations**

SIM

**which option**

No Change

**access to tobacco products**

**problem definition**

No

**explanations**

S

**which option**

No change

---

**NGO submission**

**identification**

**affiliation**

NGO

**name**

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**email**

ingrid.talu@swipnet.se

**country**

Sweden

**gender**

female

**questions scope****problem definition**

Yes

**which option**

Extend the scope of the Directive

**additional comments**

Alla tobaksprodukter är hälsofarliga. Vi menar därför att direktivet ska inkludera alla nya tobaksprodukter avsedda för rökning, samtidigt som förbud mot alla nya former av oral tobak, inkluderande snus, bibehålls. All inandning av förbränningsprodukter vid rökning är skadlig varför också örtcigaretter bör inkluderas i direktivet. Alla produkter som innehåller nikotin och som nu inte är klassade som tobaksprodukter, t ex elektroniska cigaretter, nikotingel, nikotindrinkar och nikotingodis, och marknadsförs som stöd vid rökavvänjning bör vara underställda samma säkerhets- och kvalitetskrav som gäller för farmaceutiska produkter.

**questions smokeless****problem definition**

Yes

**which option**

No change

**additional option**

Det är av högsta prioritet att behålla försäljningsförbudet för snus. Det finns ingen anledning att introducera ytterligare en hälsofarlig produkt. Erfarenheter från Sverige visar att snusbruk uppmuntrar till samtidig användning av cigaretter och snus och därigenom riskerar att minska benägenheten att komma ur nikotinberoendet. Fyra av tio dagligbrukare av snus är också rökare. Snus attraherar ungdomar till tobaksbruk. Fyra av tio dagligbrukare av snus har aldrig rökt. Det finns på marknaden i dag effektiva produkter inkluderande rena nikotinläkemedel som stöd för att sluta röka. Dessa ska i första hand användas som stöd och forskning intensifieras för att få fram ännu bättre läkemedel. Rökproblemet kan inte lösas genom att en ny tobaksprodukt introduceras av tobaksindustrin. Det är också värt att notera att andra rökfria produkter än snus marknadsförs i unionen. Eftersom användningen av dessa är marginell – mest framträdande i Storbritannien av invandrargrupper – kan man, å ena sidan, anse att ett

försäljningsförbud för alla orala produkter inte är särskilt relevant. Å andra sidan kan man hävda att också dessa mindre befolkningsgrupper har rätt till det skydd för hälsan som ett försäljningsförbud avser att ge. I vilket fall bör dessa produkter regleras som tobaksprodukter.

### **questions consumer**

#### **problem definition**

No

#### **explanations**

Olikheten i märkning av tobaksprodukter på den inre marknaden är otillfredsställande – några länder har infört obligatoriska varningsbilder men de flesta har det inte. I dessa senare länder saknas den konsumentmedvetenhet och påverkan på konsumtionen som varningsbilder visat sig medföra. I Sverige är enligt Eurobarometern 2010 69 procent av befolkningen positiva till införande av bildvarningar. Vi välkomnar också insikten att tobaksförpackningar i sig alltmer utnyttjas som reklampelare för att öka konsumtionen. Fyrtioen procent av befolkningen i Sverige välkomnar införande av neutrala tobaksförpackningar enligt Eurobarometern 2010.

#### **which option**

Improve consumer information; Introduce generic or plain packaging

#### **which improvement**

Picture warnings to become mandatory; Tar, nicotine and carbon monoxide levels to be replaced with general information on harmful substances in tobacco products; Information on harmful substances in tobacco products that cannot be placed on the package would be placed inside the package; Health warnings to be put on water pipes

#### **additional option**

Bildvarningar är överlägsna textvarningar Det finns evidens för att bildvarningar är mer effektiva än textvarningar. Bilder ger en mer omedelbar reaktion och leder till att textvarningen uppmärksammas bättre. Det är underförstått att bildvarningar ska finnas på alla typer av tobaksprodukter, inte bara cigaretter.. Bildvarningar ska finnas på förpackningens två största sidor Varningsbudskapets (text + bild) storlek har betydelse – ju större desto mer effektiva Varningsbudskapen ska även växlas på förpackningarna i ett roterande system Bilder av hälsoskador orsakade av rökning har, tillsammans med ”känslösa” bilder på barn och foster, visat sig vara mest effektiva. Effektiviteten ökar ytterligare om bilderna kombineras med telefonnummer till Sluta Röka-linje och om de i större utsträckning gendranpassas i enlighet med Tobakskonventionens artikel 4.2.d. Det är av högsta prioritet att neutrala tobaksförpackningar införs! Detta innebär en standardisering av storlek och form och frånvaro av märkesspecifika kännetecken. Juridisk analys i samband med pågående införande i Australien visar att det inte finns några internationella juridiska hinder för införande av neutrala paket så som tobaksindustrin hävdar. Det är av högsta prioritet att numeriska uppgifter om nivå på nikotin och kolmonoxid ersätts med kvalitativ beskrivning av skadlig inverkan av innehållet i tobak och tobaksrök. De nu förekommande numeriska värdena har erhållits vid maskinrökta tester och är vilseledande. Hälsovarningar ska också finnas på vattenpipor och tobak som röks i dessa.

### **questions on reporting**

#### **problem definition**

Yes

**which option**

Establish a common compulsory reporting format; Introduce fees and sanctions

**additional comments**

Den nuvarande situationen med olika format och rapporteringssystem är helt otillfredsställande för alla parter. Ett nytt system – baserat på det Kommissionen utarbetat 2007 – är det minsta man kan kräva för tobaksprodukter som ju dödar i förtid varannan av sina långtidsanvändare. Årliga avgifter bör också tas ut för att bekosta hantering, analys, och bedömning av detta material samt kommunikering av resultatet till medborgarna

**regulation of ingredients****problem definition**

Yes

**which option**

Establish a common list of tobacco ingredients

**which one**

Establish a positive common list of tobacco ingredients

**additional comments**

Skapa en gemensam lista över ingredienser i tobaksprodukter Skapa en positiv gemensam lista över ingredienser i tobaksprodukter En gemensam lista som tillåter ett antal ingredienser bör skapas med avsikt att konsumenter i alla medlemsländer ska ha tillgång till samma nivå av hälsoskydd. Reglering av smaktillsatser är högt prioriterad eftersom sådana har ökat markant i produktionen för att öka attraktionen, särskilt hos unga, och minska benägenheten att sluta. Även ingredienser som ger sken av att ha hälsoeffekt, t ex vitamin, ge energi, t ex koffein, eller färgämnen bör regleras. Riktlinjerna till Tobakskonventionens artiklar 9/10, nyligen antagna vid COP 4, ska beaktas.

**access to tobacco products****problem definition**

Yes

**which option**

Ban

**which one2**

Cross-border retail sales of tobacco to be banned over the Internet; Vending machines to be banned; Promotion and displays in retail stores to be banned

**additional option**

Riktlinjerna till Tobakskonventionens artikel 13 innehåller krav på dolda tobaksprodukter på säljstället och förbud mot försäljning genom tobaksautomater. Dessa riktlinjer måste respekteras.

**additional comments**

Principen att förbjuda gränsöverskridande reklam för tobaksprodukter för att skydda folkhälsan slås fast i Tobacco Advertising Directive (2001/01 19). Det är därför logiskt att också förbjuda försäljningen av tobaksvaror mellan länder via Internet. Tobaksautomater är

redan förbjudna i 22 av 27 medlemsländer för att försvåra tillgängligheten för unga. Det är konsekvent att införa samma reglering i alla medlemsländer. Det finns en ökande grad av evidens för att dolda tobaksförpackningar på säljställen kan minska ungas rökning. Denna ordning bör därför införas i alla medlemsländer.

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## **NGO submission**

### **identification**

#### **affiliation**

NGO

#### **name**

The Swedish Society of Medicine President: Margareta Troein, MD, PhD

#### **email**

margareta.troein@med.lu.se

#### **country**

Sweden

#### **gender**

female

### **questions scope**

#### **problem definition**

Yes

#### **which option**

Extend the scope of the Directive

### **additional comments**

Alla tobaksprodukter är hälsofarliga. Vi menar därför att direktivet ska inkludera alla nya tobaksprodukter avsedda för rökning, samtidigt som förbud mot alla nya former av oral tobak, inkluderande snus, bibehålls. All inandning av förbränningsprodukter vid rökning är skadlig varför också örtcigaretter bör inkluderas i direktivet. Alla produkter som innehåller nikotin och som nu inte är klassade som tobaksprodukter, t ex elektroniska cigaretter, nikotingel, nikotindrinkar och nikotingodis, och marknadsförs som stöd vid rökavvänjning bör vara underställda samma säkerhets- och kvalitetskrav som gäller för farmaceutiska produkter.

### **questions smokeless**

#### **problem definition**

Yes

#### **which option**

No change

### **additional option**

Det är av högsta prioritet att behålla försäljningsförbudet för snus. Det finns ingen anledning

att introducera ytterligare en hälsofarlig produkt. Erfarenheter från Sverige visar att snusbruk uppmuntrar till samtidig användning av cigaretter och snus och därigenom riskerar att minska benägenheten att komma ur nikotinberoendet. Fyra av tio dagligbrukare av snus är också rökare. Snus attraherar ungdomar till tobaksbruk. Fyra av tio dagligbrukare av snus har aldrig rökt. Det finns på marknaden i dag effektiva produkter inkluderande rena nikotinläkemedel som stöd för att sluta röka. Dessa ska i första hand användas som stöd och forskning intensifieras för att få fram ännu bättre läkemedel. Rökproblemet kan inte lösas genom att en ny tobaksprodukt introduceras av tobaksindustrin. Det är också värt att notera att andra rökfria produkter än snus marknadsförs i unionen. Eftersom användningen av dessa är marginell – mest framträdande i Storbritannien av invandrargrupper – kan man, å ena sidan, anse att ett försäljningsförbud för alla orala produkter inte är särskilt relevant. Å andra sidan kan man hävda att också dessa mindre befolkningsgrupper har rätt till det skydd för hälsan som ett försäljningsförbud avser att ge. I vilket fall bör dessa produkter regleras som tobaksprodukter.

### **questions consumer problem definition**

No

### **explanations**

Olikheten i märkning av tobaksprodukter på den inre marknaden är otillfredsställande – några länder har infört obligatoriska varningsbilder men de flesta har det inte. I dessa senare länder saknas den konsumentmedvetenhet och påverkan på konsumtionen som varningsbilder visat sig medföra. I Sverige är enligt Eurobarometern 2010 69 procent av befolkningen positiva till införande av bildvarningar. Vi välkomnar också insikten att tobaksförpackningar i sig alltmer utnyttjas som reklampelare för att öka konsumtionen. Fyrtioen procent av befolkningen i Sverige välkomnar införande av neutrala tobaksförpackningar enligt Eurobarometern 2010.

### **which option**

Improve consumer information; Introduce generic or plain packaging

### **which improvement**

Picture warnings to become mandatory; Tar, nicotine and carbon monoxide levels to be replaced with general information on harmful substances in tobacco products; Information on harmful substances in tobacco products that cannot be placed on the package would be placed inside the package; Health warnings to be put on water pipes

### **additional option**

Bildvarningar är överlägsna textvarningar Det finns evidens för att bildvarningar är mer effektiva än textvarningar. Bilder ger en mer omedelbar reaktion och leder till att textvarningen uppmärksammas bättre. Bildvarningar ska finnas på förpackningens två största sidor Varningsbudskapets (text + bild) storlek har betydelse – ju större desto mer effektiva Varningsbudskapen ska även växlas på förpackningarna i ett roterande system Bilder av hälsoskador orsakade av rökning har, tillsammans med ”känslösa” bilder på barn och foster, visat sig vara mest effektiva. Effektiviteten ökar ytterligare om bilderna kombineras med telefonnummer till Sluta Röka-linje och om de i större utsträckning anpassas i enlighet med Tobakskonventionens artikel 4.2.d. Det är av högsta prioritet att neutrala tobaksförpackningar införs! Detta innebär en standardisering av storlek och form och frånvaro av märkesspecifika kännetecken. Juridisk analys i samband med pågående införande i Australien visar att det inte finns några internationella juridiska hinder för införande av neutrala paket så som tobaksindustrin hävdar. Det är av högsta prioritet att numeriska



avgifter om nivå på nikotin och kolmonoxid ersätts med kvalitativ beskrivning av skadlig inverkan av innehållet i tobak och tobaksrök. De nu förekommande numeriska värdena har erhållits vid maskinrökta tester och är vilseledande. Hälsovarningar ska också finnas på vattenpipor och tobak som röks i dessa.

### **questions on reporting**

#### **problem definition**

Yes

#### **which option**

Establish a common compulsory reporting format; Introduce fees and sanctions

#### **additional comments**

Den nuvarande situationen med olika format och rapporteringssystem är helt otillfredsställande för alla parter. Ett nytt system – baserat på det Kommissionen utarbetat 2007 – är det minsta man kan kräva för tobaksprodukter som ju dödar i förtid varannan av sina långtidsanvändare. Årliga avgifter bör också tas ut för att bekosta hantering, analys, och bedömning av detta material samt kommunikering av resultatet till medborgarna.

### **regulation of ingredients**

#### **problem definition**

Yes

#### **which option**

Establish a common list of tobacco ingredients

#### **which one**

Establish a positive common list of tobacco ingredients

#### **additional comments**

Skapa en gemensam lista över ingredienser i tobaksprodukter Skapa en positiv gemensam lista över ingredienser i tobaksprodukter En gemensam lista som tillåter ett antal ingredienser bör skapas med avsikt att konsumenter i alla medlemsländer ska ha tillgång till samma nivå av hälsoskydd. Reglering av smaktillsatser är högt prioriterad eftersom sådana har ökat markant i produktionen för att öka attraktionen, särskilt hos unga, och minska benägenheten att sluta. Även ingredienser som ger sken av att ha hälsoeffekt, t ex vitamin, ge energi, t ex koffein, eller färgämnen bör regleras. Riktlinjerna till Tobakskonventionens artiklar 9/10, nyligen antagna vid COP 4, ska beaktas.

### **access to tobacco products**

#### **problem definition**

Yes

#### **which option**

Ban

#### **which one2**

Cross-border retail sales of tobacco to be banned over the Internet; Vending machines to be banned; Promotion and displays in retail stores to be banned

**additional option**

Riktlinjerna till Tobakskonventionens artikel 13 innehåller krav på dolda tobaksprodukter på säljstället och förbud mot försäljning genom tobaksautomater. Dessa riktlinjer måste respekteras.

**additional comments**

Principen att förbjuda gränsöverskridande reklam för tobaksprodukter för att skydda folkhälsan slås fast i Tobacco Advertising Directive (2001/01 19). Det är därför logiskt att också förbjuda försäljningen av tobaksvaror mellan länder via Internet. Tobaksautomater är redan förbjudna i 22 av 27 medlemsländer för att försvåra tillgängligheten för unga. Det är konsekvent att införa samma reglering i alla medlemsländer. Det finns en ökande grad av evidens för att dolda tobaksförpackningar på säljställen kan minska ungas rökning. Denna ordning bör därför införas i alla medlemsländer.

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**NGO submission****identification****affiliation**

NGO

**name**

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**email**

hirscha@ligue-cancer.net

**country**

FRANCE

**questions scope****problem definition**

Yes

**which option**

Extend the scope of the Directive

**additional comments**

Tous les types de produits destinés à être fumés sont nocifs pour la santé et devrait être inclus dans le champ de la Directive.

**questions smokeless****problem definition**

Yes

**which option**

No change

**questions consumer**

**problem definition**

No

**explanations**

Il est nécessaire d'améliorer la définition du problème. Il faut en particulier soutenir l'apposition dans tous les pays européens d'avertissements sanitaires illustrés et également des emballages neutres.

**which option**

Improve consumer information; Introduce generic or plain packaging

**which improvement**

Picture warnings to become mandatory; Tar, nicotine and carbon monoxide levels to be replaced with general information on harmful substances in tobacco products; Information on harmful substances in tobacco products that cannot be placed on the package would be placed inside the package; Health warnings to be put on water pipes

**additional option**

Les études menées sur l'impact des avertissements sanitaires montrent que les messages qui cumulent texte et images sont les plus efficaces Il est recommandé que ces avertissement couvre au moins 80% de la surface sur laquelle ils sont apposés. Il est également nécessaire qu'une rotation suffisante des messages soit organisée afin de ne pas laisser le consommateur.

**questions on reporting****problem definition**

Yes

**which option**

Establish a common compulsory reporting format; Introduce fees and sanctions

**regulation of ingredients****problem definition**

Yes

**which option**

Establish a common list of tobacco ingredients

**which one**

Establish a positive common list of tobacco ingredients

**access to tobacco products****problem definition**

Yes

**which option**

Ban

**which one2**

Cross-border retail sales of tobacco to be banned over the Internet; Vending machines to be banned; Promotion and displays in retail stores to be banned

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## **NGO submission**

### **identification**

#### **affiliation**

NGO

#### **name**

Peggy Maguire, European Institute of womens Health

#### **email**

peg@eurohealth.ie

#### **country**

Ireland

#### **gender**

female

### **questions scope**

#### **problem definition**

Yes

#### **which option**

Extend the scope of the Directive

### **additional comments**

There is an urgent need to make tobacco control policies and interventions gender sensitive and take account of the socio-economic status of vulnerable and ethnic minority groups.

### **questions smokeless**

#### **problem definition**

Yes

#### **which option**

Ban on all types of smokeless tobacco products

### **questions consumer**

#### **problem definition**

Yes

#### **which option**

Improve consumer information; Introduce generic or plain packaging

### **which improvement**

Picture warnings to become mandatory; Tar, nicotine and carbon monoxide levels to be replaced with general information on harmful substances in tobacco products; Information on harmful substances in tobacco products that cannot be placed on the package would be placed inside the package; Health warnings to be put on water pipes

**additional option**

Tobacco use is rising rapidly particularly among young women. Smoking-related diseases are a major public health challenge, requiring effective prevention programmes targeted at young girls and women. Women who have never smoked appear to at 2 to 3 times greater risk than men who have never smoked. Policies and interventions need to be gender-sensitive and targeted at women focusing on poorer, socially disadvantaged and vulnerable groups.

**additional comments**

Women play a key role in the health of their children. This starts with pregnancy and continues through to the child-rearing years for which women still carry the major share. Being exposed to second-hand tobacco smoke during pregnancy has a devastating effect on their off-spring. Children are particularly vulnerable to the effects of passive smoking. Anti-smoking campaigns must be targeted at young women with convincing messages to women during pre-natal care when they may be most receptive to advice.

**questions on reporting****problem definition**

Yes

**which option**

Establish a common compulsory reporting format; Introduce fees and sanctions

**regulation of ingredients****problem definition**

Yes

**which option**

Establish a common list of tobacco ingredients

**which one**

Establish a positive common list of tobacco ingredients; Establish a negative common list of tobacco ingredients

**access to tobacco products****problem definition**

Yes

**which option**

Controlled supply and access; Ban

**which supply and access**

Age verification of buyers and other legal conditions to be set for cross-border retail sale; Access to vending machines to be restricted to adults; Tobacco display and promotion at points of sales to be restricted

**which one2**

Cross-border retail sales of tobacco to be banned over the Internet; Vending machines to be banned; Promotion and displays in retail stores to be banned

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## **NGO submission**

### **identification**

#### **affiliation**

NGO

#### **name**

Carl V. Phillips, PhD, on behalf of TobaccoHarmReduction.org

#### **email**

cvphilo@gmail.com

#### **country**

U.S. and Canada

### **questions scope**

#### **problem definition**

No

### **explanations**

We disagree with the implicit claim that just because e-cigarettes are clearly alternatives to smoking that it is necessarily appropriate to regulate them as part of this directive. It may well be appropriate for them to be regulated under this directive, but there are many alternatives to smoking that would not be appropriately regulated under this directive, and therefore that observation is not sufficient. Moreover, the devices are not generally marketed explicitly as alternatives because of regulatory concerns by reputable merchants. The observation that these are marketed without prior authorization indicates an unstated and unjustified presumption that prior authorization should be demanded. The use of the term “nicotine sweets” is intentionally inflammatory and inappropriate for government that claims to be considering policies. It suggests a lack of seriousness on the part of the writer. There are properly neutral accepted terms, such as “dissolvable tobacco/nicotine products”. Similarly, though not as extreme, the use of the neologism “ENDS” for products that have an accepted natural language name is inappropriate; these terms have been created by an extremist political faction to try to confuse the public and seize control over the products, and anyone who uses those terms is intentionally choosing to associate with that particular faction and invokes their biased research and pseudo-research (which uses that term) to the exclusion of the larger body of real research that uses the accepted terminology. (See <http://ep-ology.blogspot.com/2010/12/extremists-use-of-terminology-to-bully.html> for further discussion.) The conflation of herbal cigarettes and low-risk smokeless nicotine products is extremely misleading. The former are likely equally harmful as cigarettes, as you note, while the risks from the latter are likely to be too small to be detected.

### **which option**

No change

### **recommend option**

It is not clear what “the problem” is. The introduction of e-cigarettes and dissolvable nicotine products as substitutes for smoking is quite the opposite of a problem. Differing regulations in

different countries provides much needed natural experiments when there is rampant speculation about ideal policies. From a social welfare standpoint there is no problem defined in the “problem definition”. The only problem seems to be the desire of regulators to expand their power. Given only these two options, Option 1 is clearly better than Option 2. Whatever the flaws in Option 1, the suggestions in the loaded posing of the question and the details of Option 2 make it clear that any expansion of authority would lead to aggressive restriction of low-risk alternatives to smoking. This would be a disaster for public health in places like the UK and Germany where e-cigarette have gained popularity and might substantially reduce smoking prevalence (as snus would likely have done but for the ban). There are some useful points in Option 2, even though taken as a whole it would cause much more harm than good: - Regulating non-tobacco cigarettes alongside regular cigarettes makes sense. -Developing quality control regulation for e-cigarettes is something that needs to be done. Though these products are very low-risk and there has never been a major manufacturing problem, there remains a risk of serious contamination or other problems. It is likely that only a Western government is capable of doing anything about this currently. Thus, this would be a valuable contribution. However, this would do more harm than good if it was simply a crypto-prohibition or even if it was a well meaning “do not allow until it can be proven that quality is controlled”. Either one of these would likely destroy the local market and cause users to return to smoking. The ideal policy would regulate all products that basically substitute for each in the same market (cigarettes, snus, other Western smokeless tobacco, e-cigarettes, pharmaceutical nicotine) in the same way. Health assessments of new products would be made with reference to the products that they would displace (almost entirely cigarettes at this time) and they would be prohibited if and only if they were more harmful than the substituted product. By that standard, since these other popular nicotine products are about 99% less harmful than cigarettes, until cigarettes are no longer popular every one of these substitute products should be welcomed into the market. Herbal cigarettes are rather an oddity and regulating them as regular cigarettes or even more stringently would seem to be a net benefit. Regulating odd nicotine product with unknown properties and that have not already been used enough to make a clear assessment (drinks, dermal gels) calls for research and appropriate quality control. Indian- or African-style smokeless tobacco products that differ substantially from modern Western products (like snus) are worth some further consideration; though the evidence is rather sketchy, these products may be enough more harmful than Western smokeless tobacco or e-cigarettes that they should be treated differently. However since they are undoubtedly less harmful than smoking, restricting them would only be good if users were allowed to switch to Western-style smokes tobacco products rather than being forced to start smoking.

### **questions smokeless**

#### **problem definition**

No

#### **comments**

There are substantive important flaws in this statement: There is not, in fact, scientific support for the claim that modern Western smokeless tobacco products cause cancer. The evidence makes it quite clear that any such risk is extremely small and shows that it cannot be distinguished from the null (which is to say, the evidence is quite consistent with there being absolutely no such risk). To say that there may be some tiny risk based on all we know is reasonable; to flatly declare that there is a risk is simply incorrect. There is somewhat more reason to believe that there are cardiovascular effects, since nicotine is a mild stimulant and most mild stimulants that we have been able to study effectively seem to cause some excess

risk of cardiovascular event. As with cancer risk, there are a few studies that can be cherry-picked to claim there is affirmative evidence of risk, but taken as a whole the epidemiology does not show there is measurable risk. On the point of magnitude, no statement of the risks from smokeless tobacco can be valid without reference to the risks from the product for which it is a substitute, cigarettes. It is not enough to just know that smokeless tobacco causes some non-zero risk of disease – this statement is true about everything, and so making it is merely inflammatory, not informative. It is particularly useless information when the risk is so extremely small compared to the substitute behavior, smoking. Flying on an airplane has nonzero risk, but if the alternative is riding a motorcycle the risk of flying is so trivial as to hardly matter. This does not mean that flight safety is not worth improving, but it does mean that plane crashes should not be viewed in isolation. Addressing the (largely hypothetical and undoubtedly very low) risks from snus without comparison can only be seen as intentionally misleading. The simplistic declaration that these products are addictive is also inappropriate in a serious discussion. The term “addictive” is a colloquialism that lacks an accepted scientific or medical definition. As commonly used, it can mean anything from simply “likes in any way” up to “is so captivating that it rapidly destroys someone’s life”; in many cases “is addicted” is used to simply denote “uses”. These make it useless for serious discourse and inappropriate for official government statements. Moreover, when considering what most people mean when they use the term, most of the evidence suggests that smokeless tobacco is not addictive for most users. It certainly does not seem to be “addictive” in any way that is terribly destructive to individuals or society. The claim, “substitution of smoking by the use of smokeless tobacco products would probably decrease the incidence of some tobacco-related diseases”, while literally true, is so understated that it must be considered false. There is overwhelming evidence that substitution of snus for smoking would definitely reduce the overall incidence of disease, and as far as we can tell it would reduce the risk of every “tobacco-related” disease and not increase the risk of any disease. The use of “probably” and “some” is indefensible, and seems intended to mislead the reader. There is overwhelming evidence about the successful use of smokeless tobacco as a substitute for smoking in Sweden, the United States, and Norway. Many who oppose tobacco harm reduction for personal political reasons persist in pretending that there is no such evidence – despite the obvious substitution of snus for smoking in the Swedish population, the epidemiologic studies, and the countless personal reports – but to repeat this claim is either extremely naïve or complicit in the disinformation. (...continued in "additional specific comments"...)

### **which option**

Lifting the ban on snus

### **additional option**

Option 2 is clearly best. The ban on snus is a strange and deadly accident of political history. No one would even consider banning snus sales today if there were no such restriction existed. The rule persists only because of inertia. This is a terrible reason for a prohibition to exist, particularly one that causes so much harm to public health. Appropriate health warnings would be of great value. The appropriate health warning is something along the lines of “this probably causes some small disease risk, though we are not sure; it is estimated to 99% less harmful than smoking”. There seems to be outsized distress that snus is banned while other similar products that differ only in popularity (and perhaps because some of them are a bit more harmful) are legal. But this is of trivial consequence – to anyone but regulators – compared the huge harm being done by preventing the exporting of Sweden’s great success in reducing smoking prevalence. To improve on Option 2, snus should be not just allowed but should be actively promoted by the government as a better substitute for smoking.



### **additional comments**

(...continued from errors in the problem definition...) By contrast, there is no reason to believe that smokeless tobacco use causes smoking to any measurable degree. A reading of the claims of such evidence that have been made by anti- smokeless-tobacco activists makes it clear that they simply show that that people who like one nicotine product are more likely to like another. There is not a shred of evidence that actually shows causation, that someone who would not have smoked becomes a smoker because of exposure to snus. Of course, it is reasonable to predict that at least one person who never would have smoked otherwise would try snus and later go on to smoke. But this speculative individual is overwhelmed by the many who would not smoke because they had snus as an option. (Just think about it: If snus use causes more smoking, why is there so little smoking in Sweden?) Also absent from the problem definition is the fact that the current policy interferes with free trade. Moreover, it encourages the criminal activity that great demand for a restricted product inevitably generates. While this is not our main area of concern, it seems odd that it is not included in the statement.

### **questions consumer problem definition**

No

### **explanations**

Contrary to widespread assertions, there is no evidence that aggressive labeling has any effect on consumption in populations that already know that smoking is risky (which obviously includes 21st century Europe). There is certainly no possibility for better informing people about the risks, since there is virtually no one who does not already know them (and, in fact, most people overestimate the major risks). Thus the only possibility is that such labels could create disgust or otherwise inflict psychological violence on users and thereby manipulate them, via non-informational pathways, into reducing their consumption. It is not valid to describe such manipulations as “warnings”. Any effect of labeling policies that have been implemented (other than the initial labels that were part of the initial education about the risks almost a half century ago) is so small that it cannot be detected given the noise from time trends, short-term demand shocks from unknown sources, measurement error, and effects of prices. There is certainly no evidence that larger warnings are more effective; it should be obvious from common-sense knowledge of how people think and act that no magical effect will be achieved by expanding the label. Statistical games can be used to “show” most anything, but it should be pretty clear that the actual statistical association is just the opposite: The small original warning labels coincided with the greatest reduction in smoking ever, while recent large or graphic labels could not have caused any major decreases (because there have been no recent major decreases). The existing product labeling is, of course, used to promote brands, though to call it an advertising tool (other than by directing the consumer to the brand, since it communicates no other information beyond “this is what is contained in here”) or suggesting it attracts consumers (other than to their favored brand) seem without basis. Certainly saying that it is “increasingly” doing this is flatly wrong, since it has always done it. It is difficult to imagine how a package label could convey glamour, let alone freedom. It is even more difficult to imagine how it could distract from the stark warning label (or, for that matter, why doing so would matter, given that all smokers already know the information contained in the warning). It is true that labels about chemical composition or delivery, technical information that consumers cannot really understand (and may even misinterpret as being added ingredients that cause the health risk), are a bad idea for

prominent product labeling, whatever the product. However, consumers' perception that less of particular harmful chemicals is better than more is certainly more accurate than the insinuation in problem definition that this is false. The absurdity of this "problem definition" lies in the subtext. If you do not want consumers finding and smoking their favorite brands or knowing which brands have milder flavor because those make it nicer to be a smoker, then you are obviously looking for a way to punish smokers for smoking. There is no health benefit in causing consumers to choose a product other than the one they prefer. But no explanation other than wanting to harass users is apparent for lamenting such information communication. This appears to be "warning theater", performing something that looks like warning while actually just trying to put on a show and perhaps create annoyance. The concern about varying labeling requirements creating trade confusion seems valid, though it also seems to be of little practical consequence beyond the convenience of merchants. The upside of the varying requirements is a natural experiment, which will likely demonstrate that these rules about labels have no detectable effect on consumption. The worst flaw in this discussion of labeling is the lack of what would be the most useful information: inter-category comparisons (see below).

### **which option**

No change

### **additional option**

None of the options address the real problem, the lack of the most useful information. Given the choices, the best option is probably Option 1, no change. Since none of the proposals are likely to accomplish anything, keeping the present system would at least have the advantage of continuing the natural experiment. Since labeling of this sort has no significant effects on anyone, none of the proposals is likely to do much harm either. The one exception is plain packaging, which makes it particularly easy for low-quality operations to make and sell counterfeit black-market product, with all that implies. Option 2d labeling of "water pipes" (which people actually call hookahs, by the way) to communicate that they are roughly as harmful as cigarettes (so long as the claim is that this is true if and only if they are used in a similar way) could be useful for public health. It appears that some users do not understand this, in contrast with the universal knowledge of the harm from cigarettes. It cannot be called the "most effective option", though, because it is in no way exclusive of any of the other options (or the better option listed below). Also, implementing this seems rather challenging without an enormous expansion of regulatory control over the glass vessel and tube sector, since it will be difficult to define what exactly constitutes a hookah. Perhaps you should instead considering labeling the shisha (which, by the way, is what most people call the tobacco used in "water pipes"). The only new label on cigarettes that could possibly have any substantial effect on consumption would be something like "cigarettes are by far the most harmful way to use nicotine or tobacco; you should consider trying snus, e-cigarettes, or pharmaceutical nicotine instead". This communicates the only important piece of information (i.e., the only actual warning) that people do not already know. Short of something like this, it is difficult to imagine that fiddling with the labels will accomplish anything worthwhile.

### **questions on reporting**

#### **problem definition**

No

### **explanations**

The statement seems fine except for the last two words: There is no such thing as an

addictiveness test. There are tests that some people have labeled as such, and some of them may test for something useful. But since neither they nor anyone else defines what is meant by addictiveness (other than circularly, as what their favorite test detects), it is impossible to test for it, let alone quantify its intensity.

**which option**

Establish a common compulsory reporting format

**additional options**

Harmonization of requirements seems to have no downside, so long as it is not used as a backdoor method of pursuing other goals. It should not, however, require chimerical evidence about degree of addictiveness or differences in health effects based only on analyzing the product and not health outcomes; there is no science currently available that could provide useful measures. The devil is in the details, however, and we do not consider any of the proposed options to be detailed enough to assess. It is not clear that these requirements would have any impact on public health, as opposed to just on commerce. Requirements about health-relevant reporting would have to follow from evidence about what ingredients actually affect health.

**regulation of ingredients**

**problem definition**

No

**explanations**

The actual problem stated here is another case of simplifying commerce. The attempt to dress it up as a public health concern is baseless, given that there is simply no evidence that particular flavoring ingredients change the harmfulness of smoking.

**which option**

No Change

**additional comments**

Option 1 seems like the only defensible choice. While harmonization is, by itself, better in many ways, it seems quite likely that this harmonization would be used as a method for forcing the lowering of the quality of cigarettes (i.e., taking away some of the taste benefits of smoking without changing the health effects). If the EU wants to consider banning cigarettes, they should consider it. But regulators should not be allowed to pursue backdoor bans of legal product by sabotaging them (see: <http://ep-ology.blogspot.com/2010/08/fda-regulation-of-tobacco-as.html>). Option 3 requires chimerical evidence that is either undefined (degree of addictiveness), unknown (harm from particular ingredients), or likely to be abused as part of a backdoor ban (what people like)

**access to tobacco products**

**problem definition**

No

**explanations**

Chasing after specific market pathways is popular among those who want to pretend to be pursuing anti-smoking but wish to avoid any serious fights. What undermines tobacco control efforts more than anything else is the fact that tobacco can be bought at the corner store.

Going after fringe sales pathways is just “tobacco control theater”. (This is not to say that we recommend banning all tobacco sales, which we certainly do not. It is intended to illustrate the oddity of this particular concern.) Internet and other inter-jurisdiction sales are a good way to avoid taxes and restrictions in general – there is nothing particularly unique about tobacco.

**which option**

No change

**additional option**

We do not actually argue that there should be no change, but the way the checkboxes are set up, it is impossible to give a better answer than that. Option 2a, verifying the age of people ordering nicotine products, seems reasonable and appropriate. Vending machine restrictions, Option 2b or even 3b, might be wise also, though some evidence is needed to show that the benefits of doing this (i.e., that there is actually substantial underage sale via vending machines that would not happen through other channels) exceed the presumably minor inconvenience it would cause; we have no knowledge that would allow us to judge and will not opine on matters we are not informed about. Point-of-sale display restrictions – Option 2c and more so Option 3c – on the other hand, are a terrible idea. It is probably the most effective way to prevent smokers from learning about low- risk alternatives. Such restrictions did exactly this in Canada, basically shutting down a budding harm reduction effort there. There is no known benefit from such a policy; smokers and want-to-be smokers will not somehow forget where they can buy cigarettes. Additionally, small British retailers have loudly proclaimed that it comes at great expense to them, with no offsetting benefit (except for some of their large retail competitors) and their claims seem credible. Option 3a would be similarly bad for public health. Cross-border sales are a great safety valve for misguided government prohibitions. In this case, they are best hope for reducing the harmful effects of the snus ban and other current restrictions. Taking away this option would force those who have learned about low-risk alternatives in spite of the restrictions to return to smoking. It would also be a great boon to black marketers. However, it is not entirely clear that there is actually a problem, so it is difficult to say what would effectively address it.

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**questions scope**  
**problem definition**  
Yes

**which option**  
Extend the scope of the Directive

**additional comments**  
There is an Urgent need to make tobacco control policies and interventions gender sensitive and take account of the socio-economic status of vulnerable and ethnic minority groups

**questions smokeless**  
**problem definition**  
Yes

**which option**  
Ban on all types of smokeless tobacco products

**questions consumer**  
**problem definition**  
Yes

**which option**  
Improve consumer information; Introduce generic or plain packaging

**which improvement**  
Picture warnings to become mandatory; Tar, nicotine and carbon monoxide levels to be replaced with general information on harmful substances in tobacco products; Information on harmful substances in tobacco products that cannot be placed on the package would be placed inside the package; Health warnings to be put on water pipes

**questions on reporting**  
**problem definition**  
Yes

**which option**  
Establish a common compulsory reporting format; Introduce fees and sanctions

**regulation of ingredients**  
**problem definition**  
Yes

**which option**  
Establish a common list of tobacco ingredients

**which one**  
Establish a positive common list of tobacco ingredients; Establish a negative common list of tobacco ingredients

**access to tobacco products****problem definition**

Yes

**which option**

Controlled supply and access; Ban

**which supply and access**

Age verification of buyers and other legal conditions to be set for cross-border retail sale; Access to vending machines to be restricted to adults; Tobacco display and promotion at points of sales to be restricted

**which one2**

Cross-border retail sales of tobacco to be banned over the Internet; Vending machines to be banned; Promotion and displays in retail stores to be banned

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**NGO submission****identification****affiliation**

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**questions scope****problem definition**

Yes

**which option**

Extend the scope of the Directive

**additional comments**

Alla tobaksprodukter är hälsofarliga. Vi menar därför att direktivet ska inkludera alla nya tobaksprodukter avsedda för rökning, samtidigt som förbud mot alla nya former av oral tobak, inkluderande snus, bibehålls. All inandning av förbränningsprodukter vid rökning är skadlig varför också örtcigaretter bör inkluderas i direktivet. Alla produkter som innehåller nikotin och som nu inte är klassade som tobaksprodukter, t ex elektroniska cigaretter, nikotingel,

nikotindrinkar och nikotingodis, och marknadsförs som stöd vid rökavvänjning bör vara underställda samma säkerhets- och kvalitetskrav som gäller för farmaceutiska produkter.

#### **questions smokeless**

##### **problem definition**

Yes

##### **which option**

No change

##### **additional option**

Det är av högsta prioritet att behålla försäljningsförbudet för snus. Det finns ingen anledning att introducera ytterligare en hälsofarlig produkt. Erfarenheter från Sverige visar att snusbruk uppmuntrar till samtidig användning av cigaretter och snus och därigenom riskerar att minska benägenheten att komma ur nikotinberoendet. Fyra av tio dagligbrukare av snus är också rökare. Snus attraherar ungdomar till tobaksbruk. Fyra av tio dagligbrukare av snus har aldrig rökt. Det finns på marknaden i dag effektiva produkter inkluderande rena nikotinläkemedel som stöd för att sluta röka. Dessa ska i första hand användas som stöd och forskning intensifieras för att få fram ännu bättre läkemedel. Rökproblemet kan inte lösas genom att en ny tobaksprodukt introduceras av tobaksindustrin. Det är också värt att notera att andra rökfria produkter än snus marknadsförs i unionen. Eftersom användningen av dessa är marginell – mest framträdande i Storbritannien av invandrargrupper – kan man, å ena sidan, anse att ett försäljningsförbud för alla orala produkter inte är särskilt relevant. Å andra sidan kan man hävda att också dessa mindre befolkningsgrupper har rätt till det skydd för hälsan som ett försäljningsförbud avser att ge. I vilket fall bör dessa produkter regleras som tobaksprodukter.

#### **questions consumer**

##### **problem definition**

No

##### **explanations**

Olikheten i märkning av tobaksprodukter på den inre marknaden är otillfredsställande – några länder har infört obligatoriska varningsbilder men de flesta har det inte. I dessa senare länder saknas den konsumentmedvetenhet och påverkan på konsumtionen som varningsbilder visat sig medföra. I Sverige är enligt Eurobarometern 2010 69 procent av befolkningen positiva till införande av bildvarningar. Vi välkomnar också insikten att tobaksförpackningar i sig alltmer utnyttjas som reklampelare för att öka konsumtionen. Fyrtioen procent av befolkningen i Sverige välkomnar införande av neutrala tobaksförpackningar enligt Eurobarometern 2010.

##### **which option**

Improve consumer information; Introduce generic or plain packaging

##### **which improvement**

Picture warnings to become mandatory; Tar, nicotine and carbon monoxide levels to be replaced with general information on harmful substances in tobacco products; Information on harmful substances in tobacco products that cannot be placed on the package would be placed inside the package; Health warnings to be put on water pipes

##### **additional option**

Bildvarningar är överlägsna textvarningar Det finns evidens för att bildvarningar är mer

effektiva än textvarningar. Bilder ger en mer omedelbar reaktion och leder till att textvarningen uppmärksammas bättre. Bildvarningar ska finnas på förpackningens två största sidor. Varningsbudskapets (text + bild) storlek har betydelse – ju större desto mer effektiva. Varningsbudskapen ska även växlas på förpackningarna i ett roterande system. Bilder av hälsoskador orsakade av rökning har, tillsammans med ”känslösamma” bilder på barn och foster, visat sig vara mest effektiva. Effektiviteten ökar ytterligare om bilderna kombineras med telefonnummer till Sluta Röka-linje och om de i större utsträckning gendranpassas i enlighet med Tobakskonventionens artikel 4.2.d. Det är av högsta prioritet att neutrala tobaksförpackningar införs! Detta innebär en standardisering av storlek och form och frånvaro av märkesspecifika kännetecken. Juridisk analys i samband med pågående införande i Australien visar att det inte finns några internationella juridiska hinder för införande av neutrala paket så som tobaksindustrin hävdar. Det är av högsta prioritet att numeriska uppgifter om nivå på nikotin och kolmonoxid ersätts med kvalitativ beskrivning av skadlig inverkan av innehållet i tobak och tobaksrök. De nu förekommande numeriska värdena har erhållits vid maskinrökta tester och är vilseledande. Hälsovarningar ska också finnas på vattenpipor och tobak som röks i dessa.

**questions on reporting**  
**problem definition**

Yes

**which option**

Establish a common compulsory reporting format; Introduce fees and sanctions

**additional comments**

Den nuvarande situationen med olika format och rapporteringssystem är helt otillfredsställande för alla parter. Ett nytt system – baserat på det Kommissionen utarbetat 2007 – är det minsta man kan kräva för tobaksprodukter som ju dödar i förtid varannan av sina långtidsanvändare. Årliga avgifter bör också tas ut för att bekosta hantering, analys, och bedömning av detta material samt kommunikering av resultatet till medborgarna.

**regulation of ingredients**  
**problem definition**

Yes

**which option**

Establish a common list of tobacco ingredients

**which one**

Establish a positive common list of tobacco ingredients

**additional comments**

En gemensam lista som tillåter ett antal ingredienser bör skapas med avsikt att konsumenter i alla medlemsländer ska ha tillgång till samma nivå av hälsoskydd. Reglering av smaktillsatser är högt prioriterad eftersom sådana har ökat markant i produktionen för att öka attraktionen, särskilt hos unga, och minska benägenheten att sluta. Även ingredienser som ger sken av att ha hälsoeffekt, t ex vitamin, ge energi, t ex koffein, eller färgämnen bör regleras. Riktlinjerna till Tobakskonventionens artiklar 9/10, nyligen antagna vid COP 4, ska beaktas.

**access to tobacco products**



**problem definition**

Yes

**which option**

Ban

**which one2**

Cross-border retail sales of tobacco to be banned over the Internet; Vending machines to be banned; Promotion and displays in retail stores to be banned

**additional option**

Riktlinjerna till Tobakskonventionens artikel 13 innehåller krav på dolda tobaksprodukter på säljstället och förbud mot försäljning genom tobaksautomater. Dessa riktlinjer måste respekteras.

**additional comments**

Principen att förbjuda gränsöverskridande reklam för tobaksprodukter för att skydda folkhälsan slås fast i Tobacco Advertising Directive (2001/01 19). Det är därför logiskt att också förbjuda försäljningen av tobaksvaror mellan länder via Internet. Tobaksautomater är redan förbjudna i 22 av 27 medlemsländer för att försvåra tillgängligheten för unga. Det är konsekvent att införa samma reglering i alla medlemsländer. Det finns en ökande grad av evidens för att dolda tobaksförpackningar på säljställen kan minska ungas rökning. Denna ordning bör därför införas i alla medlemsländer.

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**questions scope****problem definition**

Yes

**which option**

No change

**recommend option**

O Âmbito da directiva pode ser estendido para cobrir esses produtos, mas isto não deve incluir a proibição automática de uma categoria de produtos (novas formas de tabaco ORAL) QUALQUER proibição deverá ser baseadas em avaliações científicas.

**questions smokeless****problem definition**

Yes

**which option**

Lifting the ban on snus

**questions consumer****problem definition**

No

**explanations**

NÃO HÁ EVIDÊNCIAS de que as advertências MAIOR SÃO MAIS EFECTIVAS. Não há nenhuma evidência de que a embalagem incolor irá MELHORAR O FUNCIONAMENTO DO MERCADO INTERNO OU TEM ALGUMA benefícios de saúde pública. Além disso, tornaria mais fácil para os criminosos copiarem as MARCAS E LEGÍTIMAS, levariam a um incremento da venda ilegal de cigarros.

**which option**

No change

**questions on reporting****problem definition**

No

**explanations**

Os Estados-membros já podem taxar e criar sanções. Aplicação das disposições da directiva deverá continuar a ser responsabilidade dos ESTADOS-MEMBROS.

**which option**

Establish a common compulsory reporting format

**regulation of ingredients****problem definition**

No

**explanations**

O foco do teste de ingredientes deve ser sobre se o resulta do do aumento da toxidade da fumaça do tabaco

**which option**

No Change

## **access to tobacco products**

### **problem definition**

No

### **explanations**

A exposição dos produtos de tabaco no ponto de venda é crucial para o que o consumidor possa visualizar os produtos de tabaco no acto da compra e assim exercer livremente a sua escolha e é particularmente importante para que os consumidores tomem conhecimento sobre a disponibilidade de novos produtos ou marcas, bem como de produtos importados. Acresce que, a não exposição das marcas dos produtos (designadamente, através de máquinas de venda automática de tabaco) tende a favorecer grandemente a venda das marcas mais conhecidas em detrimento das marcas de tabaco de menor circulação. No que à segurança respeita, em Portugal a venda de tabaco em máquinas automáticas é realizada exclusivamente em estabelecimentos comerciais e obrigatoriamente com recurso a dispositivos de bloqueio. Tal quer dizer que a verificação da idade dos possíveis compradores é comprovada pelos responsáveis dos estabelecimentos comerciais de forma activa, garantindo que não há menores que adquirem tabaco. Por outro lado, temos é, aliás, nossa a firme convicção que as máquinas de venda automática de tabaco, desde que dotadas de dispositivos de bloqueio, como é o caso em Portugal, constituem a forma mais eficaz de prevenir o acesso por parte de jovens menores de idade aos produtos de tabaco. As máquinas automáticas de venda de tabaco contribuem também activamente para impedir a venda de tabaco contrafeito ou contrabandeado. Na verdade, o tabaco vendido nas máquinas de venda automática é fiscalizado regularmente pela Autoridade de Segurança Alimentar e Económica, sendo eficazmente punidas as vendas ou tentativas de vendas de tabaco contrafeito ou que não tenha sido objecto de tributação. Nessa medida, proibir a venda de tabaco nas máquinas automáticas de venda é potenciar a venda de tabaco contrafeito ou contrabandeado, o qual poderá ser vendido ilicitamente .por nem sempre existirem as condições mais adequadas à fiscalização da respectiva venda directa pelos retalhistas. No que à contrafacção respeita, é importante reter que no ano de 2010 em Portugal foram já apreendidos 42 milhões de cigarros, num valor superior a sete milhões de Euros. Todo o tabaco contrafeito não apreendido pelas autoridades portuguesas pode, com alguma facilidade, ser comercializado directamente junto dos consumidores, mas não poderá, definitivamente, ser comercializado em máquinas de venda automática. De um ponto de vista de mercado e financeiro em Portugal, uma medida de proibição de venda de tabaco em máquinas automáticas teria graves consequências económicas para os grossistas de tabaco. Independentemente de eventuais considerações sobre a redução de venda de produto e do impacto que isso teria nos resultados das empresas e no emprego gerado pelas mesmas (que são aqui menos importantes), é fundamental que se retenham os seguintes factos: a) existem em Portugal cerca de 50000 máquinas de venda de tabaco, que representam cerca de 40% da venda de tabaco ao consumidor; b) cada máquina representa para o grossista um investimento médio (a preços actuais) de €2000.; c) a colocação de máquinas de venda automática no mercado obrigou os grossistas a avultados investimentos e à contracção de empréstimos bancários; d) o parque de máquinas de venda automática em funcionamento no mercado representa um investimento global dos grossistas superior a cem milhões de euros; a)e) as máquinas de venda automática de tabaco não são reconvertíveis para venda de outros produtos. Termos em que a proibição da venda de tabaco em máquinas automáticas importará para os grossistas de tabaco em Portugal uma perda imediata superior a cem milhões de euros. Tudo visto e ponderado, é convicção de que uma eventual proibição de venda de tabaco em máquinas automáticas causará graves problemas ao

mercado e que, ao invés, a manutenção da venda de tabaco por máquinas automáticas se constitui como um pilar fundamental contra a venda de tabaco contrafeito nos mercados.

**which option**

No change

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**NGO submission**

**identification**

**affiliation**

NGO

**name**

Dentistry Against Tobacco Sweden Chair: Lena Sjöberg

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**country**

Sweden

**gender**

female

**questions scope**

**problem definition**

Yes

**which option**

Extend the scope of the Directive

**additional comments**

Alla tobaksprodukter är hälsofarliga. Vi menar därför att direktivet ska inkludera alla nya tobaksprodukter avsedda för rökning, samtidigt som förbud mot alla nya former av oral tobak, inkluderande snus, bibehålls. All inandning av förbränningsprodukter vid rökning är skadlig varför också örtcigaretter bör inkluderas i direktivet. Alla produkter som innehåller nikotin och som nu inte är klassade som tobaksprodukter, t ex elektroniska cigaretter, nikotingel, nikotindrinkar och nikotingodis, och marknadsförs som stöd vid rökavvänjning bör vara underställda samma säkerhets- och kvalitetskrav som gäller för farmaceutiska produkter.

**questions smokeless**

**problem definition**

Yes

**which option**

No change

**additional option**

Det är av högsta prioritet att behålla försäljningsförbudet för snus. Det finns ingen anledning att introducera ytterligare en hälsofarlig produkt. Erfarenheter från Sverige visar att snusbruk uppmuntrar till samtidig användning av cigaretter och snus och därigenom riskerar att minska benägenheten att komma ur nikotinberoendet. Fyra av tio dagligbrukare av snus är också rökare. Snus attraherar ungdomar till tobaksbruk. Fyra av tio dagligbrukare av snus har aldrig rökt. Det finns på marknaden i dag effektiva produkter inkluderande rena nikotinläkemedel som stöd för att sluta röka. Dessa ska i första hand användas som stöd och forskning intensifieras för att få fram ännu bättre läkemedel. Rökproblemet kan inte lösas genom att en ny tobaksprodukt introduceras av tobaksindustrin. Det är också värt att notera att andra rökfria produkter än snus marknadsförs i unionen. Eftersom användningen av dessa är marginell – mest framträdande i Storbritannien av invandrargrupper – kan man, å ena sidan, anse att ett försäljningsförbud för alla orala produkter inte är särskilt relevant. Å andra sidan kan man hävda att också dessa mindre befolkningsgrupper har rätt till det skydd för hälsan som ett försäljningsförbud avser att ge. I vilket fall bör dessa produkter regleras som tobaksprodukter.

**questions consumer  
problem definition**

No

**explanations**

Olikheten i märkning av tobaksprodukter på den inre marknaden är otillfredsställande – några länder har infört obligatoriska varningsbilder men de flesta har det inte. I dessa senare länder saknas den konsumentmedvetenhet och påverkan på konsumtionen som varningsbilder visat sig medföra. I Sverige är enligt Eurobarometern 2010 69 procent av befolkningen positiva till införande av bildvarningar. Vi välkomnar också insikten att tobaksförpackningar i sig alltmer utnyttjas som reklampelare för att öka konsumtionen. Fyrtioen procent av befolkningen i Sverige välkomnar införande av neutrala tobaksförpackningar enligt Eurobarometern 2010.

**which option**

Improve consumer information; Introduce generic or plain packaging

**which improvement**

Picture warnings to become mandatory; Tar, nicotine and carbon monoxide levels to be replaced with general information on harmful substances in tobacco products; Information on harmful substances in tobacco products that cannot be placed on the package would be placed inside the package; Health warnings to be put on water pipes

**additional option**

Bildvarningar är överlägsna textvarningar Det finns evidens för att bildvarningar är mer effektiva än textvarningar. Bilder ger en mer omedelbar reaktion och leder till att textvarningen uppmärksammas bättre. Bildvarningar ska finnas på förpackningens två största sidor Varningsbudskapets (text + bild) storlek har betydelse – ju större desto mer effektiva Varningsbudskapen ska även växlas på förpackningarna i ett roterande system Bilder av hälsoskador orsakade av rökning har, tillsammans med ”känsllosamma” bilder på barn och foster, visat sig vara mest effektiva. Effektiviteten ökar ytterligare om bilderna kombineras med telefonnummer till Sluta Röka-linje och om de i större utsträckning gendranpassas i enlighet med Tobakskonventionens artikel 4.2.d. Det är av högsta prioritet att neutrala tobaksförpackningar införs! Detta innebär en standardisering av storlek och form och frånvaro av märkesspecifika kännetecken. Juridisk analys i samband med pågående införande i Australien visar att det inte finns några internationella juridiska hinder för införande av

neutrala paket så som tobaksindustrin hävdar. Det är av högsta prioritet att numeriska uppgifter om nivå på nikotin och kolmonoxid ersätts med kvalitativ beskrivning av skadlig inverkan av innehållet i tobak och tobaksrök. De nu förekommande numeriska värdena har erhållits vid maskinrökta tester och är vilseledande. Hälsovarningar ska också finnas på vattenpipor och tobak som röks i dessa.

**questions on reporting**  
**problem definition**

Yes

**which option**

Establish a common compulsory reporting format; Introduce fees and sanctions

**additional comments**

Den nuvarande situationen med olika format och rapporteringssystem är helt otillfredsställande för alla parter. Ett nytt system – baserat på det Kommissionen utarbetat 2007 – är det minsta man kan kräva för tobaksprodukter som ju dödar i förtid varannan av sina långtidsanvändare. Årliga avgifter bör också tas ut för att bekosta hantering, analys, och bedömning av detta material samt kommunikering av resultatet till medborgarna.

**regulation of ingredients**  
**problem definition**

Yes

**which option**

Establish a common list of tobacco ingredients

**which one**

Establish a positive common list of tobacco ingredients

**additional comments**

En gemensam lista som tillåter ett antal ingredienser bör skapas med avsikt att konsumenter i alla medlemsländer ska ha tillgång till samma nivå av hälsoskydd. Reglering av smaktillsatser är högt prioriterad eftersom sådana har ökat markant i produktionen för att öka attraktionen, särskilt hos unga, och minska benägenheten att sluta. Även ingredienser som ger sken av att ha hälsoeffekt, t ex vitamin, ge energi, t ex koffein, eller färgämnen bör regleras. Riktlinjerna till Tobakskonventionens artiklar 9/10, nyligen antagna vid COP 4, ska beaktas.

**access to tobacco products**  
**problem definition**

Yes

**which option**

Ban

**which one2**

Cross-border retail sales of tobacco to be banned over the Internet; Vending machines to be banned; Promotion and displays in retail stores to be banned

**additional option**

Riktlinjerna till Tobakskonventionens artikel 13 innehåller krav på dolda tobaksprodukter på säljstället och förbud mot försäljning genom tobaksautomater. Dessa riktlinjer måste respekteras.

### **additional comments**

Principen att förbjuda gränsöverskridande reklam för tobaksprodukter för att skydda folkhälsan slås fast i Tobacco Advertising Directive (2001/01 19). Det är därför logiskt att också förbjuda försäljningen av tobaksvaror mellan länder via Internet. Tobaksautomater är redan förbjudna i 22 av 27 medlemsländer för att försvåra tillgängligheten för unga. Det är konsekvent att införa samma reglering i alla medlemsländer. Det finns en ökande grad av evidens för att dolda tobaksförpackningar på säljställen kan minska ungas rökning. Denna ordning bör därför införas i alla medlemsländer.

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### **NGO submission**

#### **identification**

##### **affiliation**

NGO

##### **name**

Partners of the Dutch Partnership on Smoking Cessation: Royal Dutch Medical Association (KNMG), Royal Dutch Pharmacists Association (KNMP), Dutch College of General Practitioner (NHG), National Primary Healthcare Organization (GGD), Netherlands Public Health Federation (NPHF)

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##### **country**

the Netherlands

##### **questions scope**

##### **problem definition**

Yes

##### **which option**

Extend the scope of the Directive

##### **additional comments**

ivm het sterk verslavende karakter van de stof nicotine, dient men ervoor te waken dat andere nicotineproducten vrij de markt op komen. Dit zijn verbasteringen van nicotinevervangers en dienen derhalve goedgekeurd te worden door de daartoe ingestelde instanties

##### **questions smokeless**

##### **problem definition**

Yes

##### **which option**

No change

**additional comments**

Ook snuss en andere rookloze tabaksproducten zijn schadelijk voor de gezondheid en zijn verslavend. Ze zouden daarom niet toegelaten moeten worden op de Europese markt. Toelating op de markt zal de sociale norm van tabaksgebruik niet verbeteren, en mogelijk ook gebruik van sigaretten in stand houden. Ook het toelaten van andere rookloze tabaksproducten zal niet bijdragen aan het denormaliseren van roken.

**questions consumer  
problem definition**

No

**explanations**

We erkennen dat de interne markt er last van ondervindt dat het toepassen van grafische waarschuwingen binnen de EU landen verschilt. Dit leidt uiteindelijk ook tot verschil in kennis over de gevolgen van roken en dus tot verschil in rookgedrag. Daarbij kan worden geconcludeerd dat verpakkingen van tabaksproducten gebruikt worden om een schadelijk product aantrekkelijk te maken en reclame ervoor te maken. Er is ruimte voor verbetering en concretisering van de probleem definitie. Het zou goed zijn om het marketing van tabaksproducten via de verpakkingen ook onder deze directive te laten vallen. Er blijkt breed draagvlak te zijn voor het invoeren van plaatjes op de pakjes in heel Europa (aldus de Eurobarometer van 2010). Gemiddeld is 75% van de EU bevolking voorstander van het invoeren van plaatjes op de pakjes en meer dan de helft is voorstander van 'plain packaging'.

**which option**

Improve consumer information; Introduce generic or plain packaging

**which improvement**

Picture warnings to become mandatory; Tar, nicotine and carbon monoxide levels to be replaced with general information on harmful substances in tobacco products; Information on harmful substances in tobacco products that cannot be placed on the package would be placed inside the package; Health warnings to be put on water pipes

**additional option**

Onderzoek toont aan dat tekstuele waarschuwingen minder effectief zijn dan plaatjes op de pakjes. Plaatjes, in het bijzonder de angstaanjagende uitingen maken gebruikers bewuster van de boodschap – ze roepen meteen een reactie op die ertoe leidt dat mensen ook de teksten lezen. Het verwijzen naar een nationaal telefoonnummer voor het krijgen van ondersteuning bij stoppen zal leiden tot succesvolle stoppogingen. Plaatjes zouden aan beide zijden van de verpakking moeten zitten om het grootste resultaat te kunnen realiseren en de afbeeldingen zouden moeten roteren. De grootte van de plaatjes dient ongeveer 80% van de verpakking te bedekken. Waarschuwingen dienen op alle vormen van tabaksproducten te worden vermeld, dus ook op waterpijpen. Aanvullend op grafische waarschuwingen is het introduceren van plaatjes op de pakjes noodzakelijk. Een enkel land heeft dit reeds ingevoerd en sommige landen overwegen dit. Ten tijde van de implementatie van deze herziene richtlijn is de kans reëel dat plain packaging heel gebruikelijk is. Het niet nu op nemen in deze directive, is een gemiste kans. Juridisch is er geen enkele belemmering om dit in te voeren.

**additional comments**



Op dit moment hebben 7 lidstaten plaatjes op de pakjes geïntroduceerd. Dit leidt tot ongelijkheid in de interne markten. Het is daarom wenselijk dat plaatjes op de pakjes worden opgenomen in deze Directive zodat in de EU minder verschil is hierover.

### **questions on reporting**

#### **problem definition**

Yes

#### **which option**

Establish a common compulsory reporting format; Introduce fees and sanctions

#### **additional comments**

De huidige systematiek van verschillende formats en rapportagemethodieken is ingewikkeld en lastig te vergelijken met elkaar. Het is wenselijk om een methodiek te gebruiken, waar alle industrieën zich aan moeten houden. Alleen dan is het mogelijk om goede analyses te maken en besluiten te nemen tbv veiligheid en informatievoorziening. Een dergelijk format bestaat al (2007) en kan derhalve eenvoudig ingevoegd worden. Een jaarlijkse bijdrage kan ertoe bijdragen dat er budget is voor het nauwkeurig analyseren van de gegevens en onderzoek te doen naar toxicologische en verslavende werking. Hetzelfde geldt voor het bestraffen van overtredingen met geldboetes. Als uiteindelijk alleen geregistreerde producten op de markt worden toegelaten, is smokkel en namaak ook eenvoudig te bestrijden.

### **regulation of ingredients**

#### **problem definition**

Yes

#### **which option**

Establish a common list of tobacco ingredients

#### **which one**

Establish a positive common list of tobacco ingredients

#### **additional comments**

Vanwege de verslavende en schadelijke werking van ingrediënten van tabaksproducten, is het belangrijk om deze zo goed mogelijk te reguleren. Het bijhouden van lijsten van ingrediënten is daarom belangrijk. Dit kan leiden tot betere bescherming voor de gezondheid doordat verboden toevoegingen eenvoudig kunnen worden bestraft. Het toevoegen van smaakjes aan stoffen is een belangrijke manier voor de industrie om hun product aantrekkelijk te maken voor, met name jonge, rokers. Ze weerhouden rokers er over het algemeen ook van om te stoppen met roken. Door bepaalde ingrediënten te verbieden, zoals suikers, kruiden, zullen de producten minder aantrekkelijk zijn, met name voor jonge rokers. Toevoegingen die misleidend kunnen werken door de schijn te wekken dat een product gezonder is, vanwege het toevoegen van vitamines, of die middels cafeïne geassocieerd worden met energie en vitaliteit en aantrekkelijk worden gemaakt door gekleurd papier te gebruiken, dienen ook verboden te worden. Tijdens de COP4 in Uruguay onlangs zijn de hiervoor relevante richtlijnen 9 en 10 geadopteerd.

### **access to tobacco products**

#### **problem definition**

Yes

**which option**

Ban

**which one2**

Cross-border retail sales of tobacco to be banned over the Internet; Vending machines to be banned; Promotion and displays in retail stores to be banned

**additional comments**

internet Het verbieden van verkoop via het internet heeft alleen zin als dit in heel Europa effectief is. Dit kan daarom niet nationaal geregeld worden en hoort thuis in deze Directive. Tabaksautomaten Er zijn slechts 2 lidstaten die geen regelgeving hebben op automaten – gelijke regelgeving in heel Europa is ook mbt deze vorm van promotie belangrijk. Verkooppunten In geheel Europa bestaat regelgeving op het toestaan van reclame in verkooppunten. In toenemende mate is echter bekend dat het uit het zicht halen van tabaksproducten op verkooppunten bijdraagt aan minder rokende jongeren. Een aantal lidstaten heeft deze maatregel reeds ingevoerd of is dit van plan. Ook hier geldt dat het voorkeur verdient dit op EU niveau te regelen.

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**NGO submission****identification****affiliation**

NGO

**name**

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**country**

Guatemala

**age**

32

**gender**

female

**questions scope****problem definition**

No

**explanations**

La Directiva debería ampliar su alcance a otros productos, sin embargo no estamos de acuerdo con que la prohibición también se haga de forma automática sobre una categoría de productos específicos , como por ejemplo las formas novedosas de tabaco de uso oral. Consideramos

que cualquier prohibición, debe estar respaldada por valoraciones científicas.

**which option**

No change

**questions smokeless**

**problem definition**

Yes

**which option**

Lifting the ban on snus

**additional option**

Muchos adultos en los países de Europa utilizan varios sustitutos o formas de tabaco, consideramos que siendo adultos pueden o no tener la opción de comprar el snus que es un producto menos dañino que los cigarrillos convencionales. Creemos importante levantar la prohibición del uso de snus.

**questions consumer**

**problem definition**

No

**explanations**

Esta demostrado que las personas no reaccionan favorablemente a las advertencias de mayor tamaño y tampoco persuaden el uso o no de los cigarrillos. Tampoco y desde que este tema se regula, se ha evidenciado un beneficio en la salud pública o bien se haya disminuído el uso del tabaco.

**which option**

No change

**questions on reporting**

**problem definition**

No

**explanations**

Los Estados Miembros de la Unión Europea, pueden introducir tarifas y sancioines, este es un tema que deben seguir regulando los propios Estados y no convertirlas en políticas o directivas de caracter comunitario.

**which option**

Establish a common compulsory reporting format

**regulation of ingredients**

**problem definition**

No

**explanations**

El enfoque de las pruebas de los ingredientes, deberían tener en sí los ingredientes dan como resultado un aumento en la toxicidad del humo del tabaco.

**which option**

No Change

**access to tobacco products****problem definition**

No

**explanations**

No se ha aportado evidencia científica de que por qué las advertencias aparecen, esto mejoraría sustancialmente el funcionamiento del mercado interno o lograrían algún progreso en la consecución de los objetivos de la salud pública. Por lo que tampoco debería aplicar a las máquinas expendedoras de cigarrillos o bien puntods de exhibición o venta.

**which option**

No change

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**NGO submission****identification****affiliation**

NGO

**name**

Freedom Organisation for the Right to Enjoy Smoking Tobacco (FOREST)

**email**

contact@forestonline.org

**country**

United Kingdom

**questions scope****problem definition**

No

**explanations**

We believe the problem definition is fundamentally flawed, notably the focus on electronic nicotine delivery systems (ENDS) and nicotine drinks and other products that do not contain tobacco and are therefore beyond the scope of a revised Tobacco Products Directive. In our view the consultation not only ignores the very important issue of consumer choice, it is also looking for problems that do not exist. It is also our opinion that the EC should not be proposing further regulations and/or restrictions that are not based on clear scientific evidence. For these reasons FOREST supports Option 1: no change.

**which option**

No change

**questions smokeless  
problem definition**

No

**comments**

The problem definition considers this question from a regulator's perspective, not a consumers' perspective. The real problem, not addressed, is that the consumer is being denied a real choice of tobacco products, including smokeless tobacco products, in all European member states. Europe is supposed to be a single market. It is therefore wrong to deny consumers in all EU member states the opportunity to purchase a product that is freely available and widely used in another member state. Consumers want clear scientific evidence about the health risks of all tobacco products, including smokeless tobacco products. Beyond that consumers in a free society should be left to make their own choices about which tobacco products they wish to consume. For these reasons FOREST supports Option 2: lifting the ban on snus

**which option**

Lifting the ban on snus

**questions consumer  
problem definition**

No

**explanations**

We reject the suggestion that packaging is used as an "advertising tool". Packaging allows the consumer to differentiate between different brands. There is no credible evidence that packaging is a significant reason why anyone, let alone "vulnerable groups", start or even continue to smoke. It has been noted that the introduction of pictorial warnings have an initial downward impact on smoking rates, but in the medium to long-term picture warnings have far less impact as the consumer gets used to the imagery and simply ignores it. Regulators then propose increasing the size of the picture warning and so we go through the same process all over again, to very little overall effect. Increasing the size of the picture warning will, we believe, have little or no long-term impact other than adding to the unnecessary "uglification" of our surroundings and the unacceptable "denormalisation" of a legal consumer product. Opponents of picture warnings quite naturally ask "What's next? Graphic warnings on alcohol, fatty foods and dairy products?" The problem definition talks of "current package design ... generating evocative images such as luxury, freedom and glamour". Tobacco control campaigners often refer to "glitzy" packaging. Writing as a UK-based consumer group, we are not aware of ANY tobacco packaging that falls into these categories. "Glitzy" packaging? The problem does not exist. Finally, there is the bogus assumption that, with regard to information about, for example, lower levels of tar, "Some consumers might even decide to smoke or increase their consumption of cigarettes". On what evidence is this suggestion based? Anecdotal evidence or supposition is no basis for further regulation. A much bigger problem, not addressed by the problem definition, is the exaggerated "quit or die" message implicitly promoted by most health warnings, supported by pictorial warnings that are not only ugly and offensive but exaggerate the risks to most consumers. We do not question the health risks associated with smoking but we do question the way those risks are communicated to the general public. In our experience the health messages are now so gruesome (and run counter to most people's personal experience) that the opportunity to educate consumers in a sensible way is being lost. For these reasons FOREST supports

Option 1: no change.

**which option**

No change

**questions on reporting**

**problem definition**

No

**explanations**

No further comment

**which option**

No change

**regulation of ingredients**

**problem definition**

No

**explanations**

No further comment

**which option**

No Change

**access to tobacco products**

**problem definition**

No

**explanations**

The problem definition is extremely vague. There is an entire paragraph devoted to Internet sales of tobacco (a very minor issue in our experience), a passing reference to vending machines, and a reference to those countries that are proposing to ban the display of tobacco products in shops. With regard to vending machines and tobacco displays there is an unwritten, extremely biased assumption that vending machines and tobacco displays are a “problem” but it is not made clear what this “problem” is. For the record, FOREST does not want children to smoke and we support all reasonable measures that discourage or prevent children from accessing or purchasing tobacco. We support proof of age card schemes but we do not support further controls on the display of tobacco products. There is insufficient evidence to support the claim that such a move would reduce smoking rates among children or adults. Evidence from Canada and Iceland suggest that display bans have little or no effect on youth smoking rates. In the first 18 months of the display ban in the Canadian province of Saskatchewan, youth smoking rates increased from 27% to 29%. In the neighbouring province of Manitoba, where, at the time, there was no display ban, youth smoking declined from 28% to 23%. In Iceland youth smoking rates have remained virtually unchanged for a decade despite a display ban being in place since 2001. We do not believe that a ban on tobacco vending machines will reduce youth smoking rates. Instead it will restrict choice for adult consumers. Use of tokens, credit cards or radio-controlled vending machines would all but eliminate underage access without the need for a ban. We are concerned that increasing restrictions on tobacco displays and vending machines are designed to artificially

“denormalise” smoking and stigmatise adult consumers who choose to purchase a legal product in full knowledge of the health risks of smoking. Smokers do not impulse buy so banning product display will have little or no impact on their purchasing habits. The major beneficiaries of a display ban will be the larger retail stores who have both the space and the staff to provide designated counters where a far greater variety of brands will be available, albeit under the counter. The losers will be smaller retailers for whom the potential loss of revenue (to the larger stores) could put them out of business. Small retailers argue that a ban on tobacco display could cost them their business. If this happens, the ban will inconvenience not only adult smokers but many non-smokers as well. Banning tobacco display and vending machines will encourage illicit trade and the sale of counterfeit tobacco in pubs and bars. Not only will the governments lose revenue, consumers (including children) could be put at greater risk. A ban on tobacco displays is an act of commercial censorship that will eventually reduce choice for adult consumers because tobacco companies are less likely to develop new brands and products if their ability to communicate with their customers is severely restricted. Plain packaging: as long as tobacco remains a legal product, manufacturers must have the right to differentiate their products by means of graphic design and consumers should be allowed to differentiate easily between brands. We believe that plain packaging will make it substantially easier for criminals to supply illicit or counterfeit cigarettes. Young people take up smoking for a number of reasons, usually peer pressure or the influence of family members. There is no credible evidence that suggests that children are encouraged by the packaging to start smoking. We do not believe that plain packaging will have any effect on youth smoking rates, other than to make the act of smoking seem more illicit and that, for some children, will make it more not less attractive. For all these reasons FOREST supports Option 1: no change.

**which option**

No change

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**NGO submission**

**identification**

**affiliation**

NGO

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Belgium

**questions scope**

**problem definition**

Yes

**which option**

Extend the scope of the Directive

**recommend option**

PGEU agrees with the proposal to expand the scope of directive and address some additional issues that are not included in the current directive. In conjunction with measures proposed on packaging, labelling, visibility of tobacco products, we strongly believe it is important to provide help and support for those citizens that already smoke and wish to quit. Therefore, we would very much welcome inclusion of quit smoking helplines and reference to advice of healthcare professional on each pack of tobacco containing product.

**questions smokeless**

**problem definition**

Yes

**which option**

No change

**additional comments**

The prohibition on the marketing of tobacco for oral use ("snus") remains unchanged.

**questions consumer**

**problem definition**

Yes

**which option**

Introduce generic or plain packaging

**additional option**

PGEU believes that visibility and attractiveness of tobacco products should be minimised and support should be offered for those wishing to quit. This can be achieved when: - Introducing mandatory pictorial health warnings on all tobacco products (including oral and water pipe tobacco) covering 80% of the front and the back of the packs towards the top, in combination with standardized packaging; - Introducing standardised packaging with the prohibition of the use of logos, colours, brand images or promotional information on the packaging of tobacco products. This would still allow the use of brand names and product names, however displayed in a standard colour and font style; - Tobacco product manufacturers should only be allowed to have one standardised presentation (as already exist in Uruguay) and package size per cigarette brand. We believe this is important as we believe that some companies introduce package design and different cigarette sizes in order to attract some of the most vulnerable groups such as young females and uses this as 'indirect' marketing tool; - Quit line and reference to seek advice of healthcare professionals (doctor, pharmacist, etc) to quit smoking on all packs of tobacco products; - No tar, nicotine or carbon monoxide levels on the packs as we believe this creates a fake feeling of 'less harmful' products.

**questions on reporting**

**problem definition**

Yes

**which option**

Introduce fees and sanctions



**additional options**

- We would support endorsement of a positive list of ingredients flavorings and additives in tobacco products, which should not contain ingredients, flavorings or additives, which enhance attractiveness; - We would support a yearly registration fee paid to national competent authorities in order to finance their data collection and analysis work on ingredients. Only registered products would be allowed on the market.

**regulation of ingredients****problem definition**

Yes

**which option**

Establish a common list of tobacco ingredients

**which one**

Establish a positive common list of tobacco ingredients

**additional option**

- We would endorse a positive list of ingredients flavorings and additives in tobacco products, which should not contain ingredients, flavorings or additives, which enhance attractiveness.

**access to tobacco products****problem definition**

Yes

**which option**

Ban

**which one2**

Cross-border retail sales of tobacco to be banned over the Internet; Vending machines to be banned; Promotion and displays in retail stores to be banned

**additional option**

- We would endorse a ban of cross-border sales of tobacco products through internet by postal or any other mail delivery system; - We would endorse a ban of vending machines and of tobacco products displays at the point of sale by the most appropriate legal instrument, taken into consideration the EU legal competence in this field.

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**NGO submission****identification****affiliation**

NGO

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Sweden

**questions scope****problem definition**

No

**explanations**

The problem definition is incorrect in that it addresses trademark packaings as a particular problem.

**which option**

No change

**recommend option**

SACG is not in a position to provide an opinion as to the problem definition and has consequently limited its comments to counterfeiting risks and the impact on trademark rights.

**additional comments**

SACG is not in a position to provide an opinion as to the problem definition and has consequently limited its comments to counterfeiting risks and the impact on trademark rights.

**questions smokeless****problem definition**

No

**comments**

SACG is not in a position to provide an opinion as to the problem definition and has consequently limited its comments to counterfeiting risks and the impact on trademark rights.

**which option**

No change

**additional option**

SACG is not in a position to provide an opinion as to the problem definition and has consequently limited its comments to counterfeiting risks and the impact on trademark rights.

**additional comments**

SACG is not in a position to provide an opinion as to the problem definition and has consequently limited its comments to counterfeiting risks and the impact on trademark rights.

**questions consumer****problem definition**

No

**explanations**

SACG is not in a position to provide an opinion as to the problem definition and has

consequently limited its comments to counterfeiting risks and the impact on trademark rights.

**which option**

No change

**additional option**

SACG is not in a position to provide an opinion as to the problem definition and has consequently limited its comments to counterfeiting risks and the impact on trademark rights.

**additional comments**

The proposal for plain packaging is critical from a number of trademark law perspectives. Firstly the introduction of plain packaging requirements will inevitably lead to an increased risk of circulation of counterfeited tobacco products on the market since plain packaging packages will more easily be counterfeited. As a result thereof consumers and traders will have difficulties distinguishing between original and fake products. Secondly, the introduction of plain packaging requirements will impair consumer's ability to make an informed purchasing decision and will affect competition in an unfair manner since proprietors of well known figurative trademarks will be put on an equal market position to less known figurative marks. Thirdly, mandatory rules on plain packaging will deprive trademark holders of their intellectual property rights since the intellectual property rights (i) cannot be registered since that would be contrary to registration requirements under national law which set out that trademarks which are unlawful may not be registered (ii) cannot be used in the sense of the trademark directive and national law implementing the trademark directive and therefore risks cancellation throughout the European union within a five year period from the introduction of plain packaging requirements. Since a considerable number of tobacco trademarks are well known trademarks such trademarks cannot be used by third parties for other products than tobacco products. This protection will be lost under a plain packaging regime. An immediate consequence of a plain packaging requirement would thus be that tobacco trademarks within the European union which are valued at billions of Euros de facto are expropriated which violates essential property rights protected under the First Protocol of the European Convention of Human Rights (c f the European Court of Human Rights decision in Anheuser-Busch v Portugal).

**questions on reporting**

**problem definition**

No

**explanations**

SACG is not in a position to provide an opinion as to the problem definition and has consequently limited its comments to counterfeiting risks and the impact on trademark rights.

**which option**

No change

**additional options**

SACG is not in a position to provide an opinion as to the problem definition and has consequently limited its comments to counterfeiting risks and the impact on trademark rights.

**additional comments**

SACG is not in a position to provide an opinion as to the problem definition and has

consequently limited its comments to counterfeiting risks and the impact on trademark rights.

**regulation of ingredients**

**problem definition**

No

**explanations**

SACG is not in a position to provide an opinion as to the problem definition and has consequently limited its comments to counterfeiting risks and the impact on trademark rights.

**which option**

No Change

**additional option**

SACG is not in a position to provide an opinion as to the problem definition and has consequently limited its comments to counterfeiting risks and the impact on trademark rights.

**additional comments**

SACG is not in a position to provide an opinion as to the problem definition and has consequently limited its comments to counterfeiting risks and the impact on trademark rights.

**access to tobacco products**

**problem definition**

No

**explanations**

SACG is not in a position to provide an opinion as to the problem definition and has consequently limited its comments to counterfeiting risks and the impact on trademark rights.

**which option**

No change

**additional option**

SACG is not in a position to provide an opinion as to the problem definition and has consequently limited its comments to counterfeiting risks and the impact on trademark rights.

**additional comments**

SACG is not in a position to provide an opinion as to the problem definition and has consequently limited its comments to counterfeiting risks and the impact on trademark rights.

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**NGO submission**

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NGO

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Belgium

**questions scope****problem definition**

Yes

**which option**

Extend the scope of the Directive

**additional comments**

All tobacco products are hazardous to health – there is no safe level of usage. Therefore EuroHealthNet recommends that the scope of the Directive should include the regulation of any new smoked tobacco products (such as low emission or nicotine-free cigarettes), while the prohibition of any novel forms of oral tobacco, including snus, should be maintained. Herbal cigarettes are also harmful because it is the combustion and inhalation of smoke that causes most of the harm from smoking. Therefore, herbal cigarettes should be included in the scope Tobacco Products Directive and should also be subject to health warnings requirements. Finally, all forms of nicotine based products (that is, products containing nicotine but which are not tobacco products, such as electronic cigarettes, nicotine gel, drinks, and sweets) are often marketed as alternatives to cigarettes and in some cases as an aid to quitting smoking. Therefore, they should only be sold as quitting aids and comply with specific safety and quality requirements under the same regulatory framework as pharmaceutical products rather than under the scope of the Tobacco Products Directive. EuroHealthNet believes that the scope of the Directive should be extended to include smoking paraphernalia such as filters, cigarette paper, pipes, water pipes as well as the tobacco leaf. EuroHealthNet agrees with the impact assessment study conducted by RAND Europe stating that the primary benefit of extending the scope of the directive to paraphernalia and other non-tobacco nicotine products would be to increase consumers' awareness of the risks of these products. Smokers of roll-your-own cigarettes (RYO), pipes and water pipes often believe that these products are less harmful than manufactured cigarettes when in fact there is evidence to the contrary.

**questions smokeless****problem definition**

Yes

**which option**

Ban on all types of smokeless tobacco products

**additional option**

The ban on snus should definitely be maintained. This is high priority. Indeed, there is no legitimate reason to introduce a dangerous product onto the market, particularly as, from an internal market point of view, we have no idea how snus would be perceived or used in other countries. As highlighted by the Smoke Free Partnership a small study conducted by the University of Nottingham by Professor Ann McNeil showed that, in the UK, people could not see the point of snus unless it was as a cessation aid (i.e. there is currently no demand). For

internal market purposes, it really does not make sense to lift the ban. There is little evidence that smokers in EU countries other than Sweden would find snus to be an acceptable alternative to cigarettes, were it to be legalised. Moreover, if the ban on snus were to be lifted, it could encourage dual use of cigarettes and smokeless tobacco and discourage total abstinence from tobacco, thus weakening any potential health gains. Therefore, there is no legitimate reason to justify bringing a new hazardous product onto the market that could potentially undermine health outcomes and contribute to increase in the incidence of disease. Regarding other forms of smokeless tobacco products, EuroHealthNet does not believe that they should be “marketed” in all Member States. We recognise that they are as addictive and dangerous as smoked tobacco and substantially reduce health outcomes. As stated in the Opinion of the Scientific Committee on Emerging and Newly Identified Health Risks (SCENIHR), many forms of smokeless tobacco increase the risk of mouth, esophageal, pancreatic and liver cancer, and other conditions including gum and heart disease.

**questions consumer  
problem definition**

No

**explanations**

The problem definition could be improved. EuroHealthNet agrees with the Commission that the current situation, whereby some Member States have made graphic warnings compulsory and others not, has led to a disparity in labelling throughout the EU. This has an impact on the functioning of the internal market but it also on consumers' awareness. The labels perform a health promotion function by conveying the dangers of smoking and as a result, this can contribute to changing smoking behaviour and increasing health gains. Therefore, failing to make graphic health warnings compulsory in all member states had led to differences in the perception of health risks and consequences and failed to address the all the population groups, especially low socio-economic and vulnerable groups.. Moreover, we also agree that packaging as an advertising tool is not covered by the current Directive. Finally, we welcome the acknowledgement that tobacco packaging and product features are increasingly used to attract consumers, to promote products and brand image. This was further reinforced in the Eurobarometer survey released in 2010, which highlighted that on average, 75% of EU citizens are in favour of mandatory pictorial warnings, and over 54% support plain packaging measures. A stronger emphasis should be made to highlight, Through graphic warnings, the relationship between smoking and smoking related diseases, especially for vulnerable groups. Vulnerable groups generally experience lower level of life expectancy due to a number of factors including lower levels of health literacy but also due to unhealthy lifestyle determinants such as smoking.

**which option**

Improve consumer information; Introduce generic or plain packaging

**which improvement**

Picture warnings to become mandatory; Tar, nicotine and carbon monoxide levels to be replaced with general information on harmful substances in tobacco products; Information on harmful substances in tobacco products that cannot be placed on the package would be placed inside the package; Health warnings to be put on water pipes

**additional option**

Crucial importance of Graphic health warnings: Evidence shows that text only warning

messages are not as effective as graphic warnings. Pictures, especially fear inducing pictures, are proven to be effective in getting consumers more engaged with the warning message. Pictures are able to immediately provoke a reaction and prompt people to read the associated text message. This method assists in changing behaviour and thereby, can contribute to increasing health gains, especially amongst young people and amongst vulnerable groups vulnerable who are more predisposed to start smoking

The need for graphic health warnings on both sides of the pack: There is also evidence that pictures on both sides of the packaging have a greater impact. The need for LARGE pictorial health warnings (80%): Evidence clearly shows that increasing the size of warning messages (text only and combined text and picture) increases the effectiveness of the warning amongst both young and adult smokers / non smokers. Research carried out in Canada by Createc on behalf of Health Canada in 2007 showed that young and adult smokers/non smokers are sensitive to the size of health warning messages. Results showed that warning messages that cover 100% of the pack are significantly more effective across all measured effectiveness indicators compared with warning messages that cover only 50% of the pack. The importance of Rotation: Warning texts and pictures should be displayed on a rotating basis, so that each message is given equal display and can reach its target audience. The proved effectiveness of shocking health warnings & targeted messages: as specified in the Sambrook Research International report, fear inducing warnings (using strong “shocking” images related to health risks such as rotten teeth or throat cancer) and strong emotion inducing warnings (especially involving children and unborn babies) are the most effective way to educate consumers on the health risks of tobacco use and to achieve changes in attitudes and behaviour. These warnings’ effectiveness is enhanced if they are used in conjunction with a quit line. Generic or plain packaging: We strongly recommend the introduction of standardised/plain packaging. This should include not only the removal of all branding from the packaging but the size and shape of the packaging should also be standardised. Not only would this prevent the promotion of smoking through branding as occurs presently but it would reinforce the health warning messages. Tobacco packaging provides a direct link between consumers and manufacturers and is the main marketing channel, particularly in jurisdictions with tobacco advertising bans. Branding gives the misleading impression some cigarettes are safer than others. The tobacco industry claims that plain packaging would contravene intellectual property law. However, legal analysis concludes that this is incorrect and there are no international legal impediments to the implementation of generic packaging. Replace TNCO quantitative labelling with qualitative information on contents, emissions and quit-lines: The inclusion of machine-based tar, nicotine and carbon monoxide yields on cigarette packs promotes the mistaken belief that some cigarette brands are less harmful than others. We support the proposal to replace numerical measurements with descriptive information on the hazardous effects of tobacco constituents and emissions. This is particular important for vulnerable groups or people from lower socio-economic groups as they tend to experience lower levels of health literacy and higher incidence of smoking. Moreover, we stress the importance of putting quit line numbers on the package. Health warnings on water pipes: There is a growing body of evidence to show that water pipes are at least as hazardous, if not more so, than other forms of tobacco use. Warnings should also be included on the packaging of tobacco used in water pipes.

### **additional comments**

Under Article 5.3 of the TPD 2001, Member States have the option to adopt pictorial warnings. This situation emphasised the right of Member States to go further than the Directive to protect public health as set out in Article 30 of the Treaty of the Union (now article 36). Ten years after the entering into force of the TPD, four countries (the UK, Belgium, Romania and Malta) have adopted the option. More countries such as Spain and

France are planning to adopt mandatory pictorial warnings. Such measures are in compliance with the current TPD and are welcomed by the tobacco control community and public health community. However, their adoption by some Member States necessarily creates growing discrepancies between Member States. As stated above, there is clear evidence that pictorial warnings are much more powerful than written health warnings. Extending the information and protection to all EU Member States would be in harmony with Article 168 of the TFEU and consistent with the objectives of the internal market stated in Article 114.3 of the TFEU and reiterated in Recital 19 of the Directive. A revision of the TPD should, therefore, aim at making pictorial health warnings of tobacco products subject to common rules. Note: Legislation on labelling, advertising and product regulation put forward by the Commission in the field of tobacco control, has been based on the internal market legislation (Articles 26 and 114 of the TFEU). Article 26 of the TFEU establishes the internal market. Article 114 gives EU institutions the competence to regulate and set rules for the functioning of the internal market. More specifically, article 114.3 also states that when establishing rules for the functioning of the internal market in the context of health, safety, environmental protection and consumer protection, the Commission “will take as a base a high level of protection, taking account in particular of any new development based on scientific facts.” The European Court of Justice (the “ECJ”) made an extensive analysis of Article 95 EC (now Article 114) throughout the years. In *Spain v. Council*, the Court observed that “recourse to Article 100a (now Article 114) as a legal basis is possible if the aim is to prevent the emergence of future obstacles to trade resulting from multifarious development of national laws.” The TPD was adopted on the basis of Article 114 TFEU (ex Article 95). As a result, Recital 19 of the TPD states that “[t]he presentation of warning labels and yields has continued to remain variable in the different Member States. As a consequence, consumers in one Member State may be better informed as to the risks of tobacco products than in another. Such differences are unacceptable and are liable to constitute a barrier to trade and to impede the operation of the internal market in tobacco products, and should therefore be eliminated.”

**questions on reporting  
problem definition**

Yes

**which option**

Establish a common compulsory reporting format; Introduce fees and sanctions

**additional comments**

The current situation which allows different formats and reporting mechanisms is unsatisfactory, making it difficult for authorities to compare and analyse the data. All tobacco manufacturers and importers should be subject to the same reporting requirements. The SFP believes that tobacco products, which are highly harmful, should be subject to an effective reporting system that allows the gathering and analysis of relevant data, including comparison as appropriate, in order to ensure high levels of consumer safety and information. The format already exists (based on the voluntary reporting format developed by the Commission in May 2007) and it would therefore be very easy to adopt this measure and to implement it. We welcome the introduction of yearly registration fees in order to finance the data collection on ingredients by the national authorities and their analysis work on ingredients. The payment of penalties in case of non-compliance with the requirements of delivery of data on tobacco product ingredients also seems adequate and would contribute to fund the tests conducted on these products. It is crucial that the appropriate toxicological and addictiveness tests are properly conducted. Such tests would allow policy-makers to make more informed decisions



in this field, as there would be more scientific evidence. It would enhance the scientific knowledge of the dangers of tobacco products and would contribute to a high protection of health, as stated in Article 95.3 TFEU. Besides, such measures would also have an indirect impact on illicit trade, since only registered products would be allowed on the market.

### **regulation of ingredients**

#### **problem definition**

Yes

#### **which option**

Establish a common list of tobacco ingredients

#### **additional comments**

While this is outside the expertise of the EuroHealthNet we agree with the Smoke Free Partnership's view that the current situation which allows different formats and reporting mechanisms is unsatisfactory, making it difficult for authorities to compare and analyse the data. Tobacco companies should be required to use a standardised reporting format. Additionally the companies should be required to pay a yearly registration fee to cover the costs of administering this data collection.

### **access to tobacco products**

#### **problem definition**

Yes

#### **which option**

Ban

#### **which one2**

Cross-border retail sales of tobacco to be banned over the Internet; Vending machines to be banned; Promotion and displays in retail stores to be banned

#### **additional option**

We urge the Commission to call for a ban on the promotion of tobacco products at point of sale and a ban on vending machines as described in the Art 13 Guidelines of the FCTC.

#### **additional comments**

Internet. The principle of preventing cross-border promotion of tobacco products in order to protect public health was enshrined in the Tobacco Advertising directive (2001/0119). It is logical, therefore, to extend that principle to the sale of tobacco products between member states via the Internet. We support the prohibition of tobacco sales via the Internet. Vending machines. The majority of member states (22 out of 27) already prohibit the sale of tobacco products from vending machines in order to deter young people accessing cigarettes from this source. We support this measure. Point of Sale. Evidence shows that a coordinated cross border marketing strategy on the part of the tobacco companies is reflected at point of sale (i.e. point of sale marketing is similar in most EU countries (i.e.: a brand is advertised at point of sale in the same way in Germany and Belgium). There is a growing body of evidence to show that putting tobacco products out of sight in retail outlets can reduce youth smoking. To date, this measure has been adopted by Ireland and Finland (as well as Iceland and Norway). This measure is also official government policy in Scotland, Wales and Northern Ireland and

a decision is awaited in England. We strongly support an EU-wide adoption of a ban on the display of tobacco products at the point of sale.

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## **NGO submission**

### **identification**

#### **affiliation**

NGO

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### **questions scope**

#### **problem definition**

No

### **explanations**

The problem definition is incorrect, vague and unclear. For example it quotes that “the tobacco products market has increasingly diversified” but then goes on to list non-tobacco products including, electronic cigarettes and nicotine drinks and no actual tobacco products. Non-tobacco products containing nicotine are substantially different from tobacco products. They should be regulated separately. This confusion clearly demonstrates a fundamental lack of understanding of the tobacco sector. This lack of understanding is compounded by the fact that the problem definition fails to provide any scientific basis or evidence for the different options considered in this section. We do not consider that the Consultation identifies a problem in any of the areas it mentions in this section. HCTC cautions that indiscriminately banning novel forms of oral tobacco could impact the future development of potentially reduced exposure products. Finally, we note that the Consultation contains no analysis of Union competence to adopt the different options, the implications of those options for the functioning of the internal market or their proportionality. Nor is any evidence provided in the Consultation for the different options discussed in this section. We are concerned that the Commission will refer to the Final RAND Report in this regard. Therefore we will send our critique on the report separately. As the problem definition is fundamentally flawed, we are not in a position to comment on the proposed change options.

### **which option**

No change

### **recommend option**

See response to Question 1 above.

### **additional comments**

See response to Question 1 above.

**questions smokeless**

**problem definition**

No

**comments**

As mentioned before, the problem definition is incorrect, vague and unclear. Non-tobacco products containing nicotine are substantially different from tobacco products. They should be regulated separately. This confusion clearly demonstrates a fundamental lack of understanding of the tobacco sector. This lack of understanding is compounded by the fact that the problem definition fails to provide any scientific basis or evidence for the different options considered in this section.

**which option**

No change

**questions consumer**

**problem definition**

No

**explanations**

The problem definition is based upon a series of assumptions and assertions that are wrong, and which have the effect of incorrectly defining the debate regarding consumer information. First, despite being entitled “consumer information”, Section 3 only addresses tobacco packaging. Regulators have access to a variety of vehicles to communicate information to consumers, including television, print media, magazines and the internet. The “problem” is defined overly narrowly, and so fails to identify relevant policy options. Secondly, tobacco packaging and pack labelling is not a predictor of youth smoking. The considerable body of evidence and research which exists on the predictors for smoking initiation does not substantiate any link between packaging and youth uptake. The problem definition is, however, concerned with packaging from this perspective. As a result of this flaw, none of the proposed measures in Section 3 regarding packaging are likely to have an impact on youth smoking initiation. Lastly, HCTC rejects the notion of “attractiveness” as a valid public policy objective, and considers that it adds nothing to the need to identify and assess a relevant policy rationale. “Attractiveness” per se fails established criteria for issue definition in terms of it being a regulatory goal or objective: it is lacking in any evidential foundation and is inherently uncertain and arbitrary. In addition, HCTC notes that the Consultation contains no analysis of Union competence to adopt the different options, the implications of those options for the functioning of the internal market or their proportionality. Nor is any evidence provided in the Consultation for the different options discussed in this section. We are concerned that the Commission will refer to the Final RAND Report in this regard. HCTC believes that adult smokers should be appropriately reminded of the risks of smoking when they make the decision to smoke and that health warnings (HWs) and other currently mandated labelling requirements can play a role in this respect. Any changes considered by regulators to the warning and labelling regulations should be based on clear evidence that the proposed changes would significantly contribute to achieving the stated public policy objectives. Further, the Commission and Member States should adopt Better Regulation principles and procedures when formulating, adopting and reviewing all packaging regulations. Finally, the Commission must recognize that changes to packaging and pack

labelling regulation engage fundamental legal, economic and commercial rights of tobacco manufacturers and consumers. These include the right of tobacco manufacturers to brand their packaging and pack labelling in accordance with principles of the market economy and competition policy, their property right in their brands (including trademarks, goodwill and brand equity), their rights to communicate product information to their consumers, and their right to conduct their business (including the free movement of goods within the EU).

#### **which option**

No change

#### **questions on reporting**

##### **problem definition**

No

#### **explanations**

We agree with the part of the definition referring to the divergence of formats and mechanism for ingredient reporting across the EU and confirming that there are concerns on the manner by which trade secrets are dealt with. The problem definition makes no reference to the common reporting format, communicated via the European Commission's Practical Guide on tobacco product ingredients reporting. It was communicated as a non-binding format to the EU Member States but with the expectation that it should be adopted by manufacturers, importers and Member States with the desire for data to be submitted in electronic form. Despite the guidance given from the Commission, to date not all Member States have adopted the new common reporting format for ingredients disclosure or have fully implemented the new templates into their submission process. We acknowledge the significant progress that has been made in terms of defining an appropriate reporting regime for ingredients used in the manufacture of tobacco products and will continue to implement the new templates in accordance with Member State requirements. We would like to point out that problems still remain to be resolved in respect of the templates and the systems. However, it is vital that ongoing dialogue is developed and maintained in order to obtain a clear understanding of where data gaps occur, and what is meant by an incomplete data set. We note that part of the problem definition relating to the situation, i.e., "Collection and analysis of the reported data on ingredients requires substantial resources for national competent authorities", is made without reference to the EMTOC project and the progress made in this context. Furthermore, the problem definition goes on to state: "It has proven difficult to get financing for the development, validation and carrying out of the appropriate toxicological and addictiveness tests", without providing any foundation for the statement. Tobacco industry members have provided extensive toxicological data to Member States, none of which to our knowledge has been analysed or commented on. Numerous Member States have regulations on ingredients use, e.g. Germany, France, UK, Belgium, and our members only use permitted ingredients. The Commission has never set out a science-based toxicological framework or established any scientific forum for discussing these matters. The problem definition fails to mention the opinion of SCENIHR on the use of ingredients and attractiveness and addictiveness or their conclusion that they found no evidence to suggest that any ingredient adds to, or of itself contributes to tobacco products addictiveness. We note that the Consultation contains no analysis of Union competence to adopt the different options, the implications of those options for the functioning of the internal market or their proportionality. Nor is any evidence provided in the Consultation for the different options discussed in this section. We are concerned that the Commission will refer to the Final RAND Report in this regard.

**which option**

Establish a common compulsory reporting format

**regulation of ingredients****problem definition**

Yes

**which option**

Introducing the basic criteria on the EU level without a common list

**access to tobacco products****problem definition**

No

**explanations**

The problem definition is vague and incomplete. We do not consider that the problem definition or the Consultation identifies a problem in any of the areas mentioned in this section. We note that the Consultation contains no analysis of Union competence to adopt the different options, the implications of those options for the functioning of the internal market, or their proportionality. Nor is any evidence provided in the Consultation for the different options discussed in this section.

**which option**

No change

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**NGO submission****identification****affiliation**

NGO

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Belgium

**questions scope****problem definition**

Yes

**which option**

Extend the scope of the Directive

**additional comments**

Tobacco use is associated with the development of chronic kidney disease and may accelerate transition through to End Stage Renal Disease. All tobacco products are hazardous to health – and as such we recommend that the scope of the Directive is extended to include the regulation of any new smoked tobacco products (such as low emission or nicotine-free cigarettes) while the prohibition of any novel forms of oral tobacco, including snus, should be maintained. Herbal cigarettes are also harmful because it is the combustion and inhalation of smoke that causes most of the harm from smoking. Therefore, herbal cigarettes should be included in the scope Tobacco Products Directive and should also be subject to health warnings requirements. Finally, all forms of nicotine based products (that is, products containing nicotine but which are not tobacco products, such as electronic cigarettes, nicotine gel, drinks, and sweets) are often marketed as alternatives to cigarettes and in some cases as an aid to quitting smoking. Therefore, they should only be sold as quitting aids and comply with specific safety and quality requirements under the same regulatory framework as pharmaceutical products rather than under the scope of the Tobacco Products Directive.

**questions smokeless**

**problem definition**

Yes

**which option**

No change

**additional option**

The ban on snus should definitely be maintained. Snus is a dangerous product and as such should not be brought onto the market. It has been proposed that the use of smokeless tobacco products could be a way to quit smoking but there are already effective treatments for nicotine addiction available which use medicinal or ‘clean’ nicotine (NRT) that do not carry the risks association with snus.

**questions consumer**

**problem definition**

No

**explanations**

We would like to point out that attention should be paid to the Eurobarometer survey of 2010 showing that 75% of EU citizens are in favour of mandatory pictorial warnings and over 54% support plain packaging measures.

**which option**

Improve consumer information; Introduce generic or plain packaging

**which improvement**

Picture warnings to become mandatory; Tar, nicotine and carbon monoxide levels to be replaced with general information on harmful substances in tobacco products; Information on harmful substances in tobacco products that cannot be placed on the package would be placed inside the package; Health warnings to be put on water pipes

**additional option**

Crucial importance of Graphic health warnings: Evidence shows that text only warning messages are not as effective as graphic warnings. Pictures, especially fear inducing pictures,

are proven to be effective in getting consumers more engaged with the warning message. Pictures are able to immediately provoke a reaction and prompt people to read the associated text message. The need for graphic health warnings on both sides of the pack: There is also evidence that pictures on both sides of the packaging have a greater impact. The need for LARGE pictorial health warnings (80%): Evidence clearly shows that increasing the size of warning messages (text only and combined text and picture) increases the effectiveness of the warning amongst both young and adult smokers / non smokers. Research carried out in Canada by Createc on behalf of Health Canada in 2007 showed that young and adult smokers/non smokers are sensitive to the size of health warning messages. Results showed that warning messages that cover 100% of the pack are significantly more effective across all measured effectiveness indicators compared with warning messages that cover only 50% of the pack. The importance of Rotation: Warning texts and pictures should be displayed on a rotating basis, so that each message is given equal display and can reach its target audience. The proved effectiveness of shocking health warnings & targeted messages: as specified in the Sambrook Research International report, fear inducing warnings (using strong “shocking” images related to health risks such as rotten teeth or throat cancer) and strong emotion inducing warnings (especially involving children and unborn babies) are the most effective way to educate consumers on the health risks of tobacco use and to achieve changes in attitudes and behaviour. These warnings’ effectiveness is enhanced if they are used in conjunction with a quit line. Generic or plain packaging: We strongly recommend the introduction of standardised/plain packaging. This should include not only the removal of all branding from the packaging but the size and shape of the packaging should also be standardised. Not only would this prevent the promotion of smoking through branding as occurs presently but it would reinforce the health warning messages. Tobacco packaging provides a direct link between consumers and manufacturers and is the main marketing channel, particularly in jurisdictions with tobacco advertising bans. Branding gives the misleading impression some cigarettes are safer than others. The tobacco industry claims that plain packaging would contravene intellectual property law. However, legal analysis concludes that this is incorrect and there are no international legal impediments to the implementation of generic packaging.

**questions on reporting  
problem definition**

Yes

**which option**

Establish a common compulsory reporting format; Introduce fees and sanctions

**additional comments**

The current situation which allows different formats and reporting mechanisms is unsatisfactory, making it difficult for authorities to compare and analyse the data. All tobacco manufacturers and importers should be subject to the same reporting requirements. We believe that tobacco products, which are highly harmful, should be subject to an effective reporting system that allows the gathering and analysis of relevant data, including comparison as appropriate, in order to ensure high levels of consumer safety and information. The format already exists (based on the voluntary reporting format developed by the Commission in May 2007) and it would therefore be very easy to adopt this measure and to implement it. We welcome the introduction of yearly registration fees in order to finance the data collection on ingredients by the national authorities and their analysis work on ingredients. The payment of penalties in case of non-compliance with the requirements of delivery of data on tobacco

product ingredients also seems adequate and would contribute to fund the tests conducted on these products. It is crucial that the appropriate toxicological and addictiveness tests are properly conducted. Such tests would allow policy-makers to make more informed decisions in this field, as there would be more scientific evidence. It would enhance the scientific knowledge of the dangers of tobacco products and would contribute to a high protection of health, as stated in Article 95.3 TFEU. Besides, such measures would also have an indirect impact on illicit trade, since only registered products would be allowed on the market.

### **regulation of ingredients**

#### **problem definition**

Yes

#### **which option**

Establish a common list of tobacco ingredients

#### **additional comments**

We support the adoption of a positive common list of tobacco ingredients. We believe that tobacco products are highly toxic and addictive, and that their content should therefore be closely regulated, in order to achieve high standards of health protection, as stated under article 114.3. There is a need for such a list at EU level since at the moment, consumers in the internal market are not subject to the same level of protection. Some citizens may be using substances that are banned in other Member States. Apart from creating unequal health protection across the EU, this may constitute an obstacle to free movement of goods within the internal market: some countries can refuse access to their markets of cigarettes from Member States that do not comply with the importing Member State's national requirements. Regulation of Flavours and Ingredients: Flavourings are an increasingly important part of tobacco industry marketing, particularly to young people. Flavourings enhance attractiveness, encourage youth initiation, and discourage cessation. The prohibition of ingredients that may be used to increase attractiveness, such as sugars and sweeteners, flavouring substances, and spices and herbs, in cigarettes and cigarette-like tobacco products should be introduced. The prohibition of ingredients that may create the impression of a health benefit (e.g. vitamins), ingredients associated with energy and vitality (e.g. caffeine), and ingredients with colouring properties (e.g. pink cigarette paper) should also be banned. Tobacco manufacturers and importers should report sales volume information by brand. This information is essential to help governments ensure that product regulation is effective. The above measures should be compliant with the Guidelines on Art. 9/10, adopted unanimously at the Fourth Conference of the Parties in Uruguay on the 20th November 2010.

### **access to tobacco products**

#### **problem definition**

Yes

#### **which option**

Ban

#### **which one2**

Cross-border retail sales of tobacco to be banned over the Internet; Vending machines to be banned; Promotion and displays in retail stores to be banned

#### **additional option**



We urge the Commission to call for a ban on the promotion of tobacco products at point of sale and a ban on vending machines as described in the Art 13 Guidelines of the FCTC.

**additional comments**

Internet. The principle of preventing cross-border promotion of tobacco products in order to protect public health was enshrined in the Tobacco Advertising directive (2001/0119). It is logical, therefore, to extend that principle to the sale of tobacco products between member states via the Internet. We support the prohibition of tobacco sales via the Internet. Vending machines. The majority of member states (22 out of 27) already prohibit the sale of tobacco products from vending machines in order to deter young people accessing cigarettes from this source. We support this measure. Point of Sale. Evidence shows that a coordinated cross border marketing strategy on the part of the tobacco companies is reflected at point of sale (i.e. point of sale marketing is similar in most EU countries (i.e.: a brand is advertised at point of sale in the same way in Germany and Belgium). There is a growing body of evidence to show that putting tobacco products out of sight in retail outlets can reduce youth smoking. To date, this measure has been adopted by Ireland and Finland (as well as Iceland and Norway). This measure is also official government policy in Scotland, Wales and Northern Ireland and a decision is awaited in England. We strongly support an EU-wide adoption of a ban on the display of tobacco products at the point of sale.

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**questions scope**

**problem definition**

Yes

**which option**

No change

**questions smokeless  
problem definition**  
Yes

**which option**  
No change

**questions consumer  
problem definition**  
Yes

**which option**  
No change

**questions on reporting  
problem definition**  
Yes

**which option**  
No change

**regulation of ingredients  
problem definition**  
Yes

**which option**  
No Change

**access to tobacco products  
problem definition**  
Yes

**which option**  
No change

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**questions scope**  
**problem definition**

Yes

**which option**

Extend the scope of the Directive

**questions smokeless**  
**problem definition**

Yes

**which option**

Ban on all types of smokeless tobacco products

**questions consumer**  
**problem definition**

Yes

**which option**

Introduce generic or plain packaging

**questions on reporting**  
**problem definition**

Yes

**which option**

Establish a common compulsory reporting format; Introduce fees and sanctions

**regulation of ingredients**  
**problem definition**

Yes

**which option**

Establish a common list of tobacco ingredients

**which one**

Establish a positive common list of tobacco ingredients

**access to tobacco products**  
**problem definition**

Yes

**which option**

Ban

**which one2**

Cross-border retail sales of tobacco to be banned over the Internet; Vending machines to be banned; Promotion and displays in retail stores to be banned

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## **NGO submission**

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### **questions scope**

#### **problem definition**

Yes

#### **which option**

Extend the scope of the Directive

#### **recommend option**

Nee

### **additional comments**

Aangezien elk tabaksproduct schadelijk is voor de gezondheid, dient er op te worden toegezien dat de richtlijn alle tabaksproducten behelst, dus ook de elektronische sigaret. Daarnaast moet er voor worden gewaakt dat er geen nieuwe toedieningsvormen van tabak dan rooktabak worden toegelaten tot de Europese markt.

### **questions smokeless**

#### **problem definition**

Yes

#### **which option**

No change

#### **additional option**

nee

### **additional comments**

Snuss moet niet toegelaten worden op de Europese markt aangezien dit een zeer verslavend product is dat de gezondheid schaadt. Toelating op de markt zal de sociale norm van tabaksgebruik niet verbeteren, en mogelijk ook gebruik van sigaretten in stand houden. Ook het toelaten van andere rookloze tabaksproducten zal niet bijdragen aan het denormaliseren van roken. Daarnaast zijn ook deze producten schadelijk voor de gezondheid.

**questions consumer  
problem definition**

No

**explanations**

We erkennen dat de interne markt er last van ondervindt dat het toepassen van grafische waarschuwingen binnen de EU landen verschilt. Dit leidt uiteindelijk ook tot verschil in kennis over de gevolgen van roken en dus tot verschil in rookgedrag. Daarbij kan worden geconcludeerd dat verpakkingen van tabaksproducten gebruikt worden om een schadelijk product aantrekkelijk te maken en reclame ervoor te maken. Er is ruimte voor verbetering en concretisering van de probleem definitie. Het zou goed zijn om het marketing van tabaksproducten via de verpakkingen ook onder deze directive te laten vallen. Er blijkt breed draagvlak te zijn voor het invoeren van plaatjes op de pakjes in heel Europa (aldus de Eurobarometer van 2010). Gemiddeld is 75% van de EU bevolking voorstander van het invoeren van plaatjes op de pakjes en meer dan de helft is voorstander van 'plain packaging'.

**which option**

Improve consumer information; Introduce generic or plain packaging

**which improvement**

Picture warnings to become mandatory; Tar, nicotine and carbon monoxide levels to be replaced with general information on harmful substances in tobacco products; Information on harmful substances in tobacco products that cannot be placed on the package would be placed inside the package; Health warnings to be put on water pipes

**additional option**

Onderzoek toont aan dat tekstuele waarschuwingen minder effectief zijn dan plaatjes op de pakjes. Plaatjes, in het bijzonder de angstaanjagende uitingen maken gebruikers bewuster van de boodschap – ze roepen meteen een reactie op die ertoe leidt dat mensen ook de teksten lezen. Het verwijzen naar een nationaal telefoonnummer voor het krijgen van ondersteuning bij stoppen zal leiden tot succesvolle stoppogingen. Plaatjes zouden aan beide zijden van de verpakking moeten zitten om het grootste resultaat te kunnen realiseren en de afbeeldingen zouden moeten roteren. De grootte van de plaatjes dient ongeveer 80% van de verpakking te bedekken. Waarschuwingen dienen op alle vormen van tabaksproducten te worden vermeld, dus ook op waterpijpen. Aanvullend op grafische waarschuwingen is het introduceren van plaatjes op de pakjes noodzakelijk. Een enkel land heeft dit reeds ingevoerd en sommige landen overwegen dit. Ten tijde van de implementatie van deze herziene richtlijn is de kans reëel dat plain packaging heel gebruikelijk is. Het niet nu op nemen in deze directive, is een gemiste kans. Juridisch is er geen enkele belemmering om dit in te voeren.

**additional comments**

Op dit moment hebben 7 lidstaten plaatjes op de pakjes geïntroduceerd. Dit leidt tot ongelijkheid in de interne markten. Het is daarom wenselijk dat plaatjes op de pakjes worden opgenomen in deze Directive zodat in de EU minder verschil is hierover.

**questions on reporting**

**problem definition**

Yes

**which option**

Establish a common compulsory reporting format; Introduce fees and sanctions

**additional options**

Nee

**additional comments**

De huidige systematiek van verschillende formats en rapportagemethodieken is ingewikkeld en lastig te vergelijken met elkaar. Het is wenselijk om een methodiek te gebruiken, waar alle industrieën zich aan moeten houden. Alleen dan is het mogelijk om goede analyses te maken en besluiten te nemen tbv veiligheid en informatievoorziening. Een dergelijk format bestaat al (2007) en kan derhalve eenvoudig ingevoegd worden. Een jaarlijkse bijdrage kan ertoe bijdragen dat er budget is voor het nauwkeurig analyseren van de gegevens en onderzoek te doen naar toxicologische en verslavende werking. Hetzelfde geldt voor het bestraffen van overtredingen met geldboetes. Als uiteindelijk alleen geregistreerde producten op de markt worden toegelaten, is smokkel en namaak ook eenvoudig te bestrijden.

**regulation of ingredients****problem definition**

Yes

**which option**

Establish a common list of tobacco ingredients

**which one**

Establish a positive common list of tobacco ingredients

**additional option**

nee

**additional comments**

Vanwege de verslavende en schadelijke werking van ingrediënten van tabaksproducten, is het belangrijk om deze zo goed mogelijk te reguleren. Het bijhouden van lijsten van ingrediënten is daarom belangrijk. Dit kan leiden tot betere bescherming voor de gezondheid doordat verboden toevoegingen eenvoudig kunnen worden bestraft. Het toevoegen van smaakjes aan stoffen is een belangrijke manier voor de industrie om hun product aantrekkelijk te maken voor, met name jonge, rokers. Ze weerhouden rokers er over het algemeen ook van om te stoppen met roken. Door bepaalde ingrediënten te verbieden, zoals suikers, kruiden, zullen de producten minder aantrekkelijk zijn, met name voor jonge rokers. Toevoegingen die misleidend kunnen werken door de schijn te wekken dat een product gezonder is, vanwege het toevoegen van vitaminen, of die middels cafeïne geassocieerd worden met energie en vitaliteit en aantrekkelijk worden gemaakt door gekleurd papier te gebruiken, dienen ook verboden te worden. Tijdens de COP4 in Uruguay onlangs zijn de hiervoor relevante richtlijnen 9 en 10 geadopteerd.

**access to tobacco products****problem definition**

Yes

**which option**

Ban

**which one2**

Cross-border retail sales of tobacco to be banned over the Internet; Vending machines to be banned; Promotion and displays in retail stores to be banned

**additional option**

We vinden het van belang dat reclame bij verkooppunten en tabaksautomaten wordt verboden (zoals beschreven in FCTC artikel 13).

**additional comments**

Internet Het verbieden van verkoop via het internet heeft alleen zin als dit in heel Europa effectief is. Dit kan daarom niet nationaal geregeld worden en hoort thuis in deze Directive. Tabaksautomaten Er zijn slechts 2 lidstaten die geen regelgeving hebben op automaten – gelijke regelgeving in heel Europa is ook mbt deze vorm van promotie belangrijk. Verkooppunten In geheel Europa bestaat regelgeving op het toestaan van reclame in verkooppunten. In toenemende mate is echter bekend dat het uit het zicht halen van tabaksproducten op verkooppunten bijdraagt aan minder rokende jongeren. Een aantal lidstaten heeft deze maatregel reeds ingevoerd of is dit van plan. Ook hier geldt dat het voorkeur verdient dit op EU niveau te regelen.

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**questions scope**

**problem definition**

Yes

**which option**

No change

**questions smokeless**

**problem definition**

Yes

**which option**

No change

**questions consumer**

**problem definition**

Yes

**which option**

No change

**questions on reporting**

**problem definition**

Yes

**which option**

No change

**regulation of ingredients**

**problem definition**

Yes

**which option**

Introducing the basic criteria on the EU level without a common list

**access to tobacco products**

**problem definition**

Yes

**which option**

No change

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**questions scope**

**problem definition**

Yes

**which option**

No change

**questions smokeless**

**problem definition**

Yes

**which option**

No change

**questions consumer**

**problem definition**

Yes

**which option**

No change

**questions on reporting**

**problem definition**

Yes

**which option**

No change

**regulation of ingredients**

**problem definition**

Yes

**which option**

No Change

**access to tobacco products**

**problem definition**

Yes

**which option**

No change

---

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**questions scope****problem definition**

Yes

**which option**

Extend the scope of the Directive

**recommend option**

In our view, Option 2 addresses the problem more effectively than Option 1, but is still inadequate as a means of ensuring appropriate, rational and proportionate regulation for nicotine products. Current nicotine product regulation, at both EU and individual Member State level, is irrational and inconsistent. Medicinal nicotine products, which are inherently low hazard (with a safety profile of a similar order of magnitude to caffeine) are tightly regulated, as drugs; smoked tobacco, which kills half of all sustained users, enjoys market freedoms without precedent for any significantly hazardous product; sale of smokeless tobacco, which is much less hazardous than smoking and hence a logical substitute for smokers who cannot or will not quit smoking, is illegal outside Sweden; whilst other forms of nicotine delivery, such as the electronic cigarette, are unregulated and hence allowed on the market with no constraint on nicotine dose, purity or effectiveness. The status quo thus helps to perpetuate smoked tobacco as the least expensive, most easily available and convenient source of nicotine for those addicted to, experimenting with or otherwise using a nicotine product. It allows cigarette manufacturers freedom to launch new cigarette products to circumvent marketing restrictions, drive sales, and imply unsubstantiated reductions in risk to the consumer (Refs 1,2,3,4) The current system of nicotine regulation is thus strongly counterproductive to individual and public health. We therefore recommend more radical reform of the tobacco products directive to include all nicotine products, and hence to provide consistent regulation of price, promotion, availability and freedom of use to ensure that the market freedom allowed for any nicotine product is in direct inverse relation to its hazard to health. More detailed arguments in support of this position are presented elsewhere (Ref 5) . Herbal cigarettes that do not contain nicotine are an anomaly which in our view be brought under this same regulatory framework. Refs 1. BAT's CEO interviewed in the Independent, 18 June 2006 2. Euromonitor International. Global Tobacco: New product developments – creativity in adversity. September 2009. 3. Lambat I. Top Dogs. Tobacco Reporter. February 2007. 4. Euromonitor International. Innovation responds to operating environment. In: Global Tobacco – survival strategies for a savage market. 21 Nov 2008. 5. Tobacco Advisory Group of the Royal College of Physicians. Harm reduction in nicotine addiction. London: Royal College of Physicians; 2007. <http://www.rcplondon.ac.uk/pubs/contents/4fc74817-64c5-4105-951e-38239b09c5db.pdf>

**additional comments**

We believe that the scope of the Directive also include smoking paraphernalia such as filters, cigarette paper, pipes, water pipes as well as the tobacco leaf.

**questions smokeless****problem definition**

No

**comments**

The problem definition overstates the risk of smokeless tobacco in relation to smoked tobacco, and does not distinguish between the risks of different forms of smokeless tobacco. Both of these considerations were covered in detail by the SCENIHR report cited in the problem definition, which concluded that: (a) The risk profile of smokeless tobacco varies between different products, but appears to be lowest for low nitrosamine Swedish snus. It is therefore important to distinguish between the different products in describing health risks. (b) The majority of deaths caused by smoking are from lung cancer, COPD, and ischaemic heart disease. The SCENIHR report concluded that Swedish snus does not increase the risk of lung cancer or COPD. It also concluded that snus use does not increase the risk of myocardial infarction, though it does increase the proportion of myocardial infarctions that prove fatal. Snus use is associated with an increased risk of pancreas cancer, but to a much lesser extent than smoking (Ref 1) . We therefore disagree that for any individual, substitution of smoking by the use of smokeless tobacco products would probably decrease the incidence of some tobacco-related diseases: the outcome would in fact be a substantial reduction in individual and overall population risk (Ref 2,3). Also, whilst we agree that whilst use of smokeless tobacco by young people may well lead to uptake of smoking in some cases, evidence from Sweden, also summarised in the SCENIHR report, indicates that such gateway migration to smoking is far offset by the number of smokers that move from smoked to smokeless tobacco (Ref 1). It is also estimated that in practice, the likelihood that this balance of gateway progression to or from smoking would ever act against the overall public health is extremely low (Ref 3). Furthermore, an appropriate regulatory environment would help balance the risks in favour of public health. Refs 1. Scientific Committee on Emerging and Newly Identified Health Risks. Health effects of smokeless tobacco products. European Commission; 2008. 2. Tobacco Advisory Group of the Royal College of Physicians. Harm reduction in nicotine addiction. London: Royal College of Physicians; 2007. <http://www.rcplondon.ac.uk/pubs/contents/4fc74817-64c5-4105-951e-38239b09c5db.pdf> 3. Gartner C, Hall WD, Vos T, Bertram MY, Wallace AI, Lim SS. Assessment of Swedish snus for tobacco harm reduction: an epidemiological modelling study. *Lancet* 2007;369:2010-2014

**which option**

Lifting the ban on snus

**additional option**

In fact none of the three options is ideal. We have argued above that nicotine product regulation needs to change to encourage the use of less hazardous forms of nicotine. We believe that the current ban on snus, while cigarettes remain legal, is illogical when considered in relation to the relative hazard of the two products, and that snus may have a place in a rationally regulated nicotine market, in a context in which smoked cigarettes are far less available and affordable, and medicinal nicotine far more available and affordable, than snus. However we also share the concern expressed in the SCENIHR report that, whilst the

availability of snus has probably been to the benefit of public health in Sweden, there is no assurance that the same would apply if snus were introduced widely, without effective regulation, across the EU. Hence our support for consideration of a role for smokeless tobacco in the context of a nicotine market regulated to minimize harm from nicotine use (Ref 1). Since all other smokeless tobacco products that are currently legally available throughout the EU are almost certainly more hazardous than low-nitrosamine Swedish snus, their continued availability is irrational. We would recommend the establishment of standards for maximum acceptable content of nitrosamines and other hazardous constituents of smokeless tobacco, and require compliance with such standards as a condition of market access. Ref 1. Tobacco Advisory Group of the Royal College of Physicians. Harm reduction in nicotine addiction. London: Royal College of Physicians; 2007.  
<http://www.rcplondon.ac.uk/pubs/contents/4fc74817-64c5-4105-951e-38239b09c5db.pdf>

### **questions consumer**

#### **problem definition**

Yes

#### **which option**

Improve consumer information; Introduce generic or plain packaging

#### **which improvement**

Picture warnings to become mandatory; Tar, nicotine and carbon monoxide levels to be replaced with general information on harmful substances in tobacco products; Information on harmful substances in tobacco products that cannot be placed on the package would be placed inside the package; Health warnings to be put on water pipes

#### **additional option**

We support all of the the given options under 2 and 3, in line with previous advice to the EC (Ref 1) . We suggest that picture health warnings should cover most of the two largest sides of a pack that should be rectangular in shape, that telephone helpline information, qualitative information on content, and batch labeling to assist tracing of illicit supply be placed elsewhere on the pack, and that the brand name, in generic type, should cover less than 10% of any one side of the pack. These packaging requirements should apply to all tobacco products, smoking devices and paraphernalia. Ref 1. Sambrook Research International. A review of the science base to support the development of health warnings for tobacco packages. European Commission: 2009.

[http://ec.europa.eu/health/tobacco/docs/warnings\\_report\\_en.pdf](http://ec.europa.eu/health/tobacco/docs/warnings_report_en.pdf)

#### **additional comments**

We are also concerned point of sale displays are prohibited, to ensure that aggregates of plain packages are not used as alibi promotions at point of sale.

### **questions on reporting**

#### **problem definition**

Yes

#### **which option**

Establish a common compulsory reporting format; Introduce fees and sanctions

### **regulation of ingredients**

**problem definition**

Yes

**which option**

No Change

**additional option**

We suggest that additives should be included on the positive list only if proven to be beneficial to health.

**access to tobacco products****problem definition**

Yes

**which option**

Ban

**which one2**

Cross-border retail sales of tobacco to be banned over the Internet; Vending machines to be banned; Promotion and displays in retail stores to be banned

**additional option**

Point of sale displays of tobacco products have become de facto promotional displays for tobacco products and brands. We strongly support their removal from view. This applies whether or not plain generic packaging is introduced, since aggregations of tobacco packs in what is in effect alibi marketing will be exploited by tobacco companies to promote the presence of the product. We fully support the proposal to prohibit tobacco vending machines, since these are an important source of cigarettes for children and young people. We also point out that the text of the definition of the problem could state that the Irish point of sale legislation was implemented in 2009, and that similar measures are due to be introduced in Scotland in 2011 for supermarkets and 2013 for large shops.

---

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**questions scope**

**problem definition**

No

**explanations**

We have entered no as it is a compulsory answer, but please be aware that this section does not concern our organisation.

**which option**

No change

**recommend option**

As above

**questions smokeless****problem definition**

No

**comments**

We have entered no as it is a compulsory answer, but please be aware that this section does not concern our organisation.

**which option**

No change

**additional option**

As above

**questions consumer****problem definition**

No

**explanations**

The TaxPayers' Alliance does not agree with the problem definition. On packaging, the consultation document says: "Some consumers might even decide to smoke or increase their consumption with lower levels of tar, nicotine and carbon monoxide in preference to quitting". There is no evidence to support this. In the UK at present, consumers are given sufficient information for them to make an informed decision. The document also says that current package design (graphics, colours etc) distracts consumers from health warnings. Again there is no evidence to support this. Further, the Eurobarometer survey cited in the consultation document says that the packaging of cigarettes is the least influential factor in the choice of cigarettes: "The package appears to be the least influential factor of the four discussed."

**which option**

No change

**additional option**

The TPA doesn't agree that there is a problem in this regard in the first place, so we do not think it is an option to solve a problem. The phrasing of the question explicitly implies that there is a problem to start with, and in that respect we believe future consultation documents

should be far less leading and seemingly set on a range of conclusions. Option 2 would actually reduce the level of information available to consumers – in the UK there are precise amounts of potentially harmful products clearly stated on the side of the package, along with health warning images. Consumers can make an informed decision to buy a legal product with full knowledge of the health risks. Reducing the level of information on the side of the packet takes that information away. Option 3 – introducing plain packaging – is particularly egregious. To repeat, the Eurobarometer survey cited in the consultation document explicitly states that packaging is the least influential factor on purchasing tobacco products. It is unfair to regulate a legitimate industry to the extent that competing companies cannot differentiate their brands. To our knowledge, there is no evidence at all that plain packaging of tobacco products improves public health. It is not a requirement of the World Health Organisation Framework Convention on Tobacco Control, and should not be considered as an option under this EU Directive. Plain packaging would also inevitably reduce the amount of information available to consumers – a perverse move considering the objective is to improve public health and increase the role of the illicit trade. To reiterate, there should be no change from a situation where Member States are able to independently implement sufficient measures to offer public health advice and provide enough information for consumers to make an informed decision. In the UK, we currently have ingredients information and pictorial warnings. Further change to this would impose unfair restrictions on an industry that is already heavily regulated, and which has complied with these regulations.

**questions on reporting**

**problem definition**

No

**explanations**

We have entered no as it is a compulsory answer, but please be aware that this section does not concern our organisation.

**which option**

No change

**additional options**

As above

**regulation of ingredients**

**problem definition**

No

**explanations**

We have entered no as it is a compulsory answer, but please be aware that this section does not concern our organisation.

**which option**

No Change

**additional option**

As above

**access to tobacco products**

**problem definition**

No

**explanations**

The TPA does not agree with the display ban of tobacco products in the UK or anywhere else in the EU. This will appear to criminalise a legal product. More importantly, it impinges on small businesses that will have to adapt to this new measure, and whose profits will suffer as a result. The Association of Convenience Stores estimate that this will impose a cost of £40 million to the convenience industry alone. Again, the problem definitions and “options” provided in the consultation document do not allow for open and constructive debate this issue. There appears to be a pre-conceived notion of how this Directive will look, with a consultation on its severity.

**which option**

No change

**additional option**

If the options given, no change is preferable. Option 2 looks to control the supply of tobacco products. This is inherently anti free-market. Option 3 – a display ban – is a more hysterical version of this and is a grossly disproportionate response to any public health concerns. In a free market, we trust adults to make choices based on information and consumer preferences. A display ban would detract from this. The UK – as with other EU countries – is a market economy. In order to function and compete in a market economy, a company must be allowed to display its products to consumers. We believe that a display ban would increase the sales of illegal tobacco products. The Treasury in the UK loses out on around £3 billion a year in tax revenue from the sale of illicit tobacco products. A display ban would exacerbate this problem. Illegal tobacco products are often not what they are advertised as – brands are mimicked frequently. One problem with this is that a black market reduces the choice a consumer has in a free market. Another problem is that the same level of information is not available to consumers, on brand, ingredients or anything else. A final problem is that other additions to the ingredients – which haven’t been scientifically tested or regulated – could potentially be added to illicit products.

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**NGO submission****identification****affiliation**

NGO

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**gender**

female

**questions scope****problem definition**

Yes

**which option**

Extend the scope of the Directive

**recommend option**

The scope of the directive should be enlarged to ban also new tobacco products and novel forms of oral tobacco.

**additional comments**

Consumers believing these marking strategies are lured into continuation of their habit instead of giving up smoking. This is particularly true for women and girls, who have on one hand have a great concern for their health. On the other hand, giving up smoking is much harder for women and girls as it is for men... Therefore so called "less harmful" tobacco products offer an alternative to quitting and counteract targeted prevention efforts. WHO considers that the next victims of the tobacco epidemic will be women. In fact WHO expects that until 2025 the number of women smoking is expected to triple. In Europe since 1980, smoking rates have steadily decreased with men but have increased for women. An increase of women smoking rates between 1985-2003 could be shown in Lithuania (100%), Greece (95%), Malta (91%), Finland (36%), Austria (24%), Hungary (24%), Estonia (16%), Cyprus (14%), Germany (11%), Spain (8%) (Aspect report 2004). Highest smoking rates of women in Europe in 2005 were recorded in : Austria, Germany, Greece, Hungary and Luxembourg with adolescents girls having higher smoking rates than women (Women's Health in the European Union 2010). All over Europe it has been seen that socially disadvantages women smoke most. In Germany, 50% of women aged 18-39 of low socioeconomic level smoke (compared to 26% in the general population). Smoking rates rise to 54% for single mothers and to almost 60% for long term unemployed women (Lampert 2010). Especially worrying is that an average of 13% of pregnant women smoke. This figure rises to 20% for pregnant women with low socioeconomic background (Schneider 2009). Tobacco related mortality rose between 1993- 2003 for women by 45% and decreased with men in the same time period by 14% (Neubauer 2006). We would like to remind the European Commission that it has ratified and signed the Framework Convention on Tobacco Control. Therein the need for a particular attention to gender specific aspects in any comprehensive tobacco control policy is laid down. We would like to stress the need for particular attention to gender specific issues within the future directive.

**questions smokeless****problem definition**

Yes

**which option**

Ban on all types of smokeless tobacco products

**additional option**

New smoking devices have been developed to perpetuate the smoking habit and to counteract

tobacco prevention and cessation efforts by governmental and non governmental organisations. So called “electronic cigarettes” are being commercialised as less hazardous alternatives to smoking or even as smoking cessation aids. The scientific evidence shows however, that these products are simple nicotine delivery devices, are highly addictive and should therefore not be sold in the EU.

### **additional comments**

The prohibition on the marketing of tobacco for oral use ("snus") is a priority and should remain banned in the European Union. As other tobacco products they contain toxic and cancerogenic substances. They increase the risk of cardio vascular disease and oral cancer. Furthermore, tobacco for oral use is highly addictive. Data from Sweden, Norway and Finland have shown that smokeless tobacco products are particularly attractive to young people and that it can serve as an initiator to later tobacco smoking. It should therefore not be considered as an effective cessation aid, but as all other tobacco products who kill when used as intended.

### **questions consumer problem definition**

Yes

### **which option**

Introduce generic or plain packaging

### **additional option**

We support the introduction of mandatory pictorial health warnings on all tobacco products (including oral and water pipe tobacco) covering 80% of the front and the back of the packs towards the top, in combination with standardized packaging. We see standardised packaging as the prohibition of the use of logos, colours, brand images or promotional information on the packaging of tobacco products. It allows the use of brand names and product names, which have to be displayed in a standard colour and font style. Tobacco companies should only be allowed to have one standardized presentation (as already exist in Uruguay) and package size per cigarette brand.

### **additional comments**

A revision of the directive as proposed, would particularly benefit women and girls. Women and girls are a priority target group of the tobacco industry. Sophisticated marketing techniques especially designed for women and girls link symbols of beauty, attractiveness and freedom to tobacco products. Tobacco companies circumvent bans of tobacco advertising by using cigarette packs as advertising space to confer their messages. Cigarette names (Vogue, Slimline, Eve, Glamour, Balance, Diana etc.), packaging (colours such as white, light blue, pink conferring the impression of elegance and suggesting diet products), package size (tall pack suggesting slimness/elegance ) are designed to turn the cigarette packet into an indispensable, fashion accessory for women and girls. Women are very health conscious. Research of tobacco documents in Guilford Depository has shown that “light” cigarettes were especially developed and designed to preserve the female market in the light of increased consciousness of tobacco related harm. Although denominations such as “light” and “mild” suggesting that products might be less hazardous, have been banned through the current directive, colour schemes on cigarette packs in combination with varying indications of tar, nicotine or carbon monoxide yields, still confer this impression. Women remain conscious of this difference and choose “Light” cigarettes. They are still the preferred brand of women and girls. Therefore, there should be no tar, nicotine or carbon monoxide yields indicated on

tobacco packages. In this context it is also important that a Quit line telephone number ( not related to the tobacco industry or its allies) can be seen visibly on all tobacco products.

### **questions on reporting**

#### **problem definition**

Yes

#### **which option**

Establish a common compulsory reporting format; Introduce fees and sanctions

#### **additional options**

We would endorse Option 2: Establish a common compulsory reporting format Tobacco industry would be obliged to use one harmonized reporting format, ideally combined with the electronic submission of data. Non compliance should be fined severely.

### **regulation of ingredients**

#### **problem definition**

Yes

#### **which option**

Establish a common list of tobacco ingredients

#### **which one**

Establish a positive common list of tobacco ingredients

#### **additional option**

We would endorse the establishment of a positive list of ingredients, flavourings and additives which are allowed in tobacco products. These ingredients, flavourings and additives may not be cancerogenic or suspected to cause cancer, in both burnt and unburnt form. They must not have the power to increase addictiveness of tobacco products or make smoking more palatable. This is particularly important for young people and girls. Ingredients, flavourings and additives should be regularly tested to show that they correspond to the conditions listed above. If that is not the case the substance should not be allowed to be registered on the list or be removed from it.

#### **additional comments**

As an example we would like to cite menthol, which increases the addictiveness and the health damage caused by tobacco smoking. We would like to emphasise that numerous flavoured products are coming on the market which appeal especially to the young. We need to avoid the development of a “candy cigarette” culture ! Furthermore, flavourings mask the smell of tobacco smoke. This makes it even more difficult to protect especially children from the harmful effects of passive smoking, as the smell of flavoured tobacco products does not immediately alert one’s attention. In this context we do insist on the effective implementation of Guidelines on Art 9 and 10 with regard to the regulation of the contents of tobacco products and of tobacco product disclosures. We do need a comprehensive regulatory system in Europe to reduce the attractiveness of tobacco products, their addictiveness, and their overall toxicity.

### **access to tobacco products**

#### **problem definition**

Yes

**which option**

Controlled supply and access

**which supply and access**

Age verification of buyers and other legal conditions to be set for cross-border retail sale;  
Tobacco display and promotion at points of sales to be restricted

**additional option**

We request a ban of vending machines and of tobacco displays by the most appropriate legal instrument, taken into consideration the EU legal competence in this field. A ban of vending machines is a particularly high priority for Germany as more than 400.000 vending machines are available in urban and rural communities. Although a checkcard system is in place, this is easy to circumvent by young people who are under age. Tobacco products should only be sold “under the counter” and only in especially licensed outlets. In Germany cigarettes can be bought everywhere ( filling stations, supermarkets, kiosks, building supplies stores, etc). It has been shown that cigarette displays generally are displayed together with sweets at the cash desks of stores. The prominent display promotes sales through easy access, quick information on product characteristics and price. The constant confrontation with cigarettes increases the urge to buy to satisfy one’s addiction. Considering that the use of electronic media is the most important source of information and communication of young people, we request a ban of cross-border sales of tobacco products through internet by postal or any other mail delivery or through direct marketing systems.

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**NGO submission**

**identification**

**affiliation**

NGO

**name**

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France

**questions scope**

**problem definition**

Yes

**which option**

Extend the scope of the Directive

**additional comments**

All tobacco products are hazardous to health – there is no safe level of usage. Therefore we recommend that the scope of the Directive includes the regulation of any new smoked tobacco products (such as low emission or nicotine-free cigarettes), while the prohibition of any novel forms of oral tobacco, including snus, should be maintained. Herbal cigarettes are also harmful because it is the combustion and inhalation of smoke that causes most of the harm from smoking. Therefore, herbal cigarettes should be included in the scope Tobacco Products Directive and should also be subject to health warnings requirements. Finally, all forms of nicotine based products (that is, products containing nicotine but which are not tobacco products, such as electronic cigarettes, nicotine gel, drinks, and sweets) are often marketed as alternatives to cigarettes and in some cases as an aid to quitting smoking. Therefore, they should only be sold as quitting aids and comply with specific safety and quality requirements under the same regulatory framework as pharmaceutical products rather than under the scope of the Tobacco Products Directive.

**questions smokeless****problem definition**

Yes

**which option**

No change

**additional comments**

The ban on snus should definitely be maintained. If the ban on snus were to be lifted, it could encourage dual use of cigarettes and smokeless tobacco and discourage total abstinence from tobacco, thus weakening any potential health gains. In this context, we stress that there are already available effective treatments for nicotine addiction, including medicinal or ‘clean’ nicotine (NRT), that do not carry the risks associated with the use of snus. These should be promoted first and foremost. It is clear that the public health interest can be served even more by encouraging a) greater use of these treatments and b) the development of more effective cessation aids, especially those that mimic more closely the nicotine ‘hit’ delivered by cigarettes. Smokeless tobacco products should be regulated as tobacco products. They are as addictive and dangerous as smoked tobacco and increase the risk of heart disease as well as cancer.

**questions consumer****problem definition**

No

**explanations**

The problem definition does not reflect the population support for mandatory pictorial warnings and mandatory plain packaging, highlighted in the Eurobarometer survey released in 2010.

**which option**

Improve consumer information; Introduce generic or plain packaging

**which improvement**

Picture warnings to become mandatory; Tar, nicotine and carbon monoxide levels to be

replaced with general information on harmful substances in tobacco products; Information on harmful substances in tobacco products that cannot be placed on the package would be placed inside the package; Health warnings to be put on water pipes

### **additional option**

Importance of Graphic health warnings: Evidence shows that text only warning messages are not as effective as graphic warnings. Pictures, especially fear inducing pictures, are proven to be effective in getting consumers more engaged with the warning message and to immediately prompt people to read the associated text message(1). Need for graphic health warnings on both sides of the pack: There is also evidence that pictures on both sides of the packaging have a greater impact (2). Need for LARGE pictorial health warnings (80%): Evidence clearly shows that increasing the size of warning messages (text only and combined text and picture) increases the effectiveness of the warning amongst both young and adult smokers / non smokers (3). Proved effectiveness of shocking health warnings & targeted messages: fear inducing warnings (using strong “shocking” images related to health risks) and strong emotion inducing warnings (especially involving children and unborn babies) are the most effective way to educate consumers on the health risks of tobacco use and to achieve changes in attitudes and behaviour. These warnings’ effectiveness is enhanced if they are used in conjunction with a quit line. Generic or plain packaging: We strongly recommend the introduction of standardised/plain packaging. This should include not only the removal of all branding from the packaging but the size and shape of the packaging should also be standardised. The tobacco industry claims that plain packaging would contravene intellectual property law. However, legal analysis concludes that this is incorrect and there are no international legal impediments to the implementation of generic packaging (4). Replace TNCO quantitative labelling with qualitative information on contents, emissions and quit-lines: The inclusion of machine-based tar, nicotine and carbon monoxide yields on cigarette packs promotes the mistaken belief that some cigarette brands are less harmful than others. We support the proposal to replace numerical measurements with descriptive information on the hazardous effects of tobacco constituents and emissions. We stress the importance of putting quit line numbers on the package. As underlined in the Sambrook research (2), providing a telephone number on the pack is more effective than telling smokers to seek advice from a doctor or pharmacist. Health warnings on water pipes: There is a growing body of evidence to show that water pipes are at least as hazardous, if not more so, than other forms of tobacco use. Warnings should also be included on the packaging of tobacco used in water pipes. 1- Sambrook Research International. A review of the science base to support the development of health warnings for tobacco packages. A report prepared for the European Commission. May 2009: [http://ec.europa.eu/health/tobacco/docs/warnings\\_report\\_en.pdf](http://ec.europa.eu/health/tobacco/docs/warnings_report_en.pdf) p. 42 2- Sambrook Research International. A review of the science bas to support the development of health warnings for tobacco packages. A report prepared for the European Commission. May 2009: [http://ec.europa.eu/health/tobacco/docs/warnings\\_report\\_en.pdf](http://ec.europa.eu/health/tobacco/docs/warnings_report_en.pdf) p. 46 3- Createc report prepared for Health Canada (2008). Effects of modified packaging through increasing the size of warnings on cigarette packs. Quantitative study of Canadian adult smokers 4- Davison M. Plain packaging of cigarettes: Would it be lawful? Australian Intellectual Property Law Bulletin October 2010; 105-108

### **additional comments**

Under Article 5.3 of the TPD 2001, Member States have the option to adopt pictorial warnings. This situation emphasised the right of Member States to go further than the Directive to protect public health as set out in Article 30 of the Treaty of the Union (now article 36). Ten years after the entering into force of the TPD, four countries (the UK,

Belgium, Romania and Malta) have adopted the option. More countries such as Spain and France are planning to adopt mandatory pictorial warnings. Such measures are in compliance with the current TPD and are welcomed by the tobacco control community. However, their adoption by some Member States necessarily creates growing discrepancies between Member States. As stated above, there is clear evidence that pictorial warnings are much more powerful than written health warnings. Extending the information and protection to all EU Member States would be in harmony with Article 168 of the TFEU and consistent with the objectives of the internal market stated in Article 114.3 of the TFEU and reiterated in Recital 19 of the Directive. A revision of the TPD should, therefore, aim at making pictorial health warnings of tobacco products subject to common rules.

### **questions on reporting**

#### **problem definition**

Yes

#### **which option**

Establish a common compulsory reporting format; Introduce fees and sanctions

#### **additional comments**

The current situation which allows different formats and reporting mechanisms is unsatisfactory, making it difficult for authorities to compare and analyse the data. All tobacco manufacturers and importers should be subject to the same reporting requirements. Tobacco products should be subject to an effective reporting system that allows the gathering and analysis of relevant data, including comparison as appropriate, in order to ensure high levels of consumer safety and information. The format already exists (based on the voluntary reporting format developed by the Commission in May 2007) and it would therefore be very easy to adopt this measure and to implement it. It is crucial that the appropriate toxicological and addictiveness tests are properly conducted. Such tests would allow policy-makers to make more informed decisions in this field, as there would be more scientific evidence. It would enhance the scientific knowledge of the dangers of tobacco products and would contribute to a high protection of health, as stated in Article 95.3 TFEU. Besides, such measures would also have an indirect impact on illicit trade, since only registered products would be allowed on the market. We welcome the introduction of yearly registration fees in order to finance the data collection on ingredients by the national authorities and their analysis work on ingredients. The payment of penalties in case of non-compliance with the requirements of delivery of data on tobacco product ingredients also seems adequate and would contribute to fund the tests conducted on these products.

### **regulation of ingredients**

#### **problem definition**

Yes

#### **which option**

Establish a common list of tobacco ingredients

#### **which one**

Establish a positive common list of tobacco ingredients

#### **additional comments**

We support the adoption of a positive common list of tobacco ingredients. Tobacco products

are highly toxic and addictive, and their content should therefore be closely regulated, in order to achieve high standards of health protection, as stated under article 114.3. There is a need for such a list at EU level since at the moment, consumers in the internal market are not subject to the same level of protection. Some citizens may be using substances that are banned in other Member States. Apart from creating unequal health protection across the EU, this may constitute an obstacle to free movement of goods within the internal market: some countries can refuse access to their markets of cigarettes from Member States that do not comply with the importing Member State's national requirements. Regulation of Flavours and Ingredients: Flavourings are an increasingly important part of tobacco industry marketing, particularly to young people. Flavourings enhance attractiveness, encourage youth initiation, and discourage cessation. The prohibition of ingredients that may be used to increase attractiveness, such as sugars and sweeteners, flavouring substances, and spices and herbs, in cigarettes and cigarette-like tobacco products should be introduced. The prohibition of ingredients that may create the impression of a health benefit (e.g. vitamins), ingredients associated with energy and vitality (e.g. caffeine), and ingredients with colouring properties (e.g. pink cigarette paper) should also be banned. Tobacco manufacturers and importers should report sales volume information by brand. This information is essential to help governments ensure that product regulation is effective. The above measures should be compliant with the Guidelines on Art. 9/10, adopted unanimously at the Fourth Conference of the Parties in Uruguay on the 20th November 2010.

#### **access to tobacco products**

##### **problem definition**

Yes

##### **which option**

Ban

##### **which one2**

Cross-border retail sales of tobacco to be banned over the Internet; Vending machines to be banned; Promotion and displays in retail stores to be banned

##### **additional option**

We urge the Commission to call for a ban on the promotion of tobacco products at point of sale and a ban on vending machines as described in the Art 13 Guidelines of the FCTC.

##### **additional comments**

Internet. The principle of preventing cross-border promotion of tobacco products in order to protect public health was enshrined in the Tobacco Advertising directive (2001/0119). It is logical, therefore, to extend that principle to the sale of tobacco products between member states via the Internet. We support the prohibition of tobacco sales via the Internet. Vending machines. The majority of member states (22 out of 27) already prohibit the sale of tobacco products from vending machines in order to deter young people accessing cigarettes from this source. We support this measure. Point of Sale. Evidence shows that a coordinated cross border marketing strategy on the part of the tobacco companies is reflected at point of sale (i.e. point of sale marketing is similar in most EU countries (i.e.: a brand is advertised at point of sale in the same way in Germany and Belgium). There is a growing body of evidence to show that putting tobacco products out of sight in retail outlets can reduce youth smoking. We strongly support an EU-wide adoption of a ban on the display of tobacco products at the point of sale.



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**NGO submission**

**identification**

**affiliation**

NGO

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Germany

**questions scope**

**problem definition**

No

**explanations**

Kein Kommentar

**which option**

No change

**questions smokeless**

**problem definition**

No

**which option**

No change

**questions consumer**

**problem definition**

No

**explanations**

kein Kommentar

**which option**

No change

**questions on reporting**

**problem definition**

No

**explanations**

kein Kommentar

**which option**

No change

**regulation of ingredients**

**problem definition**

No

**explanations**

kein Kommentar

**which option**

No Change

**access to tobacco products**

**problem definition**

No

**explanations**

kein Kommentar

**which option**

No change

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POLAND

**questions scope**

**problem definition**

Yes

**which option**

Extend the scope of the Directive

**questions smokeless**

**problem definition**

Yes

**which option**

No change

**questions consumer**

**problem definition**

Yes

**which option**

No change

**questions on reporting**

**problem definition**

Yes

**which option**

No change

**regulation of ingredients**

**problem definition**

Yes

**which option**

No Change

**access to tobacco products**

**problem definition**

Yes

**which option**

No change

---

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**questions scope**  
**problem definition**  
No

**explanations**  
bez komentarza

**which option**  
No change

**questions smokeless**  
**problem definition**  
No

**comments**  
bez komentarza

**which option**  
Lifting the ban on snus

**questions consumer**  
**problem definition**  
No

**explanations**  
bez komentarza

**which option**  
No change

**questions on reporting**  
**problem definition**  
No

**explanations**  
bez komentarza

**which option**  
No change

**regulation of ingredients**  
**problem definition**  
No

**explanations**  
bez komentarza

**which option**  
No Change

**access to tobacco products****problem definition**

No

**explanations**

bez komentarza

**which option**

No change

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**NGO submission****identification****affiliation**

NGO

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**country**

UK

**questions scope****problem definition**

Yes

**which option**

Extend the scope of the Directive

**additional comments**

As a professional body representing Paediatricians in the UK, we have a commitment to ensuring the best outcomes for children. Therefore we want to highlight the particular implications for children and young people of appropriate tobacco control. Clearly I'd start by reiterating that smoking is bad for children, both their own smoke and other people's. RCPCH has been involved with a recent review regarding passive smoking and children (RCP, 2010) and has identified evidence that exposing children to family and household smoking increases the risk of sudden infant death, lower respiratory infection, middle ear disease, wheeze, asthma, and meningitis in the child. The report also estimates that passive smoking results in over 165,000 new episodes of disease, 300,000 primary care contacts, 9,500 hospital admissions, at least 200 cases of bacterial meningitis, and about 40 sudden infant deaths each year with the under 18 year old population within the UK. It is our view that the most effective means of protecting children from passive smoking is to reduce the prevalence of smoking in adults, and particularly young adults. We recognise that the individual components of tobacco control policy typically have relatively modest individual effects. However their collective impact can be substantial. The vast majority of smokers take up the

habit before 18 years of age, and some 70% of them regret smoking and wish to quit within a year of starting, but find it difficult to do so. Cessation programmes for young people are of uncertain efficacy, and young people will not use “mainstream” cessation services, so there is every reason to try to stop young people from starting. In terms of the scope of the directive We recommend the following: + Extend the scope of the Directive to include all smoked products including herbal cigarettes. + Maintain the ban on any novel forms of oral tobacco products including snus. + Do NOT extend the Directive to include electronic nicotine delivery systems (ENDS or E-cigarettes). It is the combustion process and inhalation of smoke that causes most of the harm from smoking. Therefore it is appropriate that herbal cigarettes, which are used in a similar way as nicotine cigarettes, are regulated in the same way as smoked tobacco products, and should be included in the scope of the Directive. All tobacco products are hazardous to health – there is no safe level of usage. Therefore we recommend that the scope of the Directive includes the regulation of any new smoked tobacco products (such as low emission or nicotine-free cigarettes), while the prohibition of any novel forms of oral tobacco, including snus, should be maintained. Novel nicotine based products (that is, products containing nicotine but not tobacco products) have the potential to offer a less hazardous alternative to cigarettes. Currently these include e-cigarettes and nicotine gel. However, as such products are generally marketed as alternatives to cigarettes and in some cases as an aid to quitting smoking, it is appropriate for them to be brought under the same regulatory framework as pharmaceutical products rather than under the scope of the tobacco products directive. The question of how nicotine containing products should be controlled is currently under consideration by the UK’s Medicines and Healthcare Regulatory Authority (MHRA) following a recent public consultation on whether to extend its remit on the regulation of nicotine replacement therapies to other nicotine containing products. The outcome of this consultation may assist the Commission in developing its policy on these products.

**questions smokeless  
problem definition**

Yes

**which option**

No change

**additional comments**

The ban on snus should remain. Although research suggests that use of Swedish snus is less hazardous compared to cigarettes with regard to the risk of contracting most forms of cancer, the product is not without risk and there is some evidence of an increased risk of cardiovascular disease. There is therefore no legitimate reason to justify bringing a new hazardous product onto the market. There is little evidence that smokers in EU countries other than Sweden would find snus to be an acceptable alternative to cigarettes, were it to be legalised. If the ban on snus were to be lifted, it could encourage dual use of cigarettes and smokeless tobacco and discourage total abstinence from tobacco, thus weakening any potential health gains.<sup>ii</sup> With regard to other smokeless products, particularly those used by ethnic minority populations, we recommend that they are more tightly regulated but we do not support a total ban on such products. A ban would likely be counter-productive and make it more difficult to engage with users and to offer help in quitting.

**questions consumer  
problem definition**

Yes

**which option**

Improve consumer information; Introduce generic or plain packaging

**which improvement**

Picture warnings to become mandatory; Tar, nicotine and carbon monoxide levels to be replaced with general information on harmful substances in tobacco products; Information on harmful substances in tobacco products that cannot be placed on the package would be placed inside the package; Health warnings to be put on water pipes

**additional comments**

Picture Warnings We strongly recommend that picture warnings should be mandatory and that they should occupy a minimum of 80% of the front and back surfaces of all tobacco packaging (i.e not just cigarettes). The warnings should be placed on the upper portion of the packs for maximum visibility. The current situation with some Member States adopting picture warnings whilst others have not done so has created a discrepancy and uneven health protection across the EU. From an internal market perspective, the differences in rules are contrary to the operation of the single market and may constitute a barrier to trade. These obstacles should therefore be removed and pictorial health warnings should be mandatory to ensure optimum health protection for all EU citizens. There is good evidence to show that health warnings are effective in conveying the dangers of smoking and helping smokers to quit. They also help deter young people from starting to smoke. Picture warnings are more effective than written warnings.<sup>iv</sup> All warnings should be displayed in rotation so that each message is given equal display to reach its target audience. There is widespread consumer support for pictorial health warnings. A Eurobarometer survey conducted in October 2009 showed that 78% of respondents supported health warnings. Information on Tar, nicotine & carbon monoxide (TNCO) Currently the Directive requires the inclusion of machine-based tar, nicotine and carbon monoxide yields on cigarette packs. This promotes the mistaken belief that some cigarette brands are less harmful than others. The EU should not only remove this requirement from the Directive but should prohibit ISO or any other emissions numbers on the pack. We support the proposal to replace numerical measurements with descriptive information on the hazardous effects of tobacco constituents and emissions. The addition of a quitline telephone service should be included on the packaging. Additional information on harmful substances in tobacco products We support the proposal to include additional information on the health effects of tobacco consumption on inserts inside the packaging. This should include advice on quitting smoking. Generic or plain packaging Plain packaging, with effective pictures of what smoking can do, would be the next step in removing the glamour of smoking and ensuring that the industry does not succeed in replacing those of its customers whom it has killed with young people. There is research to indicate that tobacco advertising does influence young people (Lovato et al, 2003 , Cochrane Database Systematic Review ; (4):CD003439) and that point of sale advertising is part of that sphere of influence. Packaging is part of the image that cigarettes build for their brand and helps to maintain their visibility as a product. Young people are particularly susceptible to such image building. The review found that nonsmoking adolescents who were more aware of or receptive to tobacco advertising were more likely to become smokers later. We strongly recommend the introduction of plain or generic packaging. This should include not only the removal of all branding from the packaging but the size and shape of the packaging should also be standardised. Not only would this prevent the promotion of smoking through branding as occurs presently but it would reinforce the health warning messages. Tobacco packaging

provides a direct link between consumers and manufacturers and is the main marketing channel, particularly in jurisdictions with tobacco advertising bans. Branding gives the misleading impression some cigarettes are safer than others. The tobacco industry claims that plain packaging would contravene intellectual property law. However, legal analysis concludes that this is incorrect and there are no international legal impediments to the implementation of generic packaging.

### **questions on reporting**

#### **problem definition**

Yes

#### **which option**

Establish a common compulsory reporting format; Introduce fees and sanctions

#### **additional comments**

The current situation which allows different formats and reporting mechanisms is unsatisfactory, making it difficult for authorities to compare and analyse the data. Tobacco companies should be required to use a standardised reporting format. Additionally the companies should be required to pay a yearly registration fee to cover the costs of administering this data collection. The above measures should be compliant with Articles 9 & 10 of the Framework Convention on Tobacco Control (FCTC).

### **regulation of ingredients**

#### **problem definition**

Yes

#### **which option**

Establish a common list of tobacco ingredients

### **access to tobacco products**

#### **problem definition**

Yes

#### **which option**

Ban

#### **which one2**

Cross-border retail sales of tobacco to be banned over the Internet; Vending machines to be banned; Promotion and displays in retail stores to be banned

#### **additional comments**

Internet. The principle of preventing cross-border promotion of tobacco products in order to protect public health was enshrined in the Tobacco Advertising directive (2001/0119). It is logical, therefore, to extend that principle to the sale of tobacco products between member states via the Internet. We support the prohibition of tobacco sales via the Internet. Vending machines. The majority of member states (22 out of 27) already prohibit the sale of tobacco products from vending machines in order to deter young people accessing cigarettes from this source. We support this measure. However, as this does not have cross-border effects, we urge the Commission to make the prohibition of tobacco vending machines a non-mandatory measure as part of the product directive. Point of Sale. Although the UK tobacco advertising



and promotion ban greatly reduced tobacco marketing, two key channels of promotion remain. The first is tobacco advertising displays at the point-of-sale. Since the tobacco advertising ban, point-of-sale displays have grown in prominence and size, and a recent survey in two cities in England showed that the vast majority of tobacco displays and gantries were provided and maintained by the tobacco industry.<sup>10</sup> Tobacco pack displays are typically placed in the most prominent position behind the main counter in shops, close to sweets or other products attractive to children, with health warnings on packs often obscured.<sup>11</sup> Given that it has been established that tobacco promotion causes children to initiate tobacco use and continue smoking,<sup>12,13</sup> point-of-sale displays should be prohibited as legislated for in the Health Act. Similarly, there is a growing body of evidence to show that putting tobacco products out of sight in retail outlets can reduce youth smoking. Point-of-sale displays have also been shown to stimulate impulse purchases of cigarettes and may reduce quitting (RCP, 2010). In July 2009, Ireland removed point-of-sale tobacco displays, with very high compliance rates and unpublished data suggest that support for this measure has remained high, while the proportion of 14- to 16-year-olds believing that more than 20% of teenagers their age smoke, has fallen significantly from 63% before to 45% after the ban. We support an EU-wide adoption of a ban on the display of tobacco products at the point of sale. As with vending machines, we urge the Commission to make the prohibition of tobacco vending machines a non-mandatory measure as part of the product directive. The Directive should also remind national governments that they should adopt a comprehensive ban on all forms of tobacco advertising, promotion and sponsorship in accordance with Article 13 of the FCTC.

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## **NGO submission**

### **identification**

#### **affiliation**

NGO

#### **name**

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#### **country**

Republic of Ireland

#### **questions scope**

#### **problem definition**

Yes

#### **which option**

Extend the scope of the Directive

#### **recommend option**

The Irish Heart Foundation (IHF) recognises that all tobacco products are hazardous to health and that there is no safe level of usage. Indeed the US Surgeon General's most recent tobacco

report – How Tobacco Causes Disease (Dec. 2010) – states that there is ‘no risk-free level of exposure to tobacco smoke’. Recognising the damage caused by tobacco products, the IHF recommends that the current prohibition within the Directive on forms of oral tobacco (including snus) should be maintained and that the scope of the Directive should now be expanded to ensure that it can regulate any new and emerging smoked products (such as, low emission or nicotine-free cigarettes). Herbal cigarettes are also harmful because it is the combustion and inhalation of smoke that causes most smoking-related damage. For this reason herbal cigarettes should be included in the scope Tobacco Products Directive and should also be required to include health warnings. Nicotine -based products (that is, products containing nicotine but which are not tobacco products, such as electronic cigarettes, nicotine gel, drinks, and sweets) are often marketed as alternatives to cigarettes and in some cases as aids to quitting smoking. In the future, these products should only be sold as quitting aids and should be required to comply with specific safety and quality requirements under the regulatory framework imposed on other pharmaceutical products.

**questions smokeless**

**problem definition**

Yes

**which option**

No change

**additional option**

The ban on snus in the Directive should be maintained. There is no legitimate reason to now introduce this dangerous product onto the market. For internal market purposes there is no need to lift the ban. A small study conducted by the University of Nottingham showed that people in the UK could not see the point of snus unless it was as a cessation aid. This indicates that there is currently no demand for this product. Furthermore, if the ban on snus were to be lifted, it could encourage dual use of cigarettes and smokeless tobacco and discourage people from quitting. Where people do wish to stop smoking there are effective treatments already available, including nicotine replacement therapies, that do not carry the risks associated with the use of snus. It is clear that the public health interest can be served even more by encouraging greater use of these treatments and the development of more effective cessation aids.

**questions consumer**

**problem definition**

No

**explanations**

The problem definition should refer to the 2010 Eurobarometer survey which showed that European citizens were in favour of the placing of health warnings on tobacco products. On average, 75% of EU citizens are in favour of mandatory pictorial warnings, and over 54% support plain packaging measures.

**which option**

Improve consumer information; Introduce generic or plain packaging

**which improvement**

Picture warnings to become mandatory; Tar, nicotine and carbon monoxide levels to be

replaced with general information on harmful substances in tobacco products; Information on harmful substances in tobacco products that cannot be placed on the package would be placed inside the package; Health warnings to be put on water pipes

### **additional option**

The IHF strongly recommends the introduction of mandatory pictorial health warnings on all tobacco products (including oral & water pipe tobacco) covering 80% of the front and the back of packs: Evidence shows that text-only warning messages are not as effective as graphic warnings. Pictures, especially fear-inducing images, are proven to be effective in getting consumers more engaged with the warning message and can prompt them to read the associated text health warnings. Graphic warnings should be continually rotated so that each picture is given an equal amount of display and reaches its particular target audience. The effectiveness of pictorial warnings is enhanced where they are used in conjunction with the number of a quit line for smokers to call. If such a measure was introduced in Ireland it would be important to ensure that the National Smokers Quitline service is properly funding and capable of answering the calls of all smokers who wish to use it. Currently, funding for the service is limited. The IHF welcomes the acknowledgement by the Commission that tobacco packaging is increasingly used to attract consumers, to promote products & improve the image of tobacco brands. This point is also strongly made in the RAND report on the TPD. The IHF strongly recommends the introduction of standardised/plain packaging for tobacco products. This should include a prohibition on the use of logos, colours, brand images or promotional information on the packaging of tobacco products. It should restrict the use of brand names and product names to a standard colour and font style. Tobacco packaging provides a direct link between consumers and manufacturers and is the main marketing channel, particularly in jurisdictions with tobacco advertising bans. Plain packaging enables health warnings to be the main message of the pack. The RAND report states that: 'There is a body of evidence that shows that pictorial warnings are seen as more effective than text-only warnings for reducing tobacco consumption and uptake. Part of this is due to the fact that pictorial warnings may be less prone to the 'wear-out effects', but another reason is that the use of shocking and disturbing images in pictorial warnings has been found to trigger a stronger response from consumers. The evidence above also showed that larger warnings have proved to be more effective because they are more salient when included on branded cigarette packs and generally 'less easy to avoid' (p.139).' Branding can also give the misleading impression, through the use of paler colours which may be associated in consumers' minds with 'health' or with lower tar and nicotine levels, that some cigarettes are safer than others. The tobacco industry claims that plain packaging would contravene intellectual property law. However, legal analysis concludes that this is incorrect and there are no international legal impediments to the implementation of generic packaging. As the RAND report highlights, 'various trademark attorneys have been presenting their views on the legal side of the debate and have come to the conclusion that plain packaging would not violate the tobacco industry's intellectual property rights' (p. 133). The current inclusion of TNCO yields on cigarette packs promotes the mistaken belief that some cigarette brands are less harmful than others. The IHF supports the proposal to replace numerical measurements with more informative descriptive information on the hazardous effects of TNCOs. Health warning should be included on water pipes. There is a growing body of evidence to show that water pipes are at least as hazardous, if not more so, than other forms of tobacco use. Warnings should also be included on the packaging of tobacco used in water pipes.

### **additional comments**

Under Article 5.3 of the Tobacco Products Directive (TPD) 2001, Member States have had

the option to adopt pictorial warnings in their own jurisdiction. This enabled Member States to go further than the Directive to protect public health. Ten years after the entering into force of the Directive, four countries have adopted pictorial warnings. Spain and France, amongst others, are also planning to adopt mandatory pictorial warnings. In Ireland, the provisions of the Public Health (tobacco) (Amendment) Act 2009 enable the Irish Government to introduce pictorial warnings. Despite this ability in law the government has been slow to introduce the necessary regulations and there is still no timeframe for the introduction of pictorial warnings. The revision of the Directive requiring the introduction of pictorial warnings would provide the necessary impetus to Ireland and other Member States. The adoption of pictorial warnings by some Member States and not by others has created considerable discrepancies between Member States. As stated above, there is clear evidence that pictorial warnings are much more powerful than written health warnings. Extending pictorial warnings to all EU Member States would be in harmony with Article 168 of the Treaty on the Functioning of the European Union (TFEU) and consistent with the objectives of the internal market stated in Article 114.3 of the TFEU and reiterated in Recital 19 of the Directive. A revision of the TPD should make pictorial health warnings of tobacco products subject to common rules.

### **questions on reporting**

#### **problem definition**

Yes

#### **which option**

Establish a common compulsory reporting format; Introduce fees and sanctions

#### **additional comments**

The current situation allowing different ingredient reporting formats and mechanisms in different Member States is unsatisfactory and makes it difficult for authorities to compare and analyse data across the EU. All tobacco manufacturers and importers in all Member States should be subject to the same reporting requirements. The Irish Heart Foundation believes that all tobacco products should be subject to an effective reporting system that allows the gathering and analysis of relevant data, including comparison across Member States, in order to ensure high levels of consumer safety and information. The format already exists (based on the voluntary reporting format developed by the Commission in May 2007) and it would therefore be very easy to adopt and implement this measure. The Irish Heart Foundation welcomes the introduction of yearly registration fees in order to finance data collection and analysis on ingredients by national authorities. Such tests would add to scientific evidence and allow policy-makers to make more informed decisions in this field. The payment of penalties by tobacco manufacturers where they fail to provide the required data would help to fund the tests conducted on these products. The Irish Heart Foundation agrees with the option discussed in the RAND report whereby, in line with the polluter-pays principle, tobacco manufacturers could be made liable for health problems associated with tobacco use and would be required to pay a compensation payment to address this cost. The production, packaging and consumption of tobacco products also exert a heavy toll on the environment. The negative environmental impact of tobacco usage is significant and the cost to Member States of cleaning up such litter is considerable. Currently, the tobacco industry bears no cost for the pollution caused by their products. The Irish Heart Foundation would recommend an environmental levy on tobacco products should be levied directly on the tobacco industry, utilising the producer pays principle.

#### **regulation of ingredients**

**problem definition**

Yes

**which option**

Establish a common list of tobacco ingredients

**which one**

Establish a positive common list of tobacco ingredients

**additional option**

The Irish Heart Foundation supports the adoption of a positive common list of tobacco ingredients. We believe that tobacco products are highly toxic and addictive and that their content should be closely regulated. There is a need for such a list at EU level – currently consumers in the internal market are not subject to the same level of protection and some citizens may be using substances that are banned in other Member States. Apart from creating unequal health protection across the EU, this may also constitute an obstacle to free movement of goods within the internal market because some countries can refuse access to their markets of cigarettes from Member States that do not comply with the importing Member State's national requirements. Tobacco manufacturers and importers should report sales volume information by brand. This information is essential in assisting governments to regulate products effectively. The flavourings added to tobacco products should be regulated. Flavourings are an increasingly important part of tobacco industry marketing. Tobacco manufacturers often include additives such as sweeteners in their products that potentially make them more palatable to young people and some manufacturers have increased levels of ammonia which enhances the absorption of nicotine, making them more addictive. Ingredients in tobacco products that may be used to increase attractiveness (such as sugars and sweeteners, flavouring substances, and spices and herbs) and ingredients that may be designed to create the illusion of a health benefit (such as vitamins), ingredients associated with energy and vitality (e.g. caffeine) and ingredients with colouring properties (e.g. pink cigarette paper) should all be banned.

**access to tobacco products****problem definition**

Yes

**which option**

Ban

**which one2**

Cross-border retail sales of tobacco to be banned over the Internet; Vending machines to be banned; Promotion and displays in retail stores to be banned

**additional option**

We urge the Commission to call for an EU-wide ban on the promotion of tobacco products at point of sale and a ban on vending machines as described in the Art 13 Guidelines of the Framework Convention on Tobacco Control.

**additional comments**

Cross-border retail sales of tobacco over the internet should be banned. The principle of preventing cross-border promotion of tobacco products in order to protect public health was

enshrined in the Tobacco Advertising directive (2001/0119). It is logical, therefore, to extend that principle to the sale of tobacco products between member states via the Internet. Sales of tobacco products through vending machines should be banned. The majority of member states, including Ireland, have restrictions on the sale of tobacco products from vending machines in order to deter young people accessing cigarettes from this source. Point of sale advertising should be banned. There is a growing body of evidence to show that putting tobacco products out of sight in retail outlets can reduce youth smoking. To date, this measure has been adopted by Ireland and Finland (as well as Iceland and Norway). This measure is also official government policy in Scotland, Wales and Northern Ireland and a decision is awaited in England. We strongly support an EU-wide adoption of a ban on the display of tobacco products at the point of sale. Recent research carried out by the University of Nottingham one year after the introduction of the point-of-sale ban in Ireland shows that the ban has had the intended effect of reducing young people's awareness of tobacco products - recall of tobacco displays among teenagers decreased from 81% before the legislation to 22% afterwards. The Irish Heart Foundation is concerned with the tobacco price variation across the EU. Tobacco taxation is the most effective tool to reduce consumption – high tobacco prices and regular price increases are the most effective measures to encourage smokers to quit. Price variation across Member States is particularly an issue when combined with indicative legal limits for cigarettes and the ability of passengers to bring large amounts of cheaper cigarettes into countries such as Ireland which have high tobacco prices. The bringing of large amounts of cheaper cigarettes undermines the effectiveness of national tobacco control and health policies.

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## **NGO submission**

### **identification**

#### **affiliation**

NGO

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#### **country**

Denmark

#### **questions scope**

#### **problem definition**

Yes

#### **which option**

Extend the scope of the Directive

#### **additional comments**

All tobacco products are hazardous to health – there is no safe level of usage. Therefore we recommend that the scope of the Directive includes the regulation of any new smoked tobacco

products (such as low emission or nicotine-free cigarettes), while the prohibition of any novel forms of oral tobacco, including snus, should be maintained. People with diabetes has a higher risk of getting heart diseases. Tobacco use increases the risk of heart attack or stroke even more (<http://www.diabetes.org/diabetes-basics/prevention/checkup-america/smoking.html>). Diabetes can block the tiny blood vessels in the eye (retinopathy). Tobacco use can make this problem worse ([http://www.tobaccofreeutah.org/tobacco\\_diabetes\\_handout.pdf](http://www.tobaccofreeutah.org/tobacco_diabetes_handout.pdf)). The Danish Diabetes Association therefore strongly recommend that everything that can be done to minimize tobacco use, is done. We therefore hope that the Directive is maintained or tighten. Herbal cigarettes are also harmful because it is the combustion and inhalation of smoke that causes most of the harm from smoking. Therefore, herbal cigarettes should be included in the scope Tobacco Products Directive and should also be subject to health warnings requirements. Finally, all forms of nicotine based products (that is, products containing nicotine but which are not tobacco products, such as electronic cigarettes, nicotine gel, drinks, and sweets) are often marketed as alternatives to cigarettes and in some cases as an aid to quitting smoking. Therefore, they should only be sold as quitting aids and comply with specific safety and quality requirements under the same regulatory framework as pharmaceutical products rather than under the scope of the Tobacco Products Directive.

**questions smokeless**

**problem definition**

Yes

**which option**

No change

**additional option**

The ban on snus should definitely be maintained. Indeed, there is no legitimate reason to reintroduce a carcinogenic and addictive product onto the EU market. Furthermore, if the ban on snus were to be lifted, it could encourage dual use of cigarettes and smokeless tobacco and discourage total abstinence from tobacco, thus weakening any potential health gains. In this context, we stress that there are already available effective treatments for nicotine addiction, including medicinal or ‘clean’ nicotine (NRT), that do not carry the risks associated with the use of snus. These should be promoted first and foremost. It is clear that the public health interest can be served even more by encouraging a) greater use of these treatments and b) the development of more effective cessation aids, especially those that mimic more closely the nicotine ‘hit’ delivered by cigarettes. Regarding other forms of smokeless tobacco products, The Danish Diabetes Association does not believe that they should be “marketed” in all Member States. We recognise that they are as addictive and dangerous as smoked tobacco.

**questions consumer**

**problem definition**

No

**explanations**

The problem definition could be improved. We agree with the Commission that the current situation, whereby some Member States have made graphic warnings compulsory and others not, has led to a disparity in labelling throughout the EU. Consequently, this has an impact on the functioning of the internal market, on consumers' awareness and as a result, on their smoking behaviour. We also agree that packaging as an advertising tool is not covered by the current Directive. Finally, we welcome the acknowledgement that tobacco packaging and

product features are increasingly used to attract consumers, to promote products and brand image. In this context, it would have been judicious to highlight the fact that, in the Eurobarometer survey released in 2010, the policy that received the most positive response is that of putting health warnings on all packages of tobacco products (on average, 75% of EU citizens are in favour of mandatory pictorial warnings, and over 54% support plain packaging measures).

### **which option**

Improve consumer information; Introduce generic or plain packaging

### **which improvement**

Picture warnings to become mandatory; Tar, nicotine and carbon monoxide levels to be replaced with general information on harmful substances in tobacco products; Information on harmful substances in tobacco products that cannot be placed on the package would be placed inside the package; Health warnings to be put on water pipes

### **additional option**

Crucial importance of Graphic health warnings: Evidence shows that text only warning messages are not as effective as graphic warnings. Pictures, especially fear inducing pictures, are proven to be effective in getting consumers more engaged with the warning message. Pictures are able to immediately provoke a reaction and prompt people to read the associated text message. The need for graphic health warnings on both sides of the pack: There is also evidence that pictures on both sides of the packaging have a greater impact. The need for LARGE pictorial health warnings (80%): The global trend is towards larger health warnings. Uruguay, for instance, has implemented legislation to make pictorial health warnings obligatory, covering 80% of the front and the back of cigarette packs. Evidence clearly shows that increasing the size of warning messages (text only and combined text and picture) increases the effectiveness of the warning amongst both young and adult smokers / non smokers. Research carried out in Canada by Createc on behalf of Health Canada in 2007 showed that young and adult smokers/non smokers are sensitive to the size of health warning messages. Results showed that warning messages that cover 100% of the pack are significantly more effective across all measured effectiveness indicators compared with warning messages that cover only 50% of the pack. The importance of Rotation: Warning texts and pictures should be displayed on a rotating basis, so that each message is given equal display and can reach its target audience. The proved effectiveness of shocking health warnings & targeted messages: as specified in the Sambrook Research International report, fear inducing warnings (using strong “shocking” images related to health risks such as rotten teeth or throat cancer) and strong emotion inducing warnings (especially involving children and unborn babies) are the most effective way to educate consumers on the health risks of tobacco use and to achieve changes in attitudes and behaviour. These warnings’ effectiveness is enhanced if they are used in conjunction with a quit line. Generic or plain packaging: We strongly recommend the introduction of standardised/plain packaging. This should include not only the removal of all branding from the packaging but the size and shape of the packaging should also be standardised. Not only would this prevent the promotion of smoking through branding as occurs presently but it would reinforce the health warning messages. Tobacco packaging provides a direct link between consumers and manufacturers and is the main marketing channel, particularly in jurisdictions with tobacco advertising bans. Branding gives the misleading impression some cigarettes are safer than others. The tobacco industry claims that plain packaging would contravene intellectual property law. However, legal analysis concludes that this is incorrect and there are no international legal impediments to the



implementation of generic packaging. Replace TNCO quantitative labelling with qualitative information on contents, emissions and quit-lines: The inclusion of machine-based tar, nicotine and carbon monoxide yields on cigarette packs promotes the mistaken belief that some cigarette brands are less harmful than others. We support the proposal to replace numerical measurements with descriptive information on the hazardous effects of tobacco constituents and emissions. We stress the importance of putting quit line numbers on the package. As underlined in the Sambrook research (p46), providing a telephone number on the pack is more effective than telling smokers to seek advice from a doctor or pharmacist. P46 Health warnings on water pipes: There is a growing body of evidence to show that water pipes are at least as hazardous, if not more so, than other forms of tobacco use. Warnings should also be included on the packaging of tobacco used in water pipes.

### **additional comments**

Under Article 5.3 of the TPD 2001, Member States have the option to adopt pictorial warnings. This situation emphasised the right of Member States to go further than the Directive to protect public health as set out in Article 30 of the Treaty of the Union (now article 36). Five years after the adoption of the library of 42 pictorial health warnings by the European commission, seven Member States have adopted legislation to introduce pictorial health warnings (Belgium, Romania, United Kingdom, Latvia, Malta, France and Spain). Such measures are in compliance with the current TPD and are welcomed by the tobacco control community. However, their adoption by some Member States necessarily creates growing discrepancies between Member States. As stated above, there is clear evidence that pictorial warnings are much more powerful than written health warnings. Extending the information and protection to all EU Member States would be in harmony with Article 168 of the TFEU and consistent with the objectives of the internal market stated in Article 114.3 of the TFEU and reiterated in Recital 19 of the Directive. A revision of the TPD should, therefore, aim at making pictorial health warnings of tobacco products subject to common rules. Note: Legislation on labelling, advertising and product regulation put forward by the Commission in the field of tobacco control, has been based on the internal market legislation (Articles 26 and 114 of the TFEU). Article 26 of the TFEU establishes the internal market. Article 114 gives EU institutions the competence to regulate and set rules for the functioning of the internal market. More specifically, article 114.3 also states that when establishing rules for the functioning of the internal market in the context of health, safety, environmental protection and consumer protection, the Commission “will take as a base a high level of protection, taking account in particular of any new development based on scientific facts.” The European Court of Justice (the “ECJ”) made an extensive analysis of Article 95 EC (now Article 114) throughout the years. In *Spain v. Council*, the Court observed that “recourse to Article 100a (now Article 114) as a legal basis is possible if the aim is to prevent the emergence of future obstacles to trade resulting from multifarious development of national laws.” The TPD was adopted on the basis of Article 114 TFEU (ex Article 95). As a result, Recital 19 of the TPD states that “[t]he presentation of warning labels and yields has continued to remain variable in the different Member States. As a consequence, consumers in one Member State may be better informed as to the risks of tobacco products than in another. Such differences are unacceptable and are liable to constitute a barrier to trade and to impede the operation of the internal market in tobacco products, and should therefore be eliminated.”

### **questions on reporting**

#### **problem definition**

Yes

**which option**

Establish a common compulsory reporting format; Introduce fees and sanctions

**additional comments**

The current situation which allows different formats and reporting mechanisms is unsatisfactory, making it difficult for authorities to compare and analyse the data. All tobacco manufacturers and importers should be subject to the same reporting requirements. The SFP believes that tobacco products, which are highly harmful, should be subject to an effective reporting system that allows the gathering and analysis of relevant data, including comparison as appropriate, in order to ensure high levels of consumer safety and information. The format already exists (based on the voluntary reporting format developed by the Commission in May 2007) and it would therefore be very easy to adopt this measure and to implement it. We welcome the introduction of yearly registration fees in order to finance the data collection on ingredients by the national authorities and their analysis work on ingredients. The payment of penalties in case of non-compliance with the requirements of delivery of data on tobacco product ingredients also seems adequate and would contribute to fund the tests conducted on these products. It is crucial that the appropriate toxicological and addictiveness tests are properly conducted. Such tests would allow policy-makers to make more informed decisions in this field, as there would be more scientific evidence. It would enhance the scientific knowledge of the dangers of tobacco products and would contribute to a high protection of health, as stated in Article 95.3 TFEU. Besides, such measures would also have an indirect impact on illicit trade, since only registered products would be allowed on the market.

**regulation of ingredients****problem definition**

Yes

**which option**

Establish a common list of tobacco ingredients

**which one**

Establish a positive common list of tobacco ingredients

**additional comments**

We support the adoption of a positive common list of tobacco ingredients. We believe that tobacco products are highly toxic and addictive, and that their content should therefore be closely regulated, in order to achieve high standards of health protection, as stated under article 114.3. There is a need for such a list at EU level since at the moment, consumers in the internal market are not subject to the same level of protection. Some citizens may be using substances that are banned in other Member States. Apart from creating unequal health protection across the EU, this may constitute an obstacle to free movement of goods within the internal market: some countries can refuse access to their markets of cigarettes from Member States that do not comply with the importing Member State's national requirements. Regulation of Flavours and Ingredients: Flavourings are an increasingly important part of tobacco industry marketing, particularly to young people. Flavourings enhance attractiveness, encourage youth initiation, and discourage cessation. The prohibition of ingredients that may be used to increase attractiveness, such as sugars and sweeteners, flavouring substances, and spices and herbs, in cigarettes and cigarette-like tobacco products should be introduced. The prohibition of ingredients that may create the impression of a health benefit (e.g. vitamins), ingredients associated with energy and vitality (e.g. caffeine), and ingredients with colouring

properties (e.g. pink cigarette paper) should also be banned. Tobacco manufacturers and importers should report sales volume information by brand. This information is essential to help governments ensure that product regulation is effective. The above measures should be compliant with the Guidelines on Art. 9/10, adopted unanimously at the Fourth Conference of the Parties in Uruguay on the 20th November 2010.

### **access to tobacco products**

#### **problem definition**

Yes

#### **which option**

Ban

#### **which one2**

Cross-border retail sales of tobacco to be banned over the Internet; Vending machines to be banned; Promotion and displays in retail stores to be banned

#### **additional option**

We urge the Commission to call for a ban on the promotion of tobacco products at point of sale and a ban on vending machines as described in the Art 13 Guidelines of the FCTC.

#### **additional comments**

Internet. The principle of preventing cross-border promotion of tobacco products in order to protect public health was enshrined in the Tobacco Advertising directive (2001/0119). It is logical, therefore, to extend that principle to the sale of tobacco products between member states via the Internet. We support the prohibition of tobacco sales via the Internet. Vending machines. Considering that only 2 Member States have no legislation on vending machines, we support harmonisation of the legislation on the basis of a prohibition of the sale of tobacco from vending machines . Point of Sale. Evidence shows that a coordinated cross border marketing strategy on the part of the tobacco companies is reflected at point of sale (i.e. point of sale marketing is similar in most EU countries (i.e.: a brand is advertised at point of sale in the same way in Germany and Belgium). There is a growing body of evidence to show that putting tobacco products out of sight in retail outlets can reduce youth smoking. To date, this measure has been adopted by Ireland and Finland (as well as Iceland and Norway). This measure is also official government policy in Scotland, Wales and Northern Ireland and a decision is awaited in England. We strongly support an EU-wide adoption of a ban on the display of tobacco products at the point of sale.

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### **NGO submission**

#### **identification**

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NGO

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**country**

Belgium

**questions scope**

**problem definition**

Yes

**which option**

Extend the scope of the Directive

**additional comments**

All tobacco products are hazardous to health – there is no safe level of usage. Therefore we recommend that the scope of the Directive includes the regulation of any new smoked tobacco products (such as low emission or nicotine-free cigarettes), while the prohibition of any novel forms of oral tobacco, including snus, should be maintained. Herbal cigarettes are also harmful because it is the combustion and inhalation of smoke that causes most of the harm from smoking. Therefore, herbal cigarettes should be included in the scope of the Tobacco Products Directive and should also be subject to health warnings requirements. Finally, all forms of nicotine based products (that is, products containing nicotine but which are not tobacco products, such as electronic cigarettes, nicotine gel, drinks, and sweets) are often marketed as alternatives to cigarettes and in some cases as an aid to quitting smoking. Therefore, they should only be sold as quitting aids and comply with specific safety and quality requirements under the same regulatory framework as pharmaceutical products rather than under the scope of the Tobacco products Directive. That includes evidence-based studies of the effectiveness of these products. Special attention should be paid to specific protection of young people and women.

**questions smokeless**

**problem definition**

Yes

**which option**

No change

**additional comments**

The ban on snus should remain. Research suggests that the use of snus in Sweden is less hazardous than cigarettes with the risk of developing most forms of cancer. It should be noted that 40% of snus users continued to smoke tobacco(1) , there is evidence of an increased risk of cardiovascular disease (2) . Removing the ban on snus would bring a new hazardous product to the market. The removal of the ban on the use of snus may encourage the dual use consumption of snus and cigarettes and discourage the cessation of tobacco consumption, losing the associated health gains. There is evidence that the use of snus is shown to produce pathological changes in the oral mucosa: dysplasia and a suggested increase in oral and pharyngeal carcinoma (3,4). The use of other smokeless products should be regulated. These are particularly used by the ethnic minority populations. A total ban on these products may make it more difficult to interface in terms of health education with this section of the population. There is also a risk that an illegal market for products of this type may be created. These issues will have a negative impact on the delivery of oral and general health. 1

Broadstock M. Systematic review of the health effects of modified smokeless tobacco products. New Zealand Health Technology Assessment. Christchurch School of Medicine and Health Sciences. NZHTA Report 2007, Volume 10 Number 1. 2 Piano MR, Benowitz NL, FitzGerald GA et al. Impact of smokeless tobacco products on cardiovascular disease: Implications for policy, prevention, and treatment. A policy statement from the American Heart Association. Circulation, 2010; DOI: 10.1161/CIR.0b013e3181f432c3. 3 Schwart JL. Brunnemann KD. Adami AJ et al Journal of Oral Medicine.39(6):453-9, 2010 July. 4 Rooscaar A. Johansson AL. Sandborgh-Englund G. International Journal of Cancer.123(1):168-73, 2008 July 1.

**questions consumer**

**problem definition**

Yes

**which option**

Improve consumer information

**which improvement**

Picture warnings to become mandatory; Tar, nicotine and carbon monoxide levels to be replaced with general information on harmful substances in tobacco products; Health warnings to be put on water pipes

**questions on reporting**

**problem definition**

Yes

**which option**

Establish a common compulsory reporting format

**additional comments**

It is unsatisfactory to have different formats and reporting mechanisms. A reporting system can only be effective if the same reporting mechanisms are used.

**regulation of ingredients**

**problem definition**

Yes

**which option**

Establish a common list of tobacco ingredients

**which one**

Establish a negative common list of tobacco ingredients

**additional comments**

We support the adoption of a negative common list of tobacco ingredients. Tobacco products are highly toxic and addictive, and their content (main substances and additives) should be closely regulated. Tobacco smoke is a complex mixture of more than 4,800 substances, of which 90 are carcinogens or suspected to cause cancer (5,6,7,8,9). In addition, nicotine and co-carcinogens promote cancer development. Tobacco smoke contains many toxic substances. During inhalation, poisonous gases, volatile substances and also some small particles will be

very quickly absorbed. The tobacco industry, in the production of its tobacco products uses 600 additives that increase the addictive potential and also facilitates the initial use of tobacco. when the cigarettes are smoked at high temperatures, new and sometimes toxic or carcinogenic substances (10) are produced from the additive ingredients. The prohibition of ingredients such as sugars and sweeteners, flavouring substances, spices and herbs, in cigarettes and cigarette-like tobacco products is necessary. The prohibition of ingredients as vitamins, ingredients associated with energy and vitality (e.g. caffeine), and ingredients with colouring properties (e.g. pink cigarette paper) should also be banned. Tobacco manufacturers and importers should report sales volume information by brand. This information is essential to help governments ensure that product regulation is effective. 5 Baker RR (1999) Smoke chemistry. In: Davis DL, Nielsen MT: Tobacco. Production, chemistry and technology. Blackwell Science, Paris, 398–409 6 California Environmental Protection Agency (2005) Proposed identification of environmental tobacco smoke as a toxic air contaminant – June 2005. California Environmental Protection Agency, Office of Environmental Health Hazard Assessment, [http://www.oehha.ca.gov/air/environmental\\_tobacco/2005etsfinal.html](http://www.oehha.ca.gov/air/environmental_tobacco/2005etsfinal.html) 7 Hecht SS (2003) Tobacco carcinogens, their biomarkers and tobacco-induced cancer. Nat Rev Cancer, 3, 733–744 8 International Agency for Research on Cancer (2004) Tobacco smoke and involuntary smoking. IARC Monographs on the evaluation of the carcinogenic risks to humans, Vol. 83. International Agency for Research on Cancer, World Health Organization, Lyon 9 Smith CJ, Perfetti TA, Garg R et al. (2004) Percutaneous penetration enhancers in cigarette mainstream smoke. Food Chem Toxicol, 42, 9–15 International Agency for Research on Cancer (2008) IARC Monographs Volumes 1–99, overall evaluations of carcinogenicity to humans, last update 28.04.08. <http://monographs.iarc.fr/ENG/Classification/crthallist.php> 10 Deutsches Krebsforschungszentrum (2005) Erhöhte Gesundheitsgefährdung durch Zusatzstoffe in Tabakerzeugnissen – Konsequenzen für die Produktregulation. Deutsches Krebsforschungszentrum, Heidelberg

### **access to tobacco products**

#### **problem definition**

Yes

#### **which option**

Controlled supply and access; Ban

#### **which supply and access**

Age verification of buyers and other legal conditions to be set for cross-border retail sale

#### **which one2**

Vending machines to be banned; Promotion and displays in retail stores to be banned

#### **additional comments**

We do not think that option 3a would be effective. A total ban on cross-border sales over the Internet would result in an increase in the black economy as already currently present in many Member States.

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### **NGO submission**

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NGO

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**questions scope****problem definition**

Yes

**which option**

Extend the scope of the Directive

**additional comments**

• The directive should be expanded to include herbal (tobacco-free and/or nicotine-free) smoked products. • We recommend that the existing ban on oral tobacco be maintained • Electronic nicotine delivery systems such as e-cigarettes and other non-smoked, non-tobacco nicotine products (such as gels) should be regulated at some level, however we believe this should be as pharmaceutical products rather than tobacco products (as was recently consulted on in the UK by the Medicines and Healthcare Regulatory Agency (MHRA)) Most of the harm to health caused by tobacco is due to the method of administration, specifically the process of combustion and inhalation common to all smoked tobacco products such as mass-manufactured cigarettes. Tobacco products that are not smoked tend to be significantly less harmful, though not harmless (Royal College of Physicians, 2008). Given this well-established observation, and emerging evidence that some types of herbal, non-tobacco or non-nicotine cigarettes are likely to be injurious to health in a similar manner to conventional tobacco cigarettes (Jorgensen et al, 2010; Gan et al 2009) it is appropriate to include such products within the Directive. Novel nicotine products that do not contain tobacco but which deliver nicotine to the user (such as electronic cigarettes) are relatively recent additions to the nicotine market. Because the method of administering nicotine in these products does not involve combustion or tobacco, they are likely to be significantly safer than smoked tobacco. There is also preliminary, but promising evidence of their efficacy as a potential cessation aid (Bullen et al, 2010). These products are largely unregulated at present throughout the Member States, and there are concerns over inconsistencies in the manufacturing process which may result in the vapour delivered to the user varying from product to product. Because of this, ASH Scotland considers that regulation of these products would have several advantages, ensuring that e-cigarettes and other novel nicotine products are demonstrably safe and effective as a tobacco alternative. The goal of such regulation should be to ensure that products are acceptably safe to the user and that the market permits access to a wide range of acceptable alternative sources of nicotine for current smokers. ASH Scotland favours a regulatory approach that encourages competition within the existing nicotine replacement market (while ensuring safety and efficacy) and that does not advantage existing

pharmaceutical NRT manufactures. Hence we supported the UK Medicines and Healthcare products Regulatory Agency's proposal to regulate e-cigarettes and other nicotine containing products in a recent public consultation, and believe that regulation as a pharmaceutical product is the most appropriate route for these products. We recommend that novel forms of oral tobacco be prohibited from the marketplace in a similar fashion to snus, as outlined in our response to Section 2. Royal College of Physicians. Harm reduction in nicotine addiction: helping people who can't quit. A report by the Tobacco Advisory Group of the Royal College of Physicians. London: RCP, 2007. Jorgensen ED, Zhao H, Traganos F, Albino AP, Darzynkiewicz Z. DNA damage response induced by exposure of human lung adenocarcinoma cells to smoke from tobacco- and nicotine-free cigarettes. *Cell Cycle*. 2010 Jun 22;9(11). Gan Q, Yang J, Yang G, Goniewicz M, Benowitz NL, Glantz SA. Chinese "herbal" cigarettes are as carcinogenic and addictive as regular cigarettes. *Cancer Epidemiol Biomarkers Prev*. 2009 Dec;18(12):3497-501. Bullen, C., McRobbie, H., Thornley, S., Glover, M., Lin, R., and Laugesen, M. Effect of an electronic nicotine delivery device (e cigarette) on desire to smoke and withdrawal, user preferences and nicotine delivery: randomised cross-over trial. *Tobacco Control* 19[2], 98-103. 2010.

### **questions smokeless**

#### **problem definition**

Yes

#### **which option**

No change

### **additional comments**

We recommend that the existing ban on snus in all Member States (except Sweden) should be maintained. Smokeless tobacco products, particularly modified low-nitrosamine products like Swedish snus, although significantly less hazardous than smoking, do not appear to be completely without risk. A systematic review (Broadstock, 2007) concluded that an increased risk of cardiovascular mortality cannot be ruled out. The European Commission's Scientific Committee on Emerging and Newly Identified Health Risks (SCENIHR, 2008) has recently published similar conclusions regarding increased risk of cardiovascular mortality. It is often argued that these potential risks are acceptable in the context of the large difference in harm between continued smoking cigarette smoking and snus use. However, it remains unclear from current evidence whether the introduction of low nitrosamine smokeless tobacco products like snus into markets where they are currently prohibited will provide a net public health benefit. The marketing of smokeless tobacco as a product for use when smoking is prohibited and the initiation of snus use in those who would otherwise not have used tobacco products remain issues of concern. Klesges et al (2010) suggest that any harm reduction strategy must balance the benefits of movement towards a less risky product with the possibility of increased dual use (concurrent use of smoked and smokeless products). Others (Frost-Pineda et al, 2010) in a review of the health outcomes of dual use suggest that it does not result in unique health risks that are not in any case present in continued smoking, and that dual users are more likely than exclusive smokers to cease smoking (this review, though not the original research it summarises, was carried out by researchers from the Altria group, the parent company of Philip Morris). Currently there is a lack of evidence that low nitrosamine smokeless tobacco will be seen as acceptable alternatives to smoking by consumers in countries such as the UK where there is no history of their use as smoking alternatives. Further, in the United Kingdom, there is no regulatory authority with the exclusive responsibility and expertise in tobacco/nicotine products that would be required to deal with



the complexities of regulation under a harm reduction mandate - that is, to encourage switching to less harmful forms of nicotine use, yet at the same time avoid any potential hazards of dual smoked/smokeless use. ASH Scotland recommends that other smokeless tobacco products that are currently marketed within the Union, such as those more commonly used by black and minority ethnic communities (e.g. gutka), should be subject to tighter regulation to ensure accurate communication of the health risks of use. Smoking cessation professionals should also be trained to effectively help individuals who use these products to quit. However, extending the ban on oral tobacco to these products may be counterproductive as it could make it more difficult to engage with the communities that use them to offer education and cessation support. Broadstock, M. Systematic review of the health effects of modified smokeless tobacco products. NZHTA Report 2007; 10(1). Scientific Committee on Emerging and Newly Identified Health Risks. Health Effects of Smokeless Tobacco Products. European Commission, 2008. Klesges RC, Sherrill-Mittleman D, Ebbert JO, Talcott GW, Debon M. Tobacco use harm reduction, elimination, and escalation in a large military cohort. Am J Public Health. 2010 Dec;100(12):2487-92. Frost-Pineda K, Appleton S, Fisher M, Fox K, Gaworski CL. Does dual use jeopardize the potential role of smokeless tobacco in harm reduction? Nicotine Tob Res. 2010 Nov;12(11):1055-67. Epub 2010 Sep 16.

### **questions consumer**

#### **problem definition**

Yes

#### **which option**

Improve consumer information; Introduce generic or plain packaging

#### **which improvement**

Picture warnings to become mandatory; Tar, nicotine and carbon monoxide levels to be replaced with general information on harmful substances in tobacco products; Information on harmful substances in tobacco products that cannot be placed on the package would be placed inside the package; Health warnings to be put on water pipes

#### **additional comments**

Picture warnings The research literature demonstrates the superiority of picture warnings over text-only warnings. Prominent graphic imagery is more likely than text-only warnings to promote accurate knowledge of the negative effects of tobacco use. Smokers who read, think about, and discuss the implications of graphic labels are more likely to quit, reduce consumption or make a quit attempt. The current situation of text-only warnings at the EU level gives inconsistent health protection to residents in Member States, with picture warnings currently having limited uptake. Mandatory health warnings through the Directive are vital to standardise health protection across Member States. We recommend picture warnings should take up 80% of both the front and back of all tobacco products (following Uruguay, the world leader in this regard). Emission information Consumers associate lower tar, nicotine and CO levels (TNCO) with reduced harm. This has been demonstrated repeatedly in the literature, and results in the misperception that some brands of cigarettes are quantifiably safer (in terms of long-term health outcomes) than others. Recent research (Gallopel-Morvan, 2010) found that 46% of adult smokers and non-smokers considered a pack displaying 0.8mg tar safer than an identical pack with 0.9mg tar. Because of the very-well established evidence that current machine-measured TNCO values are misleading to the consumer, we support the removal of TNCO emissions from the Directive, and suggest they are replaced with qualitative information on the hazardous effects of tobacco emissions, and are required to include

information on quitting smoking. Gallopel-Morvan K, Moodie C, Hammond D, Eker F, Beguinot E, Martinet Y. Consumer understanding of cigarette emission labelling. *Eur J Public Health*. 2010 Jul 2. [Epub ahead of print] Health warnings on water pipes. A recent systematic review (Akl et al, 2010) concluded that waterpipe tobacco smoking is associated with lung cancer, respiratory illness, low birth-weight and periodontal disease. Given this, and the fact there are typically very few warnings on waterpipes or their accessories it is important that hazards are communicated to consumers through the inclusion of health warnings on waterpipes and on tobacco sold for use in waterpipes. Akl EA, Gaddam S, Gunukula SK, Honeine R, Jaoude PA, Irani J. The effects of waterpipe tobacco smoking on health outcomes: a systematic review. *Int J Epidemiol*. 2010 Jun;39(3):834-57. Epub 2010 Mar 4. Additional information on harmful substances in tobacco products We support proposals to include additional information on the health effects of tobacco consumption on pack inserts. This should include information on quitting smoking and the physical, psychological and financial benefits of stopping. Plain packaging We strongly recommend the introduction of standardised packaging. Note that this refers to packaging where the format (shape, type of opening etc) is defined by regulation in addition to prohibiting the use of colour, branding and other design features. Tobacco packaging is a marketing tool that serves to promote tobacco (through branding, design, pack innovation and features like price marking), undermine health warnings, and foster misconceptions in smokers around harm differences between products through descriptors (such as ‘smooth’, ‘slims’ etc) and colour (Moodie et al, 2009). The pack is a powerful marketing opportunity, particularly as it is, in contrast to other overt forms of marketing, part of the consumer’s everyday life. The removal of all branding through standardised packaging will remove this marketing opportunity and, in combination with the other measures described in this section, also increase the prominence and salience of health warnings. Moodie C, Hastings G & Ford A. A brief review of plain packaging research for tobacco products. Report prepared for the Department of Health. 2009.

**questions on reporting  
problem definition**

Yes

**which option**

Establish a common compulsory reporting format; Introduce fees and sanctions

**additional comments**

Currently, formats for collating and submitting tobacco product ingredients vary across (and in some cases within) Member States. This is unsatisfactory as it proves to be a barrier to relevant authorities who wish to compare and analyse data across the Union. As the consultation document notes, the level of industry compliance with these reporting requirements varies. In this context, a harmonised reporting format for use across the Member States would be clearly beneficial. This reporting scheme should be compulsory. It should ideally utilise electronic submission and compilation of data to facilitate good data management and access. Doing this at EU level would free up resources for the relevant national authorities and improve the capacity for analysis of tobacco product ingredients. The costs for administering this process could be borne by tobacco manufacturers through registration fees, and appropriate sanctions should apply in the event of non-compliance with this scheme. These measures should comply with the Articles 9 and 10 of the World Health Organisation’s Framework Convention on Tobacco Control, all other Articles of the FCTC, and their associated guidelines for implementation.

**regulation of ingredients****problem definition**

Yes

**which option**

Establish a common list of tobacco ingredients

**which one**

Establish a positive common list of tobacco ingredients

**additional comments**

ASH Scotland would support the introduction of a positive common list of all ingredients in tobacco products. No additives should be permitted that enhance the attractiveness or addictiveness of the product. Working in tandem with the compulsory scheme for registration and reporting of tobacco ingredients this would ensure that only registered products, with ingredients that appear on the positive list would be permitted on the EU market. These measures should comply with Articles 9 and 10 of the World Health Organisation's Framework Convention on Tobacco Control, and their associated guidelines for implementation, particularly relating to the inclusion of additives which enhance the addictiveness or attractiveness of tobacco products.

**access to tobacco products****problem definition**

Yes

**which option**

Ban

**which one2**

Cross-border retail sales of tobacco to be banned over the Internet; Vending machines to be banned; Promotion and displays in retail stores to be banned

**additional comments**

Internet sales The principle of preventing cross-border promotion of tobacco products with the aim of protecting public health was enshrined in the Tobacco Advertising directive (2001/0119). The internet is accessible and attractive to young people, and cross border sales of tobacco products have the potential to undermine individual Member State tobacco control efforts such as age verification schemes. Given this, it is logical to extend the principles in 2001/0119 to cross border sales of tobacco products via the internet. Point of sale tobacco displays and vending machines There is a strong body of evidence supporting the relationship between exposure to tobacco products at the point of sale and onset of youth smoking (Paynter & Edwards, 2009). As a youth smoking prevention measure, Scotland has recently passed legislation to prohibit such displays. This is in accordance with Article 13 of the Framework Convention on Tobacco Control, where members should seek to adopt a comprehensive ban on all forms of tobacco promotion, advertising and sponsorship. Because tobacco displays have been demonstrated to have an influence on youth smoking uptake, ASH Scotland considers that the most effective public health protection can only be achieved by a complete and comprehensive ban on the display of tobacco products. Future legislation should learn lessons of jurisdictions where similar laws have already been implemented (such as Ireland, Iceland, and Canada) and avoid loopholes in drafting that permit exploitation by the

tobacco industry (such as the use of lighting or other features that highlight particular brands during incidental display when retrieving a product for sale). Many Member States already prohibit the sale of tobacco products from vending machines. Scotland has recently passed legislation to this effect. National surveys of young people in Scotland demonstrate that around 10% of 13 and 15 year olds access tobacco from vending machines (SALSUS, 2010). This is supported by data from test purchases carried out by local authorities where volunteer young people are frequently able to purchase tobacco products without being challenged or having their age verified. Vending machines selling tobacco are frequently situated out of the line-of-sight of establishment staff, making verification of sales difficult. Although some systems of age verification (such as token-operated or remote control) exist, these have not been adopted in Scotland due to inadequate evidence that they will be as effective as an outright ban. Because of this we believe the best means of limiting access is through a complete ban on the sale of tobacco products through vending machines. ASH Scotland supports a complete ban on the retail display of tobacco products and the sale of tobacco products through vending machines throughout the Union. Paynter J, Edwards R. The impact of tobacco promotion at the point of sale: a systematic review. *Nicotine Tob Res.* 2009 Jan;11(1):25-35. Epub 2009 Jan 27. Scottish Schools Adolescent Lifestyle and Substance use Survey (SALSUS) National Report: Smoking, Drinking and Drug Use among 13 and 15 year olds in Scotland in 2008. Edinburgh: Drug Misuse Information Scotland.2010. ASH Scotland is aware that there has been a campaign in the UK, organised by the tobacco-industry funded lobbying group FOREST, to raise a petition in opposition to many of the options proposed in the consultation document. The tobacco industry and its associated groups have a long history in working against evidence-based public health policy. We hope the Directorate will take this into account when considering consultation responses received.

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## **NGO submission**

### **identification**

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#### **questions scope**

#### **problem definition**

No

#### **explanations**

The problem definition could be improved. It should be clearly stated that the tobacco product directive sets the minimum limits to regulate the tobacco products. To ensure the high-level health protection of their citizens the member states would be allowed impose further regulations as long as those do not restrict the free movements of goods. Finland, as well as the European Commission, has ratified Framework Convention on Tobacco Control. It reaffirms the right of all people to the highest standard of health. Furthermore, article 114.3 of the Treaty states that when establishing rules for the functioning of the internal market in the context of health, safety, environmental protection and consumer protection, the Commission “will take as a base a high level of protection, taking account in particular of any new development based on scientific facts.”

**which option**

Extend the scope of the Directive

**recommend option**

Tobacco products are no ordinary commodities. Many compounds of the tobacco products contain and the smoke they produce is pharmacologically active, toxic, mutagenic and carcinogenic. There is no safe level of usage. Therefore we recommend that the scope of the Directive includes the regulation of any new smoked tobacco products (such as low emission or nicotine-free cigarettes). The prohibition of snus, should be maintained. Herbal cigarettes are also dangerous, and therefore they should be included in the scope Tobacco Products Directive and have health warnings. Some forms of nicotine based products (such as electronic cigarettes, nicotine gel, drinks, and sweets) are often marketed as alternatives to cigarettes and as quitting aid. In our opinion they should in no circumstances to be considered as an aid to quitting smoking. There are strictly regulated pharmaceutical products to help smokers in quitting.

**questions smokeless**

**problem definition**

Yes

**which option**

Ban on all types of smokeless tobacco products

**additional option**

The International Agency for Research on Cancer (IARC) in their Monographs Vol 6 (IARC Monographs on the Evaluation of Carcinogenic Risks to Humans Volume 89 (2007), Smokeless Tobacco and Some Tobacco-specific N-Nitrosamine) represent as a scientific conclusion that “there is sufficient evidence in humans for the carcinogenicity of smokeless tobacco. Smokeless tobacco causes cancers of the oral cavity and pancreas. There is sufficient evidence in experimental animals for the carcinogenicity of moist snuff.” As an overall evaluation they declare that smokeless tobacco is carcinogenic to humans (Group 1). Now that the use of smokeless tobacco products is not widely spread we recommend a ban on all types of smokeless tobacco products. We do not support lifting the ban of snus as there is no legitimate reason to introduce any new dangerous product onto the market. Finland is Sweden's neighbouring country, and was a part of Sweden for about 600 years. However, we have not get used to use snus. In Finland, due to our comprehensive tobacco control policy daily smoking has been declining constantly. Nowadays, the prevalence of daily smoking is among the lowest in the EU: 22 % men and 16 % women were daily smokers in 2009. The use of snus is minimal. Snus is not an alternative to treat nicotine addiction. There are already

available effective treatments for nicotine addiction, including medicinal or ‘clean’ nicotine (NRT), that do not carry the risks associated with the use of snus

**questions consumer**

**problem definition**

No

**explanations**

The problem definition could be clarified. The current situation, where some Member States have mandatory graphic warnings and others have not, has led to a disparity in labelling. In addition some consumers do not get enough information on the devastating effects of smoking on their health. Indeed, tobacco packaging and product features are increasingly used to attract consumers, to promote products and brand image. The importance of packaging as a marketing channel has increased when other kind of tobacco advertising has been banned or restricted. Packaging as an advertising measure is not covered by the current Directive.

**which option**

Improve consumer information; Introduce generic or plain packaging

**which improvement**

Picture warnings to become mandatory; Health warnings to be put on water pipes

**additional option**

There should be mandatory pictorial health warnings on all tobacco products (including oral and water pipe tobacco) covering 80% of the front and the back of the packs towards the top, in combination with standardized packaging. Pictures are able to create interest and make people to read the associated text message. We find it important to introduce standardised/plain packaging. Tobacco packaging and product features are used to attract consumers, especially young people. All branding from the packaging should be removed and the size and shape of the packaging should be standardised. In addition, tobacco companies should only be allowed to have one standardized package size per cigarette brand. There should be information on Quit line, preferably the number, on all packs of tobacco products.

**additional comments**

The article 114.3 of the Treaty states that when establishing rules for the functioning of the internal market in the context of health, safety, environmental protection and consumer protection, the Commission “will take as a base a high level of protection, taking account in particular of any new development based on scientific facts.”

**questions on reporting**

**problem definition**

Yes

**which option**

Establish a common compulsory reporting format; Introduce fees and sanctions

**additional comments**

The current system makes it difficult for authorities to compare and analyse the data. All tobacco manufacturers and importers should have the same reporting requirements. We welcome a yearly registration fee paid by the tobacco companies to national competent

authorities in order to finance their data collection and analysis work on ingredients. To control smuggling it is extremely important that only registered products would be allowed on the market.

### **regulation of ingredients**

#### **problem definition**

Yes

#### **which option**

Establish a common list of tobacco ingredients

#### **which one**

Establish a positive common list of tobacco ingredients

#### **additional option**

.

#### **additional comments**

Cigarettes and some other products containing tobacco are highly engineered to create and maintain dependence. Many of the compounds they contain and the smoke they produce are pharmacologically active, toxic, mutagenic and carcinogenic. Flavourings are an increasingly important element of tobacco marketing, particularly to young people. Flavourings, such as sugars and sweeteners, flavouring substances, and spices and herbs enhance attractiveness, encourage youth initiation, and discourage cessation. The prohibition of these kinds of ingredients in cigarettes and cigarette-like tobacco products should be introduced. The ingredients that may create the impression of a health benefit, ingredients associated with energy and vitality (e.g. caffeine), and ingredients with colouring properties (e.g. coloured cigarette paper) should also be banned. The above measures should be compliant with Articles 9 & 10 of the Framework Convention on Tobacco Control (FCTC).

### **access to tobacco products**

#### **problem definition**

Yes

#### **which option**

Ban

#### **which one2**

Cross-border retail sales of tobacco to be banned over the Internet; Vending machines to be banned; Promotion and displays in retail stores to be banned

#### **additional option**

We urge the Commission to call for a ban on the promotion of tobacco products at point of sale and a ban on vending machines. These measures are important for health protection. The Directive should also remind national governments that they should adopt a comprehensive ban on all forms of tobacco advertising, promotion and sponsorship in accordance with Article 13 of the FCTC which calls on Parties to.

#### **additional comments**

Internet. The principle of preventing cross-border promotion of tobacco products in order to

protect public health was highlighted in the Tobacco Advertising directive (2001/0119). Buying tobacco through Internet has become easier and more common. The problem includes the sale of tobacco products to minors, tax evasion and uncontrolled sales promotion of tobacco products. Therefore, we support the prohibition of tobacco sales via the Internet. Vending machines. In Finland vending machines will be banned in 2015. Point of Sale. In the EU member states the tobacco companies' marketing strategy is to advertise their products by making them very visible at point of sale. In Finland tobacco displays are banned on 1st January 2012. The measure has also been adopted by Ireland, and there are some other member states planning to do so. There is a growing body of evidence to show that putting tobacco products out of sight in retail outlets can reduce youth smoking. We support an EU-wide adoption of a ban on the display of tobacco products at the point of sale.

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### **questions scope**

#### **problem definition**

No

### **explanations**

Der Definition ist nicht zuzustimmen. Die Direktive geht aus von den Gefahren des Passivrauchens für Nichtraucher. Diese werden zurückgeführt auf den Rauch von Zigaretten u.ä. Bei „Elektronischen Zigaretten“ oder „Nikotin-Drinks“ bestehen diese Gefahren nicht mangels Rauch. Eine Ausweitung der Richtlinie auf diese Produkte dient daher nicht dem Nichtraucherschutz und ist daher nicht erforderlich. Der Vorschlag greift produktionslenkend ein in die Geschäftstätigkeit der Unternehmen. Zudem vermischt der Vorschlag unterschiedliche Produktarten: -„Nikotin Drinks“ dürften zum Bereich „Lebensmittel“ gehören. Hier bestehen bereits erhebliche Kontrollen. Neue Kontrollmechanismen einzuführen erscheint wenig zweckmäßig. -Elektronisch Zigaretten können, so die Ausführungen, dazu führen, dass Rauer das Rauchen aufgeben. Fraglich ist insoweit bereits der Schutzbedarf der Verbraucher. -Überdies werden Nikotin-Pflaster, die vergleichbar wären mit rauchfreien Zigaretten, nicht erfasst -Für „Kräuterzigaretten“ dürfte etwas anderes gelten. Sie produzieren Rauch und dürften damit für Passivraucher gefährlich sein.

### **which option**

No change



**additional comments**

So lange „Kräuterzigaretten“ mit Nikotin-Drinks und elektronischen Zigaretten gleichgesetzt werden kann eine Änderung des Wortlautes nicht befürwortet werden. „Kräuterzigaretten“ sind nach der Tabak-Richtlinie keine Tabakprodukte. Hier gibt es daher zwei Möglichkeiten: Die Schaffung einer eigenen Richtlinie für „Kräuterzigaretten“, wegen des bürokratischen Aufwandes allerdings abzulehnen oder die Gleichsetzung von Kräuterzigaretten mit Zigaretten und Zigarren in Erweiterung der Definitionen aus der Tabakrichtlinie. Das setzt allerdings voraus, dass eine Gesundheitsgefährdung für Nichtraucher von den „Kräuterzigaretten“ ausgeht. Hierzu wäre unter Umständen ein Gutachten einzuholen.

**questions smokeless****problem definition**

No

**comments**

Der Definition ist nicht zuzustimmen. Die Richtlinie stellt (auch) auf die Gefährdung Dritter ab (Nichtraucherschutz). Von rauchfreien Tabakerzeugnissen geht für Dritte /Nichtraucher keine Gefahr aus. Zudem besteht - so die Ausführungen im Konsultations-Verfahren – die Möglichkeit, über den Konsum rauchfreier Produkte das Rauchen aufzugeben. Zudem ist die Definition rauchfreier Tabakprodukte nicht eindeutig. Auch hier werden Nikotinpflaster in der Betrachtung außer Acht gelassen.

**which option**

Lifting the ban on snus

**additional comments**

Vorzugswürdig wäre Option 2. Sie gibt dem Markt die Gelegenheit zur Selbstregulierung über das Verbraucherverhalten. Die Selbststeuerung des Marktes ist der gesetzlichen Regulierung vorzuziehen. Option 2 würde überdies für eine Einheitlichkeit im Gemeinschaftsgebiet sorgen.

**questions consumer****problem definition**

No

**explanations**

Der Definition ist nicht zuzustimmen. Die Verwendung von Bildern als Warnung scheint ungeeignet, andernfalls hätten andere Mitgliedsstaaten als die genannten die Verpflichtung zum Aufdruck derartiger Abbildungen bereits übernommen. Die Entscheidung sollte den Mitgliedsstaaten weiterhin überlassen bleiben. Insbesondere, weil dadurch die Fläche für die Aufbringung von Wortbildmarken der Unternehmen /Hersteller weiter verringert wird. Markenrechte sind eigentumsgleich, hier würde durch eine entsprechende Regelung massiv in die eigentumsgleichen Rechte der Unternehmen eingegriffen. Die Hersteller sind schon durch die umfangreichen Hinweispflichten, die sich aus der Richtlinie ergeben hinreichend beschwert in ihrer Gestaltungsfreiheit.

**which option**

No change

### **additional comments**

Vorzugswürdig erscheint Option 1, insbesondere das Labelling von Wasserpfeifen würde die Richtlinie weit über Ihren unmittelbaren Anwendungsbereich (Wortlaut: „Tabakprodukte“) hinaus ausdehnen. Wasserpfeifen sind keine Tabakprodukte. Sie sind Rauch-Utensile. Konsequenter Weise müsste dann eine Reihe anderer Produkte (Pfeifen, Mundstücke für Zigaretten, Pfeifenstopfer, Drehmaschinen, Filter, Zigarettenpapier und sogar Feuerzeuge und Streichhölzer) ebenfalls gelabelt werden. Das würde nicht nur den Wortlaut der Richtlinie überstrapazieren, sondern auch über das Ziel des Gesundheitsschutzes hinausschießen. Zudem käme es einer staatlichen Produktionslenkung gleich, anstatt die Regulierung den Marktteilnehmern zu überlassen. Tabak für Wasserpfeifen unterliegt bereits der Kennzeichnungspflicht. Vor allem Option 3 scheint völlig indiskutabel: Verpackungen ohne Design würden dazu führen, dass die Hersteller Ihre Wortbildmarken nicht länger auf den Verpackungen aufbringen dürften. Das würde einen massiven Eingriff in Ihre eigentums-gleichen Rechte darstellen.

### **questions on reporting problem definition**

Yes

### **which option**

Establish a common compulsory reporting format

### **additional options**

Eine weitere Option wäre die Prüfung durch die zuständigen Stellen vor Ort in den Unternehmen. Da die Überprüfung ohnehin Gebühren auslösen dürfte ergäbe sich daraus sogar noch ein Mehrwert für die Hersteller. Nach einer standardisierten Checkliste könnte dort geprüft werden, ob unerlaubte Stoffe den Tabakprodukten beigemischt sind (Die Mengen-Anteile der Inhaltstoffe ergeben sich aus den Pflichtkennzeichnungen ohnehin). Damit könnte vor allem ein gegebenenfalls unsicherer Datenübermittlungsprozess vermieden werden. Solche Überprüfungen dürften für die zuständigen Stellen auch machbar sein, da die Anzahl der Unternehmen überschaubar ist.

### **additional comments**

Der Definition kann zugestimmt werden. Für die Prüfung der Inhaltstoffe von Ziga-retten kann eine im Mitgliedsgebiet einheitliche, standardisierte Angabe dieser Zutaten sinnvoll sein, um den Behörden die Kontrolle der Produkte zu erleichtern. Zweckmäßig könnte dann auch die elektronische Übermittlung an die zuständigen Stellen sein. Dies Maßgeblich dafür dürfte dennoch sein, dass die Übermittlung si-cher ist und die Geschäftsgeheimnisse der Hersteller gewahrt bleiben. Die Rezepturen sind wesentlicher Bestandteil der Produktion durch die Berichtspflichten der Hersteller gegenüber den zuständigen Stellen darf daher der Geheimnis-Schutz der Unternehmen nicht unterlaufen werden. Sinnvoll kann eine Vereinheitlichung auch deswegen sein, weil die Hersteller danach nicht mehr unterschiedliche Formulare in unterschiedlichen Ländern ausfüllen müssen. Dies dient der Entbürokratisierung und nützt damit den Unternehmen im Tagesgeschäft unmittelbar. Insofern bietet bei einer Novellierung der Richtlinie Option 2 eine Möglichkeit zur Entbürokratisierung und auch zur Vereinheitlichung des Nichtraucher-schutzes im Mitgliedsgebiet.

### **regulation of ingredients problem definition**

Yes

**which option**

Establish a common list of tobacco ingredients

**which one**

Establish a negative common list of tobacco ingredients

**additional comments**

Der Definition kann zugestimmt werden. Die unterschiedliche Handhabung von Positiv- oder Negativlisten für Zusatzstoffe wie Lakritz oder Menthol stellen nicht nur für die zuständigen Stellen, sondern auch für die Unternehmen einen erheblichen Unsicherheitsfaktor dar. Insofern ist der Definition des Problems zuzustimmen. Ein einheitliches Verfahren in der Handhabung wäre daher zu begrüßen. Vorzugswürdig wäre eine Negativ-Liste (Option 3b), da es für die Hersteller einfacher ist zu prüfen, welche Stoffe (gegebenenfalls ab welcher Menge) als Zutaten verboten sind. Eine einheitliche Internetseite zum erleichterten Überblick könnte hier hilfreich sein. Das setzt voraus, dass diese Liste ständig aktuell gehalten wird und Änderungen stets schnell erkennbar sind. Transparenz schafft hier Sicherheit. Eine solche Liste fördert zudem die Suche nach Zusatzstoffen, die „weniger gefährlich“ sind. Maßgeblich ist allerdings, dass die Negativliste nur Zusatzstoffe enthält und die wesentlichen Inhaltsstoffe von Zigaretten oder Zigarren (Papier, Tabak etc.) nicht darin aufgenommen werden. nicht, wenn wesentliche Inhalte betroffen sind z.B. Tabak.

**access to tobacco products****problem definition**

No

**explanations**

Der Definition kann nicht zugestimmt werden Das Werbeverbot und das Verbot, Tabak Produkte zu präsentieren ist ein erheblicher Eingriff in die Berufsausübungsfreiheit. Die Wort-Bild-Marken, mit denen die Unternehmen am Markt agieren stellen eigentums-gleiche Rechte dar. Die Einschränkung der Verwendung dieser Wort-Bild-Marken wäre daher einem Eingriff in das Eigentum der Unternehmen gleichzusetzen, der sich unserer Auffassung nicht mit dem Schutzzweck Nichtraucherschutz vereinbaren ließe. Gleiches gilt für die Präsentation der Wort-Bild-Marken oder die Ausstellung von Tabak-Produkten. Hier hätte ein Präsentationsverbot unmittelbar in das Recht am eingerichteten und ausgeübten Gewerbebetrieb darstellen. Das Verbot von Zigaretten-Automaten, um Minderjährigen den Zugang zu erschweren würde das Verbot eines kompletten Absatzweges mit sich führen.

**which option**

Controlled supply and access

**which supply and access**

Age verification of buyers and other legal conditions to be set for cross-border retail sale;  
Access to vending machines to be restricted to adults

**additional option**

(Vorzugswürdig wäre Option 2a, die Zugangsregulierung in Verantwortung der Nationalstaaten. Diese könnte zum Beispiel über EC-Karten ( heute schon Praxis an Automaten) oder z.B. beim Kauf im Internet über die neuen Personalausweise erfolgen.

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## **NGO submission**

### **identification**

#### **affiliation**

NGO

#### **name**

The Scottish Coalition on Tobacco (SCOT). SCOT is a dynamic coalition of partners which campaigns on all matters related to tobacco and health. Members include ASH Scotland, British Heart Foundation Scotland, British Lung Foundation Scotland, British Medical Association, Cancer Research UK, Chest, Heart & Stroke Scotland, Macmillan Cancer Support, Royal College of Nursing, The Roy Castle Lung Cancer Foundation, Royal College of Physicians of Edinburgh, Royal College of Psychiatrists, The Stroke Association, and the Royal Environmental Health Institute of Scotland. This is the agreed SCOT coalition response representing the majority view of members. Where individual members have taken a different position on particular points, this is reflected in their own submissions.

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rory.morrison@ashscotland.org.uk (on behalf of Sheila Duffy, chair of SCOT)

#### **country**

Scotland

#### **questions scope**

#### **problem definition**

Yes

#### **which option**

Extend the scope of the Directive

#### **additional comments**

• The directive should be expanded to include herbal (tobacco-free and/or nicotine-free) smoked products. • The existing ban on oral tobacco should be maintained. • E-cigarettes and other non-smoked, non-tobacco nicotine products (such as gels or drinks) should be regulated at some level, however we believe this should be achieved through regulation as a pharmaceutical product (as was recently consulted on in the UK by the Medicines and Healthcare Regulatory Agency (MHRA)) Most of the harm to health caused by tobacco is due to the fact that tobacco products are typically smoked. Tobacco products that are not smoked tend to be significantly less harmful, though not harmless (Royal College of Physicians, 2008). Given this and considering emerging evidence that some types of herbal, non-tobacco or non-nicotine cigarettes are likely to be injurious to health in a similar manner to conventional tobacco cigarettes (Jorgensen et al, 2010; Gan et al 2009) it is appropriate to include such products within the Directive. Novel nicotine products that do not contain tobacco and are not combusted but which deliver nicotine to the user (such as electronic cigarettes) are relatively recent additions to the nicotine market. Because the method of administering nicotine in these products does not involve combustion or tobacco, they are likely to be significantly safer than smoked tobacco. These products are largely unregulated at present throughout the Member States, and there are concerns over inconsistencies in the

manufacturing process which may result in the vapour delivered to the user varying from product to product. Because of this, regulation of these products would have several advantages, ensuring that e-cigarettes and other novel nicotine products are demonstrably safe and effective as a tobacco alternative. However, as these products are conceptually more similar to pharmaceutical nicotine products than smoked tobacco, SCOT believes the most appropriate means to achieve suitable regulation should be as pharmaceuticals (as a recent consultation by the UK's Medicines and Healthcare Regulatory Agency discussed). The outcome and background of the MHRA consultation may be useful for the Commission to consider in order to inform its decision. We recommend that novel forms of oral tobacco be prohibited from the marketplace in a similar fashion to snus, as outlined in our response to Section 2. Royal College of Physicians. Harm reduction in nicotine addiction: helping people who can't quit. A report by the Tobacco Advisory Group of the Royal College of Physicians. London: RCP, 2007. Jorgensen ED, Zhao H, Traganos F, Albino AP, Darzynkiewicz Z. DNA damage response induced by exposure of human lung adenocarcinoma cells to smoke from tobacco- and nicotine-free cigarettes. *Cell Cycle*. 2010 Jun 22;9(11). Gan Q, Yang J, Yang G, Goniewicz M, Benowitz NL, Glantz SA. Chinese "herbal" cigarettes are as carcinogenic and addictive as regular cigarettes. *Cancer Epidemiol Biomarkers Prev*. 2009 Dec;18(12):3497-501.

**questions smokeless  
problem definition**

Yes

**which option**

No change

**additional comments**

We recommend that the existing ban on snus in all Member States (except Sweden) should be maintained. Smokeless tobacco products, although significantly less hazardous than smoking, do not appear to be completely without risk (Broadstock, 2007; SCENIHR, 2008). It is often argued that these potential risks are acceptable in the context of the large difference in harm between continued cigarette smoking and snus use. However, it remains unclear from current evidence whether the introduction of low nitrosamine smokeless tobacco products like snus into markets where they are currently prohibited will provide a net public health benefit. Currently there is a lack of compelling evidence that low nitrosamine smokeless tobacco will be culturally acceptable to consumers in countries such as the UK where there is no history of their use as smoking alternatives. Further, in the United Kingdom, there is no regulatory authority with the exclusive responsibility and expertise in tobacco/nicotine products that would be required to deal with the complexities of regulation under a harm reduction mandate. SCOT recommends that other smokeless tobacco products that are currently marketed within the Union (such as those more commonly used by black and minority ethnic communities, e.g. gutka) should be subject to tighter regulation to ensure accurate communication of the health risks of use, in a similar manner to other tobacco products. Cessation professionals should also be trained to effectively help individuals who use these products to quit. However extending the ban on oral tobacco to these products may be counterproductive as it could make it more difficult to engage with the communities that use them to offer education and cessation support. Broadstock, M. Systematic review of the health effects of modified smokeless tobacco products. NZHTA Report 2007; 10(1). Scientific Committee on Emerging and Newly Identified Health Risks. Health Effects of Smokeless Tobacco Products. European Commission, 2008.

**questions consumer  
problem definition**

Yes

**which option**

Improve consumer information; Introduce generic or plain packaging

**which improvement**

Picture warnings to become mandatory; Tar, nicotine and carbon monoxide levels to be replaced with general information on harmful substances in tobacco products; Information on harmful substances in tobacco products that cannot be placed on the package would be placed inside the package; Health warnings to be put on water pipes

**additional comments**

Picture warnings Research consistently demonstrates graphic warnings to be superior to text-only warnings. Smokers who read, think about, and discuss the implications of graphic labels are more likely to quit, reduce consumption or make a quit attempt. We recommend that picture warnings should become mandatory and they should, by regulation, occupy the largest possible area on the pack. We recommend picture warnings should take up 80% of both the front and back of all tobacco products. The current situation of text-only warnings at the EU level gives inconsistent health protection to residents in Member States, with picture warnings currently having limited uptake. Mandatory health warnings through the Directive are vital to standardise health protection across Member States, and will also assist some EU countries, currently dealing with the threat of tobacco industry legal action to delay warnings, in implementing them swiftly. Emission information Consumers associate lower tar, nicotine and CO levels (TNCO) with reduced harm. This has been demonstrated repeatedly in the literature, and results in the misperception that some brands of cigarettes are quantifiably safer (in terms of long-term health outcomes) than others. Because of the very-well established evidence that current machine-measured TNCO values are misleading to the consumer, we support the removal of TNCO emissions from the Directive, and suggest they are replaced with qualitative information on the hazardous effects of tobacco emissions, and are required to include information on quitting smoking. Health warnings on water pipes The World Health Organisation (WHO, 2005) concludes that initial research suggests waterpipe smoking may involve similar health hazards to cigarette use. A more recent systematic review (Akl et al, 2010) concludes that waterpipe tobacco smoking is associated with lung cancer, respiratory illness, low birth-weight and periodontal disease. Given this, and the fact there are typically very few warnings on waterpipes or their accessories it is important that hazards are communicated to consumers through the inclusion of health warnings on waterpipes and on tobacco sold for use in waterpipes. WHO Study Group on Tobacco Product Regulation (TobReg). TobReg Advisory Note, Waterpipe Tobacco Smoking: Health Effects, Research Needs and Recommended Actions by Regulators. WHO, 2005. Akl EA, Gaddam S, Gunukula SK, Honeine R, Jaoude PA, Irani J. The effects of waterpipe tobacco smoking on health outcomes: a systematic review. *Int J Epidemiol.* 2010 Jun;39(3):834-57. Epub 2010 Mar 4. Additional information on harmful substances in tobacco products We support proposals to include additional information on the health effects of tobacco consumption on pack inserts. This should include information on quitting smoking. Plain packaging We recommend the introduction of standardised packaging. Note that this refers to packaging where the format (shape, type of opening etc) is defined by regulation in addition to prohibiting the use of colour, branding and other design features. Tobacco packaging is a marketing tool that serves

to promote tobacco (though branding, design, pack innovation and features like price marking), undermine health warnings, and foster misconceptions in smokers around harm differences between products through descriptors (such as ‘smooth’, ‘slims’ etc) and colour (Moodie et al, 2009). The pack is a powerful marketing opportunity, particularly as it is, in contrast to other overt forms of marketing, part of the consumer’s everyday life. The removal of all branding through standardised packaging will remove this marketing opportunity and, in combination with the other measures described in this section, also increase the prominence and salience of health warnings. Moodie C, Hastings G & Ford A. A brief review of plain packaging research for tobacco products. Report prepared for the Department of Health. 2009.

### **questions on reporting**

#### **problem definition**

Yes

#### **which option**

Establish a common compulsory reporting format; Introduce fees and sanctions

#### **additional comments**

Currently, formats for collating and submitting tobacco product ingredients vary across (and in some cases within) Member States. This is unsatisfactory as it proves to be a barrier to relevant authorities who wish to compare and analyse data across the Union. As the consultation document notes, the level of industry compliance with these reporting requirements varies. A mandatory common reporting format would assist with these issues. These measures should comply with the Articles 9 and 10 of the World Health Organisation’s Framework Convention on Tobacco Control, and their associated guidelines for implementation.

### **regulation of ingredients**

#### **problem definition**

Yes

#### **which option**

Establish a common list of tobacco ingredients

#### **which one**

Establish a positive common list of tobacco ingredients

#### **additional comments**

We would support a positive common list of all ingredients in tobacco products. No additives should be permitted that enhance the attractiveness or addictiveness of the product. Working in tandem with the compulsory scheme for registration and reporting of tobacco ingredients this would ensure that only registered products with ingredients that appear on the positive list would be permitted on the EU market. These measures should comply with the Articles 9 and 10 of the World Health Organisation’s Framework Convention on Tobacco Control, and their associated guidelines for implementation, particularly relating to the inclusion of additives which enhance the addictiveness or attractiveness of tobacco products.

### **access to tobacco products**

#### **problem definition**

Yes

**which option**

Ban

**which one2**

Cross-border retail sales of tobacco to be banned over the Internet; Vending machines to be banned; Promotion and displays in retail stores to be banned

**additional comments**

Internet sales The internet is accessible and attractive to young people, and cross border sales of tobacco products have the potential to undermine individual Member State tobacco control efforts such as age verification schemes. Given this, it is logical to extend the principles in the Tobacco Advertising Directive 2001/0119 to cross border sales of tobacco products via the internet. Point of sale tobacco displays and vending machines There is a strong body of evidence supporting the relationship between exposure to tobacco products at the point of sale and onset of youth smoking (Paynter & Edwards, 2009). As a youth smoking prevention measure, Scotland has recently passed legislation to prohibit such displays. This is in accordance with Article 13 of the Framework Convention on Tobacco Control, where members should seek to adopt a comprehensive ban on all forms of tobacco promotion, advertising and sponsorship. Because tobacco displays have been demonstrated to have an influence on youth smoking uptake, SCOT considers that the most effective public health protection is achieved by a complete and comprehensive ban on the display of tobacco products. Many Member States already prohibit the sale of tobacco products from vending machines. Scotland has recently passed legislation to this effect. Survey evidence and test-purchasing activity shows young people can and do access tobacco products through self-service vending machines. Because of this SCOT believes the most effective means of limiting access is through a complete ban on the sale of tobacco products through vending machines. For both of these measures, SCOT strongly recommends that all Member States should adopt a complete ban on the retail display of tobacco products and prohibit the sale of tobacco products through vending machines. Paynter J, Edwards R. The impact of tobacco promotion at the point of sale: a systematic review. *Nicotine Tob Res.* 2009 Jan;11(1):25-35. Epub 2009 Jan 27.

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**NGO submission****identification****affiliation**

NGO

**name**

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**country**

UK



**questions scope**  
**problem definition**

Yes

**which option**

Extend the scope of the Directive

**additional comments**

The BMA stresses the importance of differentiating between smokeless tobacco and nicotine products and those products that have been scientifically proven to be Nicotine Replacement Therapy (NRT) products. The BMA supports: - the development of tobacco-free harm reduction strategies in member states as part of a structured approach leading to permanent smoking cessation. This should focus on the use of pure nicotine products and be developed as a part of a comprehensive strategy aimed at reducing the demand for and supply of tobacco - the strengthening of nicotine regulation in the EU to facilitate the development of pure nicotine products that are high dose, longer-lasting, rapid in their delivery and readily available - further research into the long-term use of NRT - the development of communications strategies in all member states to raise awareness of the relative safety of nicotine

**questions smokeless**  
**problem definition**

Yes

**which option**

Ban on all types of smokeless tobacco products

**additional comments**

The use of smokeless tobacco products is associated with serious health problems, the most significant being oral cancer. [Reference 1, 2 and 3 below] The use of smokeless tobacco is also associated with keratosis, gum erosion and increases the risk of periodontal disease. [Reference 4 and 5] It is important to note that risks from smokeless tobacco products differ significantly in approximate relation to the content of toxins in the tobacco. [Reference 1] References [1] Royal College of Physicians (2007) Harm reduction in nicotine addiction; helping people who can't quit. London: The Royal College of Physicians. [2] Critchley JA & Unal B (2003) Health effects associated with smokeless tobacco: A systematic review. Thorax58: 435-43. [3] Boffetta P, Aagnes B, Weiderpass E et al (2005) Smokeless tobacco use and risk of cancer of the pancreas and other organs. International Journal of Cancer114: 992-5. [4] Winn DM (2001) Tobacco use and oral disease. Journal of Dental Education65: 306-12. [5] Fisher MA, Taylor GW, Tilashalski KR (2005) Smokeless tobacco and severe active periodontal disease, National Health and Nutrition Examination Survey (NHANES) III. Journal of Dental Research84: 705-10.

**questions consumer**  
**problem definition**

Yes

**which option**

Improve consumer information; Introduce generic or plain packaging

**which improvement**

Picture warnings to become mandatory; Tar, nicotine and carbon monoxide levels to be replaced with general information on harmful substances in tobacco products; Information on harmful substances in tobacco products that cannot be placed on the package would be placed inside the package; Health warnings to be put on water pipes

**additional comments**

Smoking remains the leading cause of morbidity and mortality in the UK. Nearly one in four adults still smoke and many others continue to take up the habit. The vast majority of individuals start smoking before the age of 25. During this time, people, and particularly young people, are exposed to a mix of personal, social and environmental influences that serve to normalise the habit and encourage the onset of smoking. These influences are reinforced by the positive images created by pervasive tobacco industry marketing and persistent media portrayals of smoking. Evidence of the pro-smoking effects of tobacco marketing strategies is discussed in detail in the BMA report *Forever Cool: the influence of smoking imagery on young people* (2008) [Reference 6]. It is essential that further action is taken to promote a tobacco-free lifestyle that both 'deglamourise' and 'denormalise' its use. Reference: [6] British Medical Association (2008). *Forever Cool: the influence of smoking imagery on young people*. London: British Medical Association. [http://www.bma.org.uk/images/forevercool\\_tcm41-169812.pdf](http://www.bma.org.uk/images/forevercool_tcm41-169812.pdf)

**questions on reporting****problem definition**

Yes

**which option**

Establish a common compulsory reporting format; Introduce fees and sanctions

**additional comments**

The BMA stresses the need for full disclosure on the ingredients and effects of all tobacco products to be reported and published. It is essential for future research into the effects of tobacco usage that we know the ingredients in all tobacco products. No chemical can ever be 100% "safe" and we will need to continue to monitor the effects of using tobacco on smokers, and to look for different patterns of morbidity and mortality which might be related to ingredients other than tobacco, or to manipulation of tobacco. Data is essential. There should be both a common data capture system and penalties for non compliance, thus both options 2 and 3 are supported.

**regulation of ingredients****problem definition**

Yes

**which option**

Establish a common list of tobacco ingredients

**additional comments**

(See also our answer to section 4.) We would support option 3 but would expect the European Commission to take expert advice on whether a positive or negative list would be a more effective regulatory process.

**access to tobacco products****problem definition**

Yes

**which option**

Ban

**which one2**

Cross-border retail sales of tobacco to be banned over the Internet; Vending machines to be banned; Promotion and displays in retail stores to be banned

**additional comments**

The BMA stresses the need to: - prohibit the display of tobacco products at the point-of-sale and prohibit the sale of tobacco products from vending machines, as this will help to put an end to the loopholes that allow tobacco products to be advertised to children - reduce the number of outlets selling tobacco through the introduction of a system of positive licensing, as is the case for selling alcohol in the UK.

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**NGO submission****identification****affiliation**

NGO

**name**

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**country**

United Kingdom

**questions scope****problem definition**

Yes

**which option**

Extend the scope of the Directive

**recommend option**

The majority of the harm caused by cigarettes stems from a combination of the combustion process and smoke inhalation. For this reason, we believe that it is appropriate to extend the scope of the Directive to include all smoked products, including herbal cigarettes. This should also include the regulation of any new smoked tobacco products, such as low emission or nicotine-free cigarettes. Extending the scope of the Directive to include smoking paraphernalia such as filters, cigarette paper, pipes, water pipes and tobacco leaf would also help to raise awareness of the risks of these products among consumers. This has been

highlighted in the recent impact assessment study conducted by RAND Europe.

**additional comments**

Ideally we would like to see smokers switch to a less harmful alternative as a means of ultimately quitting. However, for many people that are unable or unwilling to completely quit significant health benefits can result through harm reduction that does not lead to quitting completely. Novel pure nicotine products (containing nicotine but not tobacco) could aid the principle of harm reduction by providing a less hazardous alternative to cigarettes, provided that they are regulated to ensure adequate safety and quality. These include e-cigarettes and nicotine gel. However, as these products are often marketed as alternatives to cigarettes and in some cases as a quitting aid, it is appropriate for them to be regulated as pharmaceutical products rather than through this Directive. Within the UK, the Medicines and Healthcare Regulatory Authority (MHRA) has recently consulted on whether to extend its remit on the regulation of nicotine replacement therapies to other nicotine containing products. The ultimate result may assist the Commission in developing its policy on these types of nicotine products.

**questions smokeless**

**problem definition**

Yes

**which option**

No change

**additional option**

Other smokeless tobacco such as gutka and zarda, largely used by people from south Asia, is legal and unregulated in the UK and has been found to have higher rates of toxins than snus. In contrast to snus, we do not believe that extending the ban to all types of smokeless tobacco would be progressive, and such a move could in fact hamper efforts to engage with ethnic minority populations on the dangers of smoking and in encouraging them to quit. These products are harmful to consumers, but it is more appropriate at this stage to regulate these more tightly rather than ban these completely. A complete ban could create an illegal market that would be more difficult to control than the present situation.

**questions consumer**

**problem definition**

Yes

**which option**

Improve consumer information; Introduce generic or plain packaging

**which improvement**

Picture warnings to become mandatory; Tar, nicotine and carbon monoxide levels to be replaced with general information on harmful substances in tobacco products; Information on harmful substances in tobacco products that cannot be placed on the package would be placed inside the package; Health warnings to be put on water pipes

**additional option**

We believe that the minimum size of health warnings should be increased to 80% of the front and back surfaces of all tobacco packaging. Packaging should also include quitting helpline

telephone numbers.

### **additional comments**

Picture Warnings Health warnings are effective in conveying the dangers of smoking and helping smokers to quit. , They also help deter young people from starting to smoke. We believe that the Directive should be revised to make picture warnings mandatory and to increase their visibility by ensuring these cover a minimum of 80% of the front and back surfaces of all tobacco packaging (i.e. not just cigarettes). Evidence suggests that picture warnings of this size increase their effectiveness among young and adult smokers and non-smokers. To further maximise their visibility, these warnings should be placed on the upper part of the packs. There is a clear inconsistency across Member States with regards to adopting picture warnings which has meant that has resulted in an inconsistency in health protection across the EU. The differences in rules undermine the operation of the single market and may constitute a barrier to trade. These obstacles should therefore be removed by ensuring that pictorial health warnings are mandatory across all Member States. This will provide better health protection for all EU citizens as a result. All warnings should be displayed in rotation so that each message is given equal display to reach its target audience. We also believe that new picture warnings should be developed to ensure these remain eye-catching. Information on tar, nicotine & carbon monoxide (TNCO) In its current form the Directive requires the inclusion of machine-based tar, nicotine and carbon monoxide yields on cigarette packs. This serves to promote the mistaken beliefs that some cigarette brands are less harmful than others and that nicotine causes disease. This requirement should be removed from the Directive and ISO or any other emissions numbers should be prohibited from inclusion on the pack. Numerical measurements should be replaced with descriptive information on the hazardous effects of tobacco constituents and emissions. Additional information on harmful substances in tobacco products We support the proposal to include additional information on the health effects of tobacco consumption on inserts inside the packaging, and believe that this should include advice on quitting smoking. Health warnings on water pipes There is a growing body of evidence to show that water pipes are at least as hazardous, if not more so, than other forms of tobacco use. However, there is a common perception that tobacco smoke is 'cleansed' by the water and therefore less dangerous and some users believe flavoured shisha is not in fact tobacco. It is therefore important that these myths are countered by requiring the inclusion of health warnings on all water pipes, and on the packaging of tobacco used in water pipes. Generic or plain packaging We strongly recommend the introduction of plain or generic packaging, and believe that this would be a key measure in increasing the effectiveness of health warnings and reducing misconceptions about the risks of smoking. Tobacco companies have consistently used packaging as a marketing tool to make products more alluring. We believe that all branding from the packaging should be removed and the size and shape of the packaging should be standardised. The Australian Government has recently announced plans to introduce plain packaging from July 2012, and the UK Government recently announced that it would consult on the issue. , We believe that this is a strong move that the EU should similarly consider introducing. Tobacco packaging provides a direct link between consumers and manufacturers and is the main marketing channel, particularly in jurisdictions with tobacco advertising bans. Branding also gives the misleading impression some cigarettes are safer than others.

### **questions on reporting**

#### **problem definition**

Yes

**which option**

Establish a common compulsory reporting format; Introduce fees and sanctions

**additional comments**

The present situation which allows different formats and reporting mechanisms is unsatisfactory, and makes it difficult for authorities to compare and analyse the data. Tobacco companies should be required to use a standardised reporting format, and required to pay a yearly registration fee to cover the costs of administering this data collection. We believe that these measures should be compliant with Articles 9 & 10 of the Framework Convention on Tobacco Control (FCTC).

**regulation of ingredients****problem definition**

Yes

**which option**

Establish a common list of tobacco ingredients

**which one**

Establish a positive common list of tobacco ingredients

**additional comments**

Tobacco products are highly toxic and addictive. Their contents should be regulated in order to achieve high standards of health protection. Establishing a positive common list would ensure that only registered products containing ingredients, flavourings and additives that appear on the positive list would be permitted on the EU market. EU citizens are not subject to the same level of health protection due to this present inconsistency on ingredients and a common list of permitted ingredients would help to address this anomaly. The tobacco industry uses a range of additives to alter the composition of tobacco products. These can make the product more palatable to children or increase the addictiveness of the product. Any flavouring that may be used to enhance the addictiveness or attractiveness of tobacco products should therefore be banned.

**access to tobacco products****problem definition**

Yes

**which option**

Ban

**which one2**

Cross-border retail sales of tobacco to be banned over the Internet; Vending machines to be banned; Promotion and displays in retail stores to be banned

**additional option**

Within Finland, the recent Tobacco Act has set limits on the amount of tobacco that can be imported into the country where the labelling differs from that of tobacco products sold in Finland. This is a positive move, and we believe that similar limits should be set at EU level – for each Member State the amount of tobacco that may be imported for personal use which does not conform to domestic labelling requirements, should be limited to a maximum of 200

cigarettes, 50 cigars, 100 cigarillos and 250 grams of pipe or cigarette tobacco.

**additional comments**

Internet. The Tobacco Advertising directive (2001/0119) established the principle of preventing cross-border promotion of tobacco products in order to protect public health. It is logical, therefore, to extend that principle to the sale of tobacco products between member states via the Internet. We believe the sale of tobacco via the Internet should be prohibited.

Vending machines. The available data within the UK suggest that vending machines are a key source of cigarettes for children and young people, and we have been working to ensure that these are banned across the UK. Test purchasing by young people in the UK has found that buying from vending machines was the most successful way for children to get hold of cigarettes. In a test purchase exercise in South West England for example, 73% of attempts by 15 year olds were successful. The majority of member states (22 out of 27) already prohibit the sale of tobacco products from vending machines, and we support the introduction of a ban across all Member States.

Point of Sale. Research shows that point of sale displays have a direct impact on young people's smoking behaviour. In 2006, almost half (46%) of UK teenagers were aware of tobacco display at point of sale and those professing an intention to smoke were more likely to recall brands that they had seen at the point of sale. In addition, research in Australia and the USA has shown that point of sale display advertising of cigarettes normalises tobacco use for children and creates a perception that tobacco is easily obtainable. There is also evidence that retail displays encourage 'impulse buying' so undermining smokers' attempts to quit. To date, this measure has been adopted by Ireland and Finland (as well as Iceland and Norway) and is going through the parliamentary process in the UK. Across the EU, most forms of tobacco advertising are now prohibited but the tobacco industry continues to market its products by the use of attractive packaging. We therefore support an EU-wide adoption of a ban on the display of tobacco products at the point of sale.

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**NGO submission**

**identification**

**affiliation**

NGO

**name**

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**questions scope**

**problem definition**

Yes

**which option**

Extend the scope of the Directive

**additional comments**

A. We should explore the safety of novel nicotine products. These may be less hazardous alternative to smoking and as such should be brought under the same regulatory framework as pharmaceutical products rather than under the scope of the tobacco products directive.

**questions smokeless**

**problem definition**

Yes

**which option**

Ban on all types of smokeless tobacco products

**additional option**

A. All tobacco products (no matter how marginal) carry a real threat to public health, so all tobacco products (including snus) should be tightly regulated as opposed to banned-outright

**additional comments**

see above

**questions consumer**

**problem definition**

Yes

**which option**

Improve consumer information; Introduce generic or plain packaging

**which improvement**

Picture warnings to become mandatory; Tar, nicotine and carbon monoxide levels to be replaced with general information on harmful substances in tobacco products; Information on harmful substances in tobacco products that cannot be placed on the package would be placed inside the package; Health warnings to be put on water pipes

**additional option**

The minimum size of health warnings should be increased to 80% of the front and back surfaces of all tobacco packaging

**additional comments**

Generic or plain packaging We strongly recommend the introduction of plain or generic packaging. This should include not only the removal of all branding from the packaging but the size and shape of the packaging should also be standardised. Not only would this prevent the promotion of smoking through branding as occurs presently but it would reinforce the health warning messages. Tobacco packaging provides a direct link between consumers and manufacturers and is the main marketing channel. Branding gives the misleading impression some cigarettes are safer than others.<sup>1</sup> The tobacco industry claims that plain packaging would contravene intellectual property law. However, legal analysis for Action on Smoking and Health concludes that this is incorrect and there are no legal impediments to the implementation of generic packaging in the EU.<sup>2</sup> 1 Hammond D. et al Cigarette pack design and perceptions of risk among UK adults and youth Eur J Public Health. 2009 Dec;19(6):631-



7. 2 The lawfulness of requiring plain packaging for tobacco products. Opinion of Sir Richard Buxton. Nov 2008

**questions on reporting**

**problem definition**

Yes

**which option**

Establish a common compulsory reporting format; Introduce fees and sanctions

**additional options**

Option 2 and 3, Establish a common compulsory reporting format Introduce fees and sanctions

**regulation of ingredients**

**problem definition**

Yes

**which option**

Establish a common list of tobacco ingredients

**which one**

Establish a positive common list of tobacco ingredients

**additional comments**

We support the adoption of a positive common list of tobacco ingredients. Tobacco products are highly toxic and addictive; their contents should therefore be regulated in order to achieve high standards of health protection. A positive common list would ensure that only registered products, with ingredients, flavourings and additives that appear on the positive list would be permitted on the EU market. Currently, EU citizens are not subject to the same level of health protection and a common list of permitted ingredients would go some way towards addressing this anomaly. The tobacco industry uses a range of additives to alter the composition of tobacco products. These can make the product more palatable to children or increase the addictiveness of the product. Therefore any flavourings that may be used to enhance the addictiveness or attractiveness of tobacco products should be banned.

**access to tobacco products**

**problem definition**

Yes

**which option**

Ban

**which one2**

Cross-border retail sales of tobacco to be banned over the Internet; Vending machines to be banned; Promotion and displays in retail stores to be banned

**additional option**

A. The EU needs this ban in order to give a clear message to the public, such as ban would protect children from a predatory industry and denormalise tobacco use.

**additional comments**

as above

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**NGO submission****identification****affiliation**

NGO

**name**

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**gender**

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**questions scope****problem definition**

Yes

**which option**

Extend the scope of the Directive

**additional comments**

We recommend the following: • extend the scope of the Directive to include all smoked products including herbal cigarettes • do not extend the Directive to include electronic nicotine delivery systems (ENDS or E-cigarettes) It is the combustion process and inhalation of smoke that causes most of the harm from smoking. Therefore it is appropriate that herbal cigarettes, which are used in a similar way to nicotine cigarettes, are regulated in the same way as smoked tobacco products, and should be included in the scope of the Directive. Novel nicotine based products (that is, products containing nicotine but not tobacco products) have the potential to offer a less hazardous alternative to cigarettes. Currently these include e-cigarettes and nicotine gel. However, as such products are generally marketed as alternatives to cigarettes and in some cases as an aid to quitting smoking, it is appropriate for them to be brought under the same regulatory framework as pharmaceutical products rather than under the scope of the tobacco products directive.

**questions smokeless****problem definition**

Yes

**which option**

No change

**questions consumer  
problem definition**

Yes

**which option**

Improve consumer information; Introduce generic or plain packaging

**which improvement**

Picture warnings to become mandatory; Tar, nicotine and carbon monoxide levels to be replaced with general information on harmful substances in tobacco products; Information on harmful substances in tobacco products that cannot be placed on the package would be placed inside the package; Health warnings to be put on water pipes

**additional comments**

Picture Warnings We strongly recommend that picture warnings should be mandatory and that they should occupy a minimum of 80% of the front and back surfaces of all tobacco packaging (i.e. not just cigarettes). The warnings should be placed on the upper portion of the packs for maximum visibility. The current situation with some Member States adopting picture warnings whilst others have not done so has created a discrepancy and uneven health protection across the EU. From an internal market perspective, the differences in rules are contrary to the operation of the single market and may constitute a barrier to trade. These obstacles should therefore be removed and pictorial health warnings should be mandatory to ensure optimum health protection for all EU citizens. All warnings should be displayed in rotation so that each message is given equal display to reach its target audience. Information on tar, nicotine & carbon monoxide (TNCO) Currently the Directive requires the inclusion of machine-based tar, nicotine and carbon monoxide yields on cigarette packs. This not only promotes the mistaken beliefs that some cigarette brands are less harmful than others (and that nicotine causes disease) but also offers the user a comparative guide between differing brands or products which may influence their smoking habits or consumption. This move would be consistent with current arrangement to control messages that “may mislead the consumer into the belief that such products are less harmful and give rise to change in consumption.” (Paragraph 27). The EU should not only remove this requirement from the Directive but should prohibit ISO or any other emissions numbers on the pack. We support the proposal to replace numerical measurements with descriptive information on the hazardous effects of tobacco constituents and emissions. The addition of a quitline telephone service should be included on the packaging. Additional information on harmful substances in tobacco products We support the proposal to include additional information on the health effects of tobacco consumption on inserts inside the packaging. This should include advice on quitting smoking. Generic or plain packaging We strongly recommend the introduction of plain or generic packaging. This should include not only the removal of all branding from the packaging but the size and shape of the packaging should also be standardised. Not only would this prevent the promotion of smoking through branding as occurs presently but it would reinforce the health warning messages. The tobacco packaging is still employed as a strong marketing tool by tobacco companies. The Australian federal government has recently announced its intention to introduce plain packaging in 2012, setting a standard that the EU could follow.

**questions on reporting**

**problem definition**

Yes

**which option**

Establish a common compulsory reporting format; Introduce fees and sanctions

**additional comments**

Any amendments to the EU Directive should be used to promote standardised and consistent reporting mechanisms/formats for tobacco companies. The introduction of an annual registration fee for tobacco companies should cover the costs of administering this data collection. Any new measures should be consistent with Article 9 (content) and Article 10 (disclosure) of the Framework Convention on Tobacco Control (FCTC).

**regulation of ingredients****problem definition**

Yes

**which option**

Establish a common list of tobacco ingredients

**which one**

Establish a positive common list of tobacco ingredients

**additional comments**

We support the adoption of Option 3a – to establish a positive common list of tobacco ingredients. Tobacco products are highly toxic and addictive; their contents should therefore be regulated in order to achieve high standards of health protection. A positive common list would ensure that only registered products, with ingredients, flavourings and additives that appear on the list can be permitted on the EU market. The tobacco industry uses a range of additives to alter the composition of tobacco products. These can make the product more palatable to children or increase the addictiveness of the product. Therefore any flavouring that may be used to enhance the addictiveness or attractiveness of tobacco products should be banned and hence not be included on the “positive list”.

**access to tobacco products****problem definition**

Yes

**which option**

Ban

**which one2**

Cross-border retail sales of tobacco to be banned over the Internet; Vending machines to be banned; Promotion and displays in retail stores to be banned

**additional option**

Finland has recently introduced (via their new Tobacco Act) restrictions on tobacco imports that do not meet their labelling criteria for products sold in their country. Such measures should be considered as the basis for adoption by all Member States via amendments to the EU Directive, for example by specifying limits on imports for personal use.

**additional comments**

Internet. The principle of preventing cross-border promotion of tobacco products in order to protect public health was enshrined in the Tobacco Advertising directive (2001/0119). It is logical, therefore, to extend that principle to the sale of tobacco products between Member States via the Internet. The cross-border sale of tobacco products via the internet potentially undermines many tobacco control efforts in Member States as indicated. To overcome such anomalies and promote consistency we support the prohibition of tobacco sales via the Internet. Vending machines. The vast majority of Member States (22 out of 27) already prohibit the sale of tobacco products from vending machines. Recent activities across the Yorkshire & Humber Region (United Kingdom) in the last year has shown 64.7% (57 from 88) successful under-age test purchases of cigarettes from vending machines. Vending machines continue to be a significant access point for cigarettes for young people in the UK. We support a total ban across Member States to deter young people accessing cigarettes from this source. Point of Sale. We support an EU-wide adoption of a ban on the display of tobacco products at the point of sale. Across the EU, most forms of tobacco advertising are now prohibited but the tobacco industry continues to market its products by the use of attractive packaging. Research shows that point of sale displays of tobacco have a direct impact on young people's intention to smoke.[1] Furthermore, there is a growing body of evidence to show that putting tobacco products out of sight in retail outlets can reduce youth smoking.[2] To date, this measure has been adopted by Ireland and Finland (as well as Iceland and Norway) and is going through the parliamentary process in the UK. 1 Point of Sale Display of Tobacco Products. The Centre for Tobacco Control Research. University of Stirling, 2008. 2 Tobacco displays at the point of sale. ASH Briefing, Nov. 2010

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**NGO submission****identification****affiliation**

NGO

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**questions scope****problem definition**

Yes

**which option**

No change

**questions smokeless**

**problem definition**

Yes

**which option**

Lifting the ban on snus

**questions consumer  
problem definition**

No

**explanations**

no comments

**which option**

No change

**questions on reporting  
problem definition**

No

**explanations**

no comments

**which option**

Establish a common compulsory reporting format

**regulation of ingredients  
problem definition**

No

**explanations**

no comments

**which option**

No Change

**access to tobacco products  
problem definition**

No

**explanations**

no comments

**which option**

No change

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**NGO submission**

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NGO

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**questions scope**  
**problem definition**  
Yes

**which option**  
No change

**additional comments**  
Non reputiamo necessario un allargamento dell'ambito della Direttiva ad altre categorie di prodotti. Seppure riteniamo interessante controllare il mercato delle sigarette senza tabacco, non si può accettare il divieto proposto per tutte le forme di tabacco senza fumo tra cui lo "snus" che rappresenta sbocchi interessanti per alcuni Paesi, non essendo stata dimostrata scientificamente una nocività di questi prodotti analoga a quella degli altri prodotti del tabacco.

**questions smokeless**  
**problem definition**  
No

**comments**  
la spiegazione dettagliata è nello spazio relativo alla scelta dell' opzione

**which option**  
Lifting the ban on snus

**additional comments**  
Riteniamo ingiusto che la commercializzazione del tabacco umido in polvere per uso orale (c.d. "snus") sia consentita in un solo Stato dell'UE, ovvero la Svezia, e vietata in tutti gli altri Stati. Il divieto di vendita non è basato su prove scientifiche ed andrebbe rimosso. La nostra posizione è sostenuta anche dal fatto che, in Svezia, diverse ricerche scientifiche dimostrano la riduzione dell'incidenza delle patologie correlate al fumo rispetto alla media UE proprio grazie all'utilizzo dello "snus". Inoltre, anche la percentuale dei fumatori sul totale della popolazione è inferiore alla media UE. Tale dato dimostrerebbe l'efficacia dello "snus" come potenziale strumento di supporto per smettere di consumare prodotti da fumo. Ci auguriamo,

quindi, che lo “snus” venga liberamente commercializzato in tutti gli Stati Membri del mercato unico europeo.

**questions consumer**

**problem definition**

No

**explanations**

la spiegazione dettagliata è nello spazio relativo alla scelta dell' opzione

**which option**

No change

**additional comments**

Non esistono più fumatori che ignorano i pericoli del consumo. Le foto non hanno dato la prova della loro efficienza. La consapevolezza dei rischi sanitari connessi al prodotto, come sostenuto da più ricerche scientifiche, non aumenta con l'utilizzo di ulteriori avvertenze speciali. A nostro avviso, quindi, la possibilità di inserire avvertenze sotto forma di fotografie a colori o altre illustrazioni dovrebbe essere lasciata alla libera iniziativa degli Stati Membri, come previsto dalla Direttiva attuale. Inoltre, l'introduzione di restrizioni sul pacchetto (es. il c.d. pacchetto generico che riteniamo un'aberrazione per un prodotto da banco e il rischio di mascherare il prodotto a discapito della qualità del tabacco), come suggerito dall'opzione 3, a nostro avviso, mina seriamente la sopravvivenza stessa dell'industria legale a causa del rischio di incremento della contraffazione dei prodotti che va a tutto vantaggio del commercio illecito e delle organizzazioni criminali, rendendo il prodotto più accessibile ai giovani.

**questions on reporting**

**problem definition**

Yes

**which option**

Establish a common compulsory reporting format

**regulation of ingredients**

**problem definition**

No

**explanations**

la spiegazione dettagliata nello spazio relativo alla scelta dell' opzione

**which option**

No Change

**additional comments**

Il rischio che alcuni o anche tutti gli ingredienti, vengano vietati, senza fondamento scientifico, è troppo grande. A nostro avviso, la regolamentazione degli ingredienti inseriti nei prodotti del tabacco dovrebbe rimanere competenza degli Stati Membri, come già previsto dall'attuale Direttiva. Questo anche in virtù dei risultati del rapporto del Comitato SCENIHR, incaricato dalla Commissione Europea/DG SANCO di valutare il ruolo degli ingredienti utilizzati in riferimento all'attrattività e all'assuefazione degli stessi. Il rapporto conferma che



l'attrattività è un concetto assolutamente soggettivo. L'eventuale divieto di uso degli ingredienti avrebbe gravissime ripercussioni economiche ed occupazionali per il settore del tabacco greggio in Italia. Queste misure, infatti, renderebbero non più economicamente conveniente la coltivazione di alcune varietà di tabacco utilizzato per la produzione di sigarette di tipo American blend e la sopravvivenza dell'intero settore della coltivazione e della prima trasformazione del tabacco in Italia, che occupano circa 60.000 addetti, verrebbe seriamente minata.

**access to tobacco products**

**problem definition**

Yes

**which option**

Controlled supply and access

**which supply and access**

Age verification of buyers and other legal conditions to be set for cross-border retail sale;  
Access to vending machines to be restricted to adults

**additional comments**

Riteniamo opportuno una discussione sull'accesso controllato, ma non attraverso un approccio di restrizioni globali globale all'interno delle tabaccherie e di internet, che è difficilmente controllabile. A nostro avviso, la determinazione delle misure che stabiliscono i limiti all'accesso ai prodotti a base di tabacco dovrebbe rimanere competenza degli Stati Membri. In particolare, siamo contrari ad ulteriori ed ingiustificate restrizioni, come il divieto totale di esposizione dei prodotti, in quanto determinano una sorta di criminalizzazione del consumo di un prodotto legale, con gravi ripercussioni su tutta la filiera produttiva. Peraltro, auspichiamo che la Direttiva adotti la regolamentazione già presente in Italia, in particolare per quanto riguarda la verifica dell'età dell'acquirente e l'installazione di distributori automatici provvisti di sistema di verifica anagrafica. Infine, supportiamo le restrizioni prospettate per le vendite via internet poiché tali misure, a nostro avviso, preservano il livello qualitativo del prodotto garantito, in Italia, dal sistema di concessione delle licenze ai prodotti del tabacco tutelando, quindi, anche la salute del consumatore.

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**NGO submission**

**identification**

**affiliation**

NGO

**name**

EFA - European Federation of Allergy and Airways Diseases Patients Associations (represents half a million asthma, allergy and COPD patients across Europe), in support of and following the submissions of ENSP (European Network for Smoking and Tobacco Prevention) and ECL (Association of European Cancer Leagues)

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**questions scope****problem definition**

Yes

**which option**

Extend the scope of the Directive

**additional comments**

All tobacco products are hazardous to health – there is no safe level of usage. Therefore we recommend that the scope of the Directive includes the regulation of any new smoked tobacco products (such as low emission or nicotine-free cigarettes), while the prohibition of any novel forms of oral tobacco, including snus, should be maintained. Herbal cigarettes are also harmful because it is the combustion and inhalation of smoke that causes most of the harm from smoking. Therefore, herbal cigarettes should be included in the scope Tobacco Products Directive and should also be subject to health warnings requirements. Finally, all forms of nicotine based products (that is, products containing nicotine but which are not tobacco products, such as electronic cigarettes, nicotine gel, drinks, and sweets) are often marketed as alternatives to cigarettes and in some cases as an aid to quitting smoking. Therefore, they should only be sold as quitting aids and comply with specific safety and quality requirements under the same regulatory framework as pharmaceutical products rather than under the scope of the Tobacco Products Directive.

**questions smokeless****problem definition**

Yes

**which option**

No change

**additional option**

The ban on snus should definitely be maintained. This is high priority. Indeed, there is no legitimate reason to reintroduce a carcinogenic and addictive product onto the EU market. Furthermore, if the ban on snus were to be lifted, it could encourage dual use of cigarettes and smokeless tobacco and discourage total abstinence from tobacco, thus weakening any potential health gains. In this context, we stress that there are already available effective treatments for nicotine addiction, including medicinal or ‘clean’ nicotine (NRT), that do not carry the risks associated with the use of snus. These should be promoted first and foremost. It is clear that the public health interest can be served even more by encouraging a) greater use of these treatments and b) the development of more effective cessation aids, especially those that mimic more closely the nicotine ‘hit’ delivered by cigarettes. Regarding other forms of smokeless tobacco products, ECL does not believe that they should be “marketed” in all Member States. We recognise that they are as addictive and dangerous as smoked tobacco. As stated in the Opinion of the Scientific Committee on Emerging and Newly Identified Health Risks (SCENIHR), many forms of smokeless tobacco increase the risk of mouth, esophageal, pancreatic and liver cancer, and other conditions including gum and heart disease. However, we also know that these products are mostly consumed in the UK and used by South Asian

communities; introducing an EU-wide ban on these products now could lead to the creation of an unnecessary illegal market, pushing consumption underground. This is why we do not recommend an immediate ban on all types of smokeless tobacco products; we do recommend that they should be regulated in the same way as tobacco products.

#### **questions consumer**

#### **problem definition**

No

#### **explanations**

The problem definition could be improved. We agree with the Commission that the current situation, whereby some Member States have made graphic warnings compulsory and others not, has led to a disparity in labelling throughout the EU. Consequently, this has an impact on the functioning of the internal market, on consumers' awareness and as a result, on their smoking behaviour. We also agree that packaging as an advertising tool is not covered by the current Directive. Finally, we welcome the acknowledgement that tobacco packaging and product features are increasingly used to attract consumers, to promote products and brand image. In this context, it would have been judicious to highlight the fact that, in the Eurobarometer survey released in 2010, the policy that received the most positive response is that of putting health warnings on all packages of tobacco products (on average, 75% of EU citizens are in favour of mandatory pictorial warnings, and over 54% support plain packaging measures).

#### **which option**

Improve consumer information; Introduce generic or plain packaging

#### **which improvement**

Picture warnings to become mandatory; Tar, nicotine and carbon monoxide levels to be replaced with general information on harmful substances in tobacco products; Information on harmful substances in tobacco products that cannot be placed on the package would be placed inside the package; Health warnings to be put on water pipes

#### **additional option**

Crucial importance of Graphic health warnings: Evidence shows that text only warning messages are not as effective as graphic warnings. Pictures, especially fear inducing pictures, are proven to be effective in getting consumers more engaged with the warning message. Pictures are able to immediately provoke a reaction and prompt people to read the associated text message. The need for graphic health warnings on both sides of the pack: There is also evidence that pictures on both sides of the packaging have a greater impact. The need for LARGE pictorial health warnings (80%): The global trend is towards larger health warnings. Uruguay, for instance, has implemented legislation to make pictorial health warnings obligatory, covering 80% of the front and the back of cigarette packs. Evidence clearly shows that increasing the size of warning messages (text only and combined text and picture) increases the effectiveness of the warning amongst both young and adult smokers / non smokers. Research carried out in Canada by Createc on behalf of Health Canada in 2007 showed that young and adult smokers/non smokers are sensitive to the size of health warning messages. Results showed that warning messages that cover 100% of the pack are significantly more effective across all measured effectiveness indicators compared with warning messages that cover only 50% of the pack. The importance of Rotation: Warning texts and pictures should be displayed on a rotating basis, so that each message is given equal

display and can reach its target audience. The proved effectiveness of shocking health warnings & targeted messages: as specified in the Sambrook Research International report, fear inducing warnings (using strong “shocking” images related to health risks such as rotten teeth or throat cancer) and strong emotion inducing warnings (especially involving children and unborn babies) are the most effective way to educate consumers on the health risks of tobacco use and to achieve changes in attitudes and behaviour. These warnings’ effectiveness is enhanced if they are used in conjunction with a quit line. Generic or plain packaging: We strongly recommend the introduction of standardised/plain packaging. This should include not only the removal of all branding from the packaging but the size and shape of the packaging should also be standardised. Not only would this prevent the promotion of smoking through branding as occurs presently but it would reinforce the health warning messages. Tobacco packaging provides a direct link between consumers and manufacturers and is the main marketing channel, particularly in jurisdictions with tobacco advertising bans. Branding gives the misleading impression some cigarettes are safer than others. The tobacco industry claims that plain packaging would contravene intellectual property law. However, legal analysis concludes that this is incorrect and there are no international legal impediments to the implementation of generic packaging. Replace TNCO quantitative labelling with qualitative information on contents, emissions and quit-lines: The inclusion of machine-based tar, nicotine and carbon monoxide yields on cigarette packs promotes the mistaken belief that some cigarette brands are less harmful than others. We support the proposal to replace numerical measurements with descriptive information on the hazardous effects of tobacco constituents and emissions. We stress the importance of putting quit line numbers on the package. As underlined in the Sambrook research (p46), providing a telephone number on the pack is more effective than telling smokers to seek advice from a doctor or pharmacist. P46 Health warnings on water pipes: There is a growing body of evidence to show that water pipes are at least as hazardous, if not more so, than other forms of tobacco use. Warnings should also be included on the packaging of tobacco used in water pipes.

### **additional comments**

Under Article 5.3 of the TPD 2001, Member States have the option to adopt pictorial warnings. This situation emphasised the right of Member States to go further than the Directive to protect public health as set out in Article 30 of the Treaty of the Union (now article 36). Five years after the adoption of the library of 42 pictorial health warnings by the European commission, seven Member States have adopted legislation to introduce pictorial health warnings (Belgium, Romania, United Kingdom, Latvia, Malta, France and Spain). Such measures are in compliance with the current TPD and are welcomed by the tobacco control community. However, their adoption by some Member States necessarily creates growing discrepancies between Member States. As stated above, there is clear evidence that pictorial warnings are much more powerful than written health warnings. Extending the information and protection to all EU Member States would be in harmony with Article 168 of the TFEU and consistent with the objectives of the internal market stated in Article 114.3 of the TFEU and reiterated in Recital 19 of the Directive. A revision of the TPD should, therefore, aim at making pictorial health warnings of tobacco products subject to common rules. Note: Legislation on labelling, advertising and product regulation put forward by the Commission in the field of tobacco control, has been based on the internal market legislation (Articles 26 and 114 of the TFEU). Article 26 of the TFEU establishes the internal market. Article 114 gives EU institutions the competence to regulate and set rules for the functioning of the internal market. More specifically, article 114.3 also states that when establishing rules for the functioning of the internal market in the context of health, safety, environmental protection and consumer protection, the Commission “will take as a base a high level of

protection, taking account in particular of any new development based on scientific facts.” The European Court of Justice (the “ECJ”) made an extensive analysis of Article 95 EC (now Article 114) throughout the years. In *Spain v. Council*, the Court observed that “recourse to Article 100a (now Article 114) as a legal basis is possible if the aim is to prevent the emergence of future obstacles to trade resulting from multifarious development of national laws.” The TPD was adopted on the basis of Article 114 TFEU (ex Article 95). As a result, Recital 19 of the TPD states that “[t]he presentation of warning labels and yields has continued to remain variable in the different Member States. As a consequence, consumers in one Member State may be better informed as to the risks of tobacco products than in another. Such differences are unacceptable and are liable to constitute a barrier to trade and to impede the operation of the internal market in tobacco products, and should therefore be eliminated.”

**questions on reporting**  
**problem definition**

Yes

**which option**

Establish a common compulsory reporting format; Introduce fees and sanctions

**additional comments**

The current situation which allows different formats and reporting mechanisms is unsatisfactory, making it difficult for authorities to compare and analyse the data. All tobacco manufacturers and importers should be subject to the same reporting requirements. The SFP believes that tobacco products, which are highly harmful, should be subject to an effective reporting system that allows the gathering and analysis of relevant data, including comparison as appropriate, in order to ensure high levels of consumer safety and information. The format already exists (based on the voluntary reporting format developed by the Commission in May 2007) and it would therefore be very easy to adopt this measure and to implement it. We welcome the introduction of yearly registration fees in order to finance the data collection on ingredients by the national authorities and their analysis work on ingredients. The payment of penalties in case of non-compliance with the requirements of delivery of data on tobacco product ingredients also seems adequate and would contribute to fund the tests conducted on these products. It is crucial that the appropriate toxicological and addictiveness tests are properly conducted. Such tests would allow policy-makers to make more informed decisions in this field, as there would be more scientific evidence. It would enhance the scientific knowledge of the dangers of tobacco products and would contribute to a high protection of health, as stated in Article 95.3 TFEU. Besides, such measures would also have an indirect impact on illicit trade, since only registered products would be allowed on the market.

**regulation of ingredients**

**problem definition**

Yes

**which option**

Establish a common list of tobacco ingredients

**which one**

Establish a positive common list of tobacco ingredients

**additional comments**

We support the adoption of a positive common list of tobacco ingredients. We believe that tobacco products are highly toxic and addictive, and that their content should therefore be closely regulated, in order to achieve high standards of health protection, as stated under article 114.3. There is a need for such a list at EU level since at the moment, consumers in the internal market are not subject to the same level of protection. Some citizens may be using substances that are banned in other Member States. Apart from creating unequal health protection across the EU, this may constitute an obstacle to free movement of goods within the internal market: some countries can refuse access to their markets of cigarettes from Member States that do not comply with the importing Member State's national requirements.

**Regulation of Flavours and Ingredients:** Flavourings are an increasingly important part of tobacco industry marketing, particularly to young people. Flavourings enhance attractiveness, encourage youth initiation, and discourage cessation. The prohibition of ingredients that may be used to increase attractiveness, such as sugars and sweeteners, flavouring substances, and spices and herbs, in cigarettes and cigarette-like tobacco products should be introduced. The prohibition of ingredients that may create the impression of a health benefit (e.g. vitamins), ingredients associated with energy and vitality (e.g. caffeine), and ingredients with colouring properties (e.g. pink cigarette paper) should also be banned. Tobacco manufacturers and importers should report sales volume information by brand. This information is essential to help governments ensure that product regulation is effective. The above measures should be compliant with the Guidelines on Art. 9/10, adopted unanimously at the Fourth Conference of the Parties in Uruguay on the 20th November 2010.

#### **access to tobacco products**

##### **problem definition**

Yes

##### **which option**

Ban

##### **which one2**

Cross-border retail sales of tobacco to be banned over the Internet; Vending machines to be banned; Promotion and displays in retail stores to be banned

##### **additional option**

We urge the Commission to call for a ban on the promotion of tobacco products at point of sale and a ban on vending machines as described in the Art 13 Guidelines of the FCTC.

##### **additional comments**

Internet. The principle of preventing cross-border promotion of tobacco products in order to protect public health was enshrined in the Tobacco Advertising directive (2001/0119). It is logical, therefore, to extend that principle to the sale of tobacco products between member states via the Internet. We support the prohibition of tobacco sales via the Internet. Vending machines. Considering that only 2 Member States have no legislation on vending machines, we support harmonisation of the legislation on the basis of a prohibition of the sale of tobacco from vending machines . Point of Sale. Evidence shows that a coordinated cross border marketing strategy on the part of the tobacco companies is reflected at point of sale (i.e. point of sale marketing is similar in most EU countries (i.e.: a brand is advertised at point of sale in the same way in Germany and Belgium). There is a growing body of evidence to show that putting tobacco products out of sight in retail outlets can reduce youth smoking. To date, this measure has been adopted by Ireland and Finland (as well as Iceland and Norway). This

measure is also official government policy in Scotland, Wales and Northern Ireland and a decision is awaited in England. We strongly support an EU-wide adoption of a ban on the display of tobacco products at the point of sale.

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## **NGO submission**

### **identification**

#### **affiliation**

NGO

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#### **country**

Iceland

#### **gender**

female

### **questions scope**

#### **problem definition**

Yes

#### **which option**

Extend the scope of the Directive

### **additional comments**

All tobacco products are hazardous to health – there is no safe level of usage. Therefore we recommend that the scope of the Directive includes the regulation of any new smoked tobacco products (such as low emission or nicotine-free cigarettes), while the prohibition of any novel forms of oral tobacco, including snus, should be maintained. Herbal cigarettes are also harmful because it is the combustion and inhalation of smoke that causes most of the harm from smoking. Therefore, herbal cigarettes should be included in the scope Tobacco Products Directive and should also be subject to health warnings requirements. Finally, all forms of nicotine based products (that is, products containing nicotine but which are not tobacco products, such as electronic cigarettes, nicotine gel, drinks, and sweets) are often marketed as alternatives to cigarettes and in some cases as an aid to quitting smoking. Therefore, they should only be sold as quitting aids and comply with specific safety and quality requirements under the same regulatory framework as pharmaceutical products rather than under the scope of the Tobacco Products Directive.

### **questions smokeless**

#### **problem definition**

Yes

**which option**

No change

**additional option**

The ban on snus should definitely be maintained. This is high priority. Indeed, there is no legitimate reason to introduce a dangerous product onto the market, particularly as, from an internal market point of view, we have no idea how snus would be perceived or used in other countries. A small study conducted by the University of Nottingham by Professor Ann McNeil showed that, in the UK, people could not see the point of snus unless it was as a cessation aid (i.e. there is currently no demand). For internal market purposes, it really does not make sense to lift the ban. Furthermore, if the ban on snus were to be lifted, it could encourage dual use of cigarettes and smokeless tobacco and discourage total abstinence from tobacco, thus weakening any potential health gains. In this context, we stress that there are already available effective treatments for nicotine addiction, including medicinal or 'clean' nicotine (NRT), that do not carry the risks associated with the use of snus. These should be promoted first and foremost. It is clear that the public health interest can be served even more by encouraging a) greater use of these treatments and b) the development of more effective cessation aids, especially those that mimic more closely the nicotine 'hit' delivered by cigarettes. Regarding other forms of smokeless tobacco products, the SFP does not believe that they should be "marketed" in all Member States. We recognise that they are as addictive and dangerous as smoked tobacco. As stated in the Opinion of the Scientific Committee on Emerging and Newly Identified Health Risks (SCENIHR), many forms of smokeless tobacco increase the risk of mouth, esophageal, pancreatic and liver cancer, and other conditions including gum and heart disease. However, we also know that these products are mostly consumed in the UK and used by South Asian communities; introducing an EU-wide ban on these products now could lead to the creation of an unnecessary illegal market, pushing consumption underground. This is why we do not recommend an immediate ban on all types of smokeless tobacco products; we do recommend that they should be regulated in the same way as tobacco products.

**questions consumer****problem definition**

No

**explanations**

The problem definition could be improved. We agree with the Commission that the current situation, whereby some Member States have made graphic warnings compulsory and others not, has led to a disparity in labelling throughout the EU. Consequently, this has an impact on the functioning of the internal market, on consumers' awareness and as a result, on their smoking behaviour. We also agree that packaging as an advertising tool is not covered by the current Directive. Finally, we welcome the acknowledgement that tobacco packaging and product features are increasingly used to attract consumers, to promote products and brand image. In this context, it would have been judicious to highlight the fact that, in the Eurobarometer survey released in 2010, the policy that received the most positive response is that of putting health warnings on all packages of tobacco products (on average, 75% of EU citizens are in favour of mandatory pictorial warnings, and over 54% support plain packaging measures).

**which option**

Improve consumer information; Introduce generic or plain packaging



### **which improvement**

Picture warnings to become mandatory; Tar, nicotine and carbon monoxide levels to be replaced with general information on harmful substances in tobacco products; Information on harmful substances in tobacco products that cannot be placed on the package would be placed inside the package; Health warnings to be put on water pipes

### **additional option**

Crucial importance of Graphic health warnings: Evidence shows that text only warning messages are not as effective as graphic warnings. Pictures, especially fear inducing pictures, are proven to be effective in getting consumers more engaged with the warning message. Pictures are able to immediately provoke a reaction and prompt people to read the associated text message. The need for graphic health warnings on both sides of the pack: There is also evidence that pictures on both sides of the packaging have a greater impact. The need for LARGE pictorial health warnings (80%): Evidence clearly shows that increasing the size of warning messages (text only and combined text and picture) increases the effectiveness of the warning amongst both young and adult smokers / non smokers. Research carried out in Canada by Createc on behalf of Health Canada in 2007 showed that young and adult smokers/non smokers are sensitive to the size of health warning messages. Results showed that warning messages that cover 100% of the pack are significantly more effective across all measured effectiveness indicators compared with warning messages that cover only 50% of the pack. The importance of Rotation: Warning texts and pictures should be displayed on a rotating basis, so that each message is given equal display and can reach its target audience. The proved effectiveness of shocking health warnings & targeted messages: as specified in the Sambrook Research International report, fear inducing warnings (using strong “shocking” images related to health risks such as rotten teeth or throat cancer) and strong emotion inducing warnings (especially involving children and unborn babies) are the most effective way to educate consumers on the health risks of tobacco use and to achieve changes in attitudes and behaviour. These warnings’ effectiveness is enhanced if they are used in conjunction with a quit line. Generic or plain packaging: We strongly recommend the introduction of standardised/plain packaging. This should include not only the removal of all branding from the packaging but the size and shape of the packaging should also be standardised. Not only would this prevent the promotion of smoking through branding as occurs presently but it would reinforce the health warning messages. Tobacco packaging provides a direct link between consumers and manufacturers and is the main marketing channel, particularly in jurisdictions with tobacco advertising bans. Branding gives the misleading impression some cigarettes are safer than others. The tobacco industry claims that plain packaging would contravene intellectual property law. However, legal analysis concludes that this is incorrect and there are no international legal impediments to the implementation of generic packaging. Replace TNCO quantitative labelling with qualitative information on contents, emissions and quit-lines: The inclusion of machine-based tar, nicotine and carbon monoxide yields on cigarette packs promotes the mistaken belief that some cigarette brands are less harmful than others. We support the proposal to replace numerical measurements with descriptive information on the hazardous effects of tobacco constituents and emissions. We stress the importance of putting quit line numbers on the package. As underlined in the Sambrook research (p46), providing a telephone number on the pack is more effective than telling smokers to seek advice from a doctor or pharmacist. P46 Health warnings on water pipes: There is a growing body of evidence to show that water pipes are at least as hazardous, if not more so, than other forms of tobacco use. Warnings should also be included on the packaging of tobacco used in water pipes.

**additional comments**

Under Article 5.3 of the TPD 2001, Member States have the option to adopt pictorial warnings. This situation emphasised the right of Member States to go further than the Directive to protect public health as set out in Article 30 of the Treaty of the Union (now article 36). Ten years after the entering into force of the TPD, four countries (the UK, Belgium, Romania and Malta) have adopted the option. More countries such as Spain and France are planning to adopt mandatory pictorial warnings. Such measures are in compliance with the current TPD and are welcomed by the tobacco control community. However, their adoption by some Member States necessarily creates growing discrepancies between Member States. As stated above, there is clear evidence that pictorial warnings are much more powerful than written health warnings. Extending the information and protection to all EU Member States would be in harmony with Article 168 of the TFEU and consistent with the objectives of the internal market stated in Article 114.3 of the TFEU and reiterated in Recital 19 of the Directive. A revision of the TPD should, therefore, aim at making pictorial health warnings of tobacco products subject to common rules. Note: Legislation on labelling, advertising and product regulation put forward by the Commission in the field of tobacco control, has been based on the internal market legislation (Articles 26 and 114 of the TFEU). Article 26 of the TFEU establishes the internal market. Article 114 gives EU institutions the competence to regulate and set rules for the functioning of the internal market. More specifically, article 114.3 also states that when establishing rules for the functioning of the internal market in the context of health, safety, environmental protection and consumer protection, the Commission “will take as a base a high level of protection, taking account in particular of any new development based on scientific facts.” The European Court of Justice (the “ECJ”) made an extensive analysis of Article 95 EC (now Article 114) throughout the years. In *Spain v. Council*, the Court observed that “recourse to Article 100a (now Article 114) as a legal basis is possible if the aim is to prevent the emergence of future obstacles to trade resulting from multifarious development of national laws.” The TPD was adopted on the basis of Article 114 TFEU (ex Article 95). As a result, Recital 19 of the TPD states that “[t]he presentation of warning labels and yields has continued to remain variable in the different Member States. As a consequence, consumers in one Member State may be better informed as to the risks of tobacco products than in another. Such differences are unacceptable and are liable to constitute a barrier to trade and to impede the operation of the internal market in tobacco products, and should therefore be eliminated.”

**questions on reporting****problem definition**

Yes

**which option**

Establish a common compulsory reporting format

**additional comments**

The current situation which allows different formats and reporting mechanisms is unsatisfactory, making it difficult for authorities to compare and analyse the data. All tobacco manufacturers and importers should be subject to the same reporting requirements. The SFP believes that tobacco products, which are highly harmful, should be subject to an effective reporting system that allows the gathering and analysis of relevant data, including comparison as appropriate, in order to ensure high levels of consumer safety and information. The format already exists (based on the voluntary reporting format developed by the Commission in May

2007) and it would therefore be very easy to adopt this measure and to implement it. We welcome the introduction of yearly registration fees in order to finance the data collection on ingredients by the national authorities and their analysis work on ingredients. The payment of penalties in case of non-compliance with the requirements of delivery of data on tobacco product ingredients also seems adequate and would contribute to fund the tests conducted on these products. It is crucial that the appropriate toxicological and addictiveness tests are properly conducted. Such tests would allow policy-makers to make more informed decisions in this field, as there would be more scientific evidence. It would enhance the scientific knowledge of the dangers of tobacco products and would contribute to a high protection of health, as stated in Article 95.3 TFEU. Besides, such measures would also have an indirect impact on illicit trade, since only registered products would be allowed on the market.

### **regulation of ingredients**

#### **problem definition**

Yes

#### **which option**

Establish a common list of tobacco ingredients

#### **which one**

Establish a positive common list of tobacco ingredients

#### **additional comments**

We support the adoption of a positive common list of tobacco ingredients. We believe that tobacco products are highly toxic and addictive, and that their content should therefore be closely regulated, in order to achieve high standards of health protection, as stated under article 114.3. There is a need for such a list at EU level since at the moment, consumers in the internal market are not subject to the same level of protection. Some citizens may be using substances that are banned in other Member States. Apart from creating unequal health protection across the EU, this may constitute an obstacle to free movement of goods within the internal market: some countries can refuse access to their markets of cigarettes from Member States that do not comply with the importing Member State's national requirements. Regulation of Flavours and Ingredients: Flavourings are an increasingly important part of tobacco industry marketing, particularly to young people. Flavourings enhance attractiveness, encourage youth initiation, and discourage cessation. The prohibition of ingredients that may be used to increase attractiveness, such as sugars and sweeteners, flavouring substances, and spices and herbs, in cigarettes and cigarette-like tobacco products should be introduced. The prohibition of ingredients that may create the impression of a health benefit (e.g. vitamins), ingredients associated with energy and vitality (e.g. caffeine), and ingredients with colouring properties (e.g. pink cigarette paper) should also be banned. Tobacco manufacturers and importers should report sales volume information by brand. This information is essential to help governments ensure that product regulation is effective. The above measures should be compliant with the Guidelines on Art. 9/10, adopted unanimously at the Fourth Conference of the Parties in Uruguay on the 20th November 2010.

### **access to tobacco products**

#### **problem definition**

Yes

#### **which option**

Ban

**which one2**

Cross-border retail sales of tobacco to be banned over the Internet; Vending machines to be banned; Promotion and displays in retail stores to be banned

**additional option**

We urge the Commission to call for a ban on the promotion of tobacco products at point of sale and a ban on vending machines as described in the Art 13 Guidelines of the FCTC.

**additional comments**

Internet. The principle of preventing cross-border promotion of tobacco products in order to protect public health was enshrined in the Tobacco Advertising directive (2001/0119). It is logical, therefore, to extend that principle to the sale of tobacco products between member states via the Internet. We support the prohibition of tobacco sales via the Internet. Vending machines. The majority of member states (22 out of 27) already prohibit the sale of tobacco products from vending machines in order to deter young people accessing cigarettes from this source. We support this measure. Point of Sale. Evidence shows that a coordinated cross border marketing strategy on the part of the tobacco companies is reflected at point of sale (i.e. point of sale marketing is similar in most EU countries (i.e.: a brand is advertised at point of sale in the same way in Germany and Belgium). There is a growing body of evidence to show that putting tobacco products out of sight in retail outlets can reduce youth smoking. To date, this measure has been adopted by Ireland and Finland (as well as Iceland and Norway). This measure is also official government policy in Scotland, Wales and Northern Ireland and a decision is awaited in England. We strongly support an EU-wide adoption of a ban on the display of tobacco products at the point of sale.

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**NGO submission**

**identification**

**affiliation**

NGO

**name**

ASH IRELAND

**email**

ashire@iol.ie

**country**

IRELAND

**questions scope**

**problem definition**

Yes

**which option**

Extend the scope of the Directive

**recommend option**

We agree that new tobacco products and novel forms of oral tobacco should be banned similarly to snus. Herbal cigarettes and electronic nicotine delivery systems should be regulated by EU food and pharmaceutical legislation. If necessary, the inclusion in a reviewed product directive can be considered, but is not a priority.

**additional comments**

Tobacco Litter Ash Ireland wish to propose that a new and additional section be introduced in the Tobacco Product Directive. ASH Ireland proposes that all EU governments impose a levy on the tobacco industry related to each tobacco product sold in each jurisdiction, as compensation for the well recorded expenditure on dealing with tobacco related waste. Research shows that over 50% of urban litter is related to tobacco products. This proposed levy can also be dedicated to repairing the environmental damage, in particular European waterways which is caused by tobacco waste. (The healthy lobby in Ireland have made a proposal to the Irish government that a 50% levy be placed on the Irish tobacco industry for each pack of 20 cigarettes sold in the jurisdiction.)

**questions smokeless****problem definition**

Yes

**which option**

No change

**additional option**

We strongly recommend the prohibition on the marketing of tobacco for oral use (“snus”) remains unchanged.

**questions consumer****problem definition**

No

**explanations**

The problem definition could be improved.

**which option**

Improve consumer information; Introduce generic or plain packaging

**which improvement**

Picture warnings to become mandatory; Tar, nicotine and carbon monoxide levels to be replaced with general information on harmful substances in tobacco products; Information on harmful substances in tobacco products that cannot be placed on the package would be placed inside the package; Health warnings to be put on water pipes

**additional comments**

We strongly recommend the introduction of mandatory pictorial health warnings on all tobacco products (including oral and water pipe tobacco) covering 80% of the front and the back of the packs towards the top, in combination with standardized packaging. We strongly recommend the use of standardised packaging. This should include the prohibition of the use

of logos, colours, brand images or promotional information on the packaging of tobacco products. It allows the use of brand names and product names, which have to be displayed in a standard colour and font style. We strongly recommend tobacco companies being only allowed to have one standardized presentation (as already exists in Uruguay) and package size per cigarette brand.

**questions on reporting  
problem definition**

Yes

**which option**

Establish a common compulsory reporting format; Introduce fees and sanctions

**regulation of ingredients**

**problem definition**

Yes

**which option**

Establish a common list of tobacco ingredients

**which one**

Establish a positive common list of tobacco ingredients

**additional comments**

We would recommend a positive list of ingredients, flavourings and additives in tobacco products, which should not contain ingredients, flavourings or additives, which enhance attractiveness. We endorse a yearly registration fee paid to national competent authorities in order to finance their data collection and analysis work on ingredients. Only registered products would be allowed on the market.

**access to tobacco products**

**problem definition**

Yes

**which option**

Ban

**which one2**

Cross-border retail sales of tobacco to be banned over the Internet; Vending machines to be banned; Promotion and displays in retail stores to be banned

**additional comments**

We would also like to recommend a European wide legal maximum limit of the amount of cigarettes that can be transported by individuals rather than the current indicative limit.

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**NGO submission**

**identification**

**affiliation**

NGO

**name**

SRNT-E: The European Chapter of the Society for Research on Nicotine and Tobacco is a formal, self-charted chapter registered as a non-profit scientific society in Europe. SRNT-E represents SRNT members residing in Europe, defined as EU Member States and countries associated to the science and technology agreements of the EC (Switzerland, Israel, Norway, Iceland, Liechtenstein, Turkey, Croatia, the Former Yugoslav Republic of Macedonia and Serbia, Albania and Montenegro, Bosnia & Herzegovina, Faeroe Islands). Membership in SRNT-E is voluntary, based on payment of annual dues established by the SRNT-E Board. Any member of SRNT may join SRNT-E, and all SRNT-E members must be members in good standing of SRNT. Employees of the tobacco industry cannot be members of SRNT and cannot participate at the SRNT-E meetings or other activities. SRNT-E aims to engage with the European Union, as well as individual countries and the FCTC, in areas including tobacco control policy and increased funding support for nicotine and tobacco research. SRNT-E Board (2010-2011) Sakire Pogun (President) sakire.pogun@ege.edu.tr Jaakko Kaprio (President Elect and SRNT member delegate for Europe) jaakko.kaprio@helsinki.fi Christian Chiamulera (Immediate Past President) cristiano.chiamulera@univr.it Tellervo Korhonen (Secretary) tellervo.korhonen@helsinki.fi Daniel Kotz (Communication Officer) d.kotz@HAG.unimaas.nl Jacques Le Houezec (Program Committee Chair) jacques.lehouezec@amzer-glas.com Henri-Jean Aubin (Program Committee Co-Chair) henri-jean.aubin@pbr.aphp.fr Rachael Murray (Treasurer) Rachael.Murray@nottingham.ac.uk

**SRNT-E MISSION AND VALUES** The mission and goals of the SRNT-E will be identical to those of the “Society for Research on Nicotine and Tobacco, Inc. (SRNT)”, for the European region. **SOCIETY MISSION** The mission of the Society is to stimulate the generation of new knowledge concerning nicotine in all its manifestations - from molecular to societal. The Society has three main aims: 1. To sponsor scientific meetings and publications fostering the exchange of information on nicotine and tobacco. 2. To encourage scientific research on public health efforts for the prevention and treatment of tobacco use. 3. To provide a means by which legislative, governmental, regulatory and other public agencies can obtain expert advice and consultation on nicotine and tobacco. **SOCIETY VALUES** As a nonprofit, member-focused association, SRNT is mission-oriented and values-driven. The values that inform Board policy and organizational activities include: • Commitment to the public good • Accountability to the members and to the public • Respect for the worth and dignity of individuals • Inclusiveness and social justice • Respect for pluralism and diversity • Transparency, integrity, and honesty • Responsible stewardship of resources • Commitment to excellence and to maintaining the public trust • Commitment to the promotion of excellence in science • Commitment to use of the evidence base in all aspects of public policy, education and information • Commitment to personal and professional honor • Respect for all persons, regardless of race, religion, gender, sexual orientation, abilities, age or national origin • Commitment to serving the best interest of members and the profession at large

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**country**

Finland

**questions scope**

**problem definition**

Yes

**which option**

Extend the scope of the Directive

**additional comments**

All tobacco products are hazardous to health – there is no safe level of usage. Therefore we recommend that the scope of the Directive includes the regulation of any new smoked tobacco products (such as low emission or nicotine-free cigarettes), while the prohibition of any novel forms of oral tobacco, including snus, should be maintained. Tobacco policy should aim to achieve smoking cessation among all smokers and prevent initiation of any tobacco use. Herbal cigarettes are also harmful because it is the combustion and inhalation of smoke that causes most of the harm from smoking. Therefore, herbal cigarettes should be included in the scope Tobacco Products Directive and should also be subject to health warnings requirements. Finally, all forms of nicotine based products (that is, products containing nicotine but which are not tobacco products, such as electronic cigarettes, nicotine gel, drinks, and sweets) are often marketed as alternatives to cigarettes and in some cases as an aid to quitting smoking. Therefore, they should only be sold as quitting aids and comply with specific safety and quality requirements under the same regulatory framework as pharmaceutical products rather than under the scope of the Tobacco Products Directive.

**questions smokeless****problem definition**

Yes

**which option**

No change

**additional comments**

The ban on snus should definitely be maintained. This is high priority. Indeed, there is no legitimate reason to introduce a dangerous product onto the market, particularly as, from an internal market point of view, we have no idea how snus would be perceived or used in other countries. A small study conducted by the University of Nottingham by Professor Ann McNeil showed that, in the UK, people could not see the point of snus unless it was as a cessation aid (i.e. there is currently no demand). For internal market purposes, it really does not make sense to lift the ban. Furthermore, if the ban on snus were to be lifted, it could encourage dual use of cigarettes and smokeless tobacco and discourage total abstinence from tobacco, thus weakening any potential health gains. In this context, we stress that there are already available effective treatments for nicotine addiction, including medicinal nicotine (NRT), that do not carry the risks associated with the use of snus. These NRT products should be promoted first and foremost. It is clear that the public health interest can be served even more by encouraging a) greater use of these treatments and b) the development of more effective cessation aids. Regarding other forms of smokeless tobacco products, the Society for Research on Nicotine and Tobacco 's European Chapter (SRNT-E) does not believe that they should be "marketed" in any of the Member States. We recognise that they are as addictive and dangerous as smoked tobacco. As stated in the Opinion of the Scientific Committee on Emerging and Newly Identified Health Risks (SCENIHR), many forms of smokeless tobacco increase the risk of mouth, esophageal, pancreatic and liver cancer, and other conditions including gum and heart disease. They also increase the risk of cardiovascular disease and



depression. Concerning all smokeless tobacco products, the SRNT-E concludes that there is no sense of allowing new tobacco products to enter the markets of EU. There are safe nicotine products and other medications available for tobacco dependence treatment. Thus, smokeless tobacco is not justified for harm reduction or smoking cessation purposes either. Replacing one tobacco products by another tobacco product is not a justified solution of the Europe-wide tobacco epidemic.

**questions consumer  
problem definition**

No

**explanations**

The problem definition could be improved. We agree with the Commission that the current situation, whereby some Member States have made graphic warnings compulsory and others not, has led to a disparity in labelling throughout the EU. Consequently, this has an impact on the functioning of the internal market, on consumers' awareness and as a result, on their smoking behaviour. We also agree that packaging as an advertising tool is not covered by the current Directive. Finally, we welcome the acknowledgement that tobacco packaging and product features are increasingly used to attract consumers, to promote products and brand image. In this context, it would have been judicious to highlight the fact that, in the Eurobarometer survey released in 2010, the policy that received the most positive response is that of putting health warnings on all packages of tobacco products (on average, 75% of EU citizens are in favour of mandatory pictorial warnings, and over 54% support plain packaging measures).

**which option**

Improve consumer information; Introduce generic or plain packaging

**which improvement**

Picture warnings to become mandatory; Tar, nicotine and carbon monoxide levels to be replaced with general information on harmful substances in tobacco products; Information on harmful substances in tobacco products that cannot be placed on the package would be placed inside the package; Health warnings to be put on water pipes

**additional option**

Crucial importance of Graphic health warnings: Evidence shows that text only warning messages are not as effective as graphic warnings. Pictures, especially fear inducing pictures, are proven to be effective in getting consumers more engaged with the warning message. Pictures are able to immediately provoke a reaction and prompt people to read the associated text message. The need for graphic health warnings on both sides of the pack: There is also evidence that pictures on both sides of the packaging have a greater impact. The need for LARGE pictorial health warnings (80%): Evidence clearly shows that increasing the size of warning messages (text only and combined text and picture) increases the effectiveness of the warning amongst both young and adult smokers / non smokers. Research carried out in Canada by Createc on behalf of Health Canada in 2007 showed that young and adult smokers/non smokers are sensitive to the size of health warning messages. Results showed that warning messages that cover 100% of the pack are significantly more effective across all measured effectiveness indicators compared with warning messages that cover only 50% of the pack. The importance of Rotation: Warning texts and pictures should be displayed on a rotating basis, so that each message is given equal display and can reach its target audience.

The proved effectiveness of shocking health warnings & targeted messages: as specified in the Sambrook Research International report, fear inducing warnings (using strong “shocking” images related to health risks such as rotten teeth or throat cancer) and strong emotion inducing warnings (especially involving children and unborn babies) are the most effective way to educate consumers on the health risks of tobacco use and to achieve changes in attitudes and behaviour. These warnings’ effectiveness is enhanced if they are used in conjunction with a quit line. Generic or plain packaging: We strongly recommend the introduction of standardised/plain packaging. This should include not only the removal of all branding from the packaging but the size and shape of the packaging should also be standardised. Not only would this prevent the promotion of smoking through branding as occurs presently but it would reinforce the health warning messages. Tobacco packaging provides a direct link between consumers and manufacturers and is the main marketing channel, particularly in jurisdictions with tobacco advertising bans. Branding gives the misleading impression some cigarettes are safer than others. The tobacco industry claims that plain packaging would contravene intellectual property law. However, legal analysis concludes that this is incorrect and there are no international legal impediments to the implementation of generic packaging. Replace TNCO quantitative labelling with qualitative information on contents, emissions and quit-lines: The inclusion of machine-based tar, nicotine and carbon monoxide yields on cigarette packs promotes the mistaken belief that some cigarette brands are less harmful than others. We support the proposal to replace numerical measurements with descriptive information on the hazardous effects of tobacco constituents and emissions. We stress the importance of putting quit line numbers on the package. As underlined in the Sambrook research (p46), providing a telephone number on the pack is more effective than telling smokers to seek advice from a doctor or pharmacist. P46 Health warnings on water pipes: There is a growing body of evidence to show that water pipes are at least as hazardous, if not more so, than other forms of tobacco use. Warnings should also be included on the packaging of tobacco used in water pipes.

### **additional comments**

Under Article 5.3 of the TPD 2001, Member States have the option to adopt pictorial warnings. This situation emphasised the right of Member States to go further than the Directive to protect public health as set out in Article 30 of the Treaty of the Union (now article 36). Ten years after the entering into force of the TPD, four countries (the UK, Belgium, Romania and Malta) have adopted the option. More countries such as Spain and France are planning to adopt mandatory pictorial warnings. Such measures are in compliance with the current TPD and are welcomed by the tobacco control community. However, their adoption by some Member States necessarily creates growing discrepancies between Member States. As stated above, there is clear evidence that pictorial warnings are much more powerful than written health warnings. Extending the information and protection to all EU Member States would be in harmony with Article 168 of the TFEU and consistent with the objectives of the internal market stated in Article 114.3 of the TFEU and reiterated in Recital 19 of the Directive. A revision of the TPD should, therefore, aim at making pictorial health warnings of tobacco products subject to common rules. Note: Legislation on labelling, advertising and product regulation put forward by the Commission in the field of tobacco control, has been based on the internal market legislation (Articles 26 and 114 of the TFEU). Article 26 of the TFEU establishes the internal market. Article 114 gives EU institutions the competence to regulate and set rules for the functioning of the internal market. More specifically, article 114.3 also states that when establishing rules for the functioning of the internal market in the context of health, safety, environmental protection and consumer protection, the Commission “will take as a base a high level of protection, taking account in

particular of any new development based on scientific facts.” The European Court of Justice (the “ECJ”) made an extensive analysis of Article 95 EC (now Article 114) throughout the years. In *Spain v. Council*, the Court observed that “recourse to Article 100a (now Article 114) as a legal basis is possible if the aim is to prevent the emergence of future obstacles to trade resulting from multifarious development of national laws.” The TPD was adopted on the basis of Article 114 TFEU (ex Article 95). As a result, Recital 19 of the TPD states that “[t]he presentation of warning labels and yields has continued to remain variable in the different Member States. As a consequence, consumers in one Member State may be better informed as to the risks of tobacco products than in another. Such differences are unacceptable and are liable to constitute a barrier to trade and to impede the operation of the internal market in tobacco products, and should therefore be eliminated.”

### **questions on reporting**

#### **problem definition**

Yes

#### **which option**

Establish a common compulsory reporting format; Introduce fees and sanctions

#### **additional comments**

The current situation which allows different formats and reporting mechanisms is unsatisfactory, making it difficult for authorities to compare and analyse the data. All tobacco manufacturers and importers should be subject to the same reporting requirements. The SRNT-E believes that tobacco products, which are highly harmful, should be subject to an effective reporting system that allows the gathering and analysis of relevant data, including comparison as appropriate, in order to ensure high levels of consumer safety and information. The format already exists (based on the voluntary reporting format developed by the Commission in May 2007) and it would therefore be very easy to adopt this measure and to implement it. We welcome the introduction of yearly registration fees in order to finance the data collection on ingredients by the national authorities and their analysis work on ingredients. The payment of penalties in case of non-compliance with the requirements of delivery of data on tobacco product ingredients also seems adequate and would contribute to fund the tests conducted on these products. It is crucial that the appropriate toxicological and addictiveness tests are properly conducted. Such tests would allow policy-makers to make more informed decisions in this field, as there would be more scientific evidence. It would enhance the scientific knowledge of the dangers of tobacco products and would contribute to a high protection of health, as stated in Article 95.3 TFEU. Besides, such measures would also have an indirect impact on illicit trade, since only registered products would be allowed on the market.

### **regulation of ingredients**

#### **problem definition**

Yes

#### **which option**

Establish a common list of tobacco ingredients

#### **which one**

Establish a positive common list of tobacco ingredients

**additional comments**

We support the adoption of a positive common list of tobacco ingredients. We believe that tobacco products are highly toxic and addictive, and that their content should therefore be closely regulated, in order to achieve high standards of health protection, as stated under article 114.3. There is a need for such a list at EU level since at the moment, consumers in the internal market are not subject to the same level of protection. Some citizens may be using substances that are banned in other Member States. Apart from creating unequal health protection across the EU, this may constitute an obstacle to free movement of goods within the internal market: some countries can refuse access to their markets of cigarettes from Member States that do not comply with the importing Member State's national requirements.

Regulation of Flavours and Ingredients: Flavourings are an increasingly important part of tobacco industry marketing, particularly to young people. Flavourings enhance attractiveness, encourage youth initiation, and discourage cessation. The prohibition of ingredients that may be used to increase attractiveness, such as sugars and sweeteners, flavouring substances, menthol, and spices and herbs, in cigarettes and cigarette-like tobacco products should be introduced. The prohibition of ingredients that may create the impression of a health benefit (e.g. vitamins), ingredients associated with energy and vitality (e.g. caffeine), and ingredients with colouring properties (e.g. pink cigarette paper) should also be banned. Tobacco manufacturers and importers should report sales volume information by brand. This information is essential to help governments ensure that product regulation is effective. The above measures should be compliant with the Guidelines on Art. 9/10, adopted unanimously at the Fourth Conference of the Parties in Uruguay on the 20th November 2010.

**access to tobacco products****problem definition**

Yes

**which option**

Ban

**which one2**

Cross-border retail sales of tobacco to be banned over the Internet; Vending machines to be banned; Promotion and displays in retail stores to be banned

**additional option**

We urge the Commission to call for a ban on the promotion of tobacco products at point of sale and a ban on vending machines as described in the Art 13 Guidelines of the FCTC.

**additional comments**

Internet. The principle of preventing cross-border promotion of tobacco products in order to protect public health was enshrined in the Tobacco Advertising directive (2001/0119). It is logical, therefore, to extend that principle to the sale of tobacco products between member states via the Internet. We support the prohibition of tobacco sales via the Internet. Vending machines. The majority of member states (22 out of 27) already prohibit the sale of tobacco products from vending machines in order to deter young people accessing cigarettes from this source. We support this measure. Point of Sale. Evidence shows that a coordinated cross border marketing strategy on the part of the tobacco companies is reflected at point of sale (i.e. point of sale marketing is similar in most EU countries (i.e.: a brand is advertised at point of sale in the same way in Germany and Belgium). There is a growing body of evidence to show that putting tobacco products out of sight in retail outlets can reduce youth smoking. To

date, this measure has been adopted by Ireland and Finland (as well as Iceland and Norway). This measure is also official government policy in Scotland, Wales and Northern Ireland and a decision is awaited in England. We strongly support an EU-wide adoption of a ban on the display of tobacco products at the point of sale.

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## **NGO submission**

### **identification**

#### **affiliation**

NGO

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Finnish Health Association NGO

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#### **country**

Finland

### **questions scope**

#### **problem definition**

No

### **explanations**

The problem definition could be improved. It should be clearly stated that the tobacco product directive sets the minimum limits to regulate the tobacco products. To ensure the high-level health protection of their citizens the member states would be allowed impose further regulations as long as those do not restrict the free movements of goods. Finland, as well as the European Commission, has ratified Framework Convention on Tobacco Control. It reaffirms the right of all people to the highest standard of health.

### **which option**

Extend the scope of the Directive

### **recommend option**

Tobacco products are no ordinary commodities. Many compounds of the tobacco products contain and the smoke they produce is pharmacologically active, toxic, mutagenic and carcinogenic. There is no safe level of usage. Therefore we recommend that the scope of the Directive includes the regulation of any new smoked tobacco products (such as low emission or nicotine-free cigarettes). The prohibition of snus, should be maintained. Herbal cigarettes are also dangerous, and therefore they should be included in the scope Tobacco Products Directive and have health warnings. Some forms of nicotine based products (such as electronic cigarettes, nicotine gel, drinks, and sweets) are often marketed as alternatives to cigarettes and as quitting aid. However they should in no circumstances to be considered as an aid to quitting smoking.

### **questions smokeless**

**problem definition**

Yes

**which option**

Ban on all types of smokeless tobacco products

**additional option**

In Finland, due to our comprehensive tobacco control policy daily smoking has been declining constantly. Nowadays, the prevalence of daily smoking is among the lowest in the EU: 22 % men and 16 % women were daily smokers in 2009. The use of snus is minimal. The International Agency for Research on Cancer (IARC) in their Monographs Vol 6 (IARC Monographs on the Evaluation of Carcinogenic Risks to Humans Volume 89 (2007), Smokeless Tobacco and Some Tobacco-specific N-Nitrosamine) represent as a scientific conclusion that “there is sufficient evidence in humans for the carcinogenicity of smokeless tobacco. Smokeless tobacco causes cancers of the oral cavity and pancreas.” Now that the use of smokeless tobacco products is not widely spread we recommend a ban on all types of smokeless tobacco products. We do not support lifting the ban of snus as there is no legitimate reason to introduce any new dangerous product onto the market. Snus is not an alternative to treat nicotine addiction. There are already available effective treatments for nicotine addiction, including medicinal or ‘clean’ nicotine (NRT), that do not carry the risks associated with the use of snus.

**questions consumer****problem definition**

No

**explanations**

The problem definition could be clarified. The current situation, where some Member States have mandatory graphic warnings and others have not, has led to a disparity in labelling. In addition some consumers do not get enough information on the devastating effects of smoking on their health.

**which option**

Improve consumer information; Introduce generic or plain packaging

**which improvement**

Picture warnings to become mandatory; Health warnings to be put on water pipes

**additional option**

There should be mandatory pictorial health warnings on all tobacco products (including oral and water pipe tobacco) covering 80% of the front and the back of the packs towards the top, in combination with standardized packaging. Pictures are able to create interest and make people to read the associated text message. We find it important to introduce standardised/plain packaging. Tobacco packaging and product features are used to attract consumers, especially young people. All branding from the packaging should be removed and the size and shape of the packaging should be standardised. There should be information on Quit line, preferably the number, on all packs of tobacco products.

**additional comments**

The article 114.3 of the Treaty states that when establishing rules for the functioning of the

internal market in the context of health, safety, environmental protection and consumer protection, the Commission “will take as a base a high level of protection, taking account in particular of any new development based on scientific facts.”

**questions on reporting**

**problem definition**

Yes

**which option**

Establish a common compulsory reporting format; Introduce fees and sanctions

**additional comments**

The current system makes it difficult for authorities to compare and analyse the data. All tobacco manufacturers and importers should have the same reporting requirements.

**regulation of ingredients**

**problem definition**

Yes

**which option**

Establish a common list of tobacco ingredients

**which one**

Establish a positive common list of tobacco ingredients

**additional comments**

Cigarettes and some other products containing tobacco are highly engineered to create and maintain dependence. Many of the compounds they contain and the smoke they produce are pharmacologically active, toxic, mutagenic and carcinogenic. Flavourings are an increasingly important element of tobacco marketing, particularly to young people. Flavourings, such as sugars and sweeteners, flavouring substances, and spices and herbs enhance attractiveness, encourage youth initiation, and discourage cessation. The prohibition of these kinds of ingredients in cigarettes and cigarette-like tobacco products should be introduced. The ingredients that may create the impression of a health benefit, ingredients associated with energy and vitality (e.g. caffeine), and ingredients with colouring properties (e.g. coloured cigarette paper) should also be banned. The above measures should be compliant with Articles 9 & 10 of the Framework Convention on Tobacco Control (FCTC).

**access to tobacco products**

**problem definition**

Yes

**which option**

Ban

**which one2**

Cross-border retail sales of tobacco to be banned over the Internet; Vending machines to be banned; Promotion and displays in retail stores to be banned

**additional option**

We urge the Commission to call for a ban on the promotion of tobacco products at point of sale and a ban on vending machines. These measures are important for health protection. The Directive should also remind national governments that they should adopt a comprehensive ban on all forms of tobacco advertising, promotion and sponsorship in accordance with Article 13 of the FCTC which calls on Parties to.

#### **additional comments**

Internet. The principle of preventing cross-border promotion of tobacco products in order to protect public health was highlighted in the Tobacco Advertising directive (2001/0119). Buying tobacco through Internet has become easier and more common. The problem includes the sale of tobacco products to minors, tax evasion and uncontrolled sales promotion of tobacco products. Therefore, we support the prohibition of tobacco sales via the Internet. Vending machines. In Finland vending machines will be banned in 2015. Point of Sale. In the EU member states the tobacco companies' marketing strategy is to advertise their products by making them very visible at point of sale. In Finland tobacco displays are banned on 1st January 2012. There is a growing body of evidence to show that putting tobacco products out of sight in retail outlets can reduce youth smoking. We support an EU-wide adoption of a ban on the display of tobacco products at the point of sale.

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#### **NGO submission**

##### **identification**

##### **affiliation**

NGO

##### **name**

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##### **country**

Switzerland

##### **questions scope**

##### **problem definition**

Yes

##### **which option**

No change

##### **recommend option**

La portée de la Directive peut être étendue afin de couvrir ces autres produits, mais ceci ne devrait pas inclure une interdiction automatique sur l'une ou l'autre catégorie de produit (nouvelles formes de tabac oral). Toute interdiction devrait être fondée sur des expertises scientifiques.



**questions smokeless  
problem definition**

Yes

**which option**

Lifting the ban on snus

**additional comments**

Aucune raison n'est fournie quant à une interdiction sur tous les produits non combustibles du tabac. Une interdiction pourrait uniquement être justifiée s'il était prouvé que tous les produits non combustibles du tabac sont plus nocifs que d'autres formes de produits du tabac. Il n'y a pas de preuves qui suggèrent cela.

**questions consumer  
problem definition**

No

**explanations**

Il n'y a pas de preuves que des mises en garde plus grandes soient plus efficaces. Il n'y a pas de preuves que les emballages génériques amélioreraient le fonctionnement du marché commun européen ou auraient un quelconque effet bénéfique sur la santé publique.

**which option**

No change

**questions on reporting  
problem definition**

No

**explanations**

Les États membres peuvent déjà introduire des émoluments et des sanctions. L'exécution des dispositions de la Directive doivent rester de la responsabilité des États membres.

**which option**

Establish a common compulsory reporting format

**regulation of ingredients**

**problem definition**

No

**explanations**

Les tests sur les ingrédients doivent avant tout s'attacher à déterminer si les ingrédients augmentent la toxicité de la fumée du tabac.

**which option**

No Change

**access to tobacco products**

**problem definition**

No

**explanations**

Aucun problème clair n'est évoqué par rapport aux automates ou à l'exposition sur le point de vente. Aucune preuve n'est fournie expliquant pourquoi les interdictions amélioreraient le fonctionnement du marché intérieur ou comment elles feraient progresser les objectifs de santé publique.

**which option**

No change

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**NGO submission****identification****affiliation**

NGO

**name**

Slovak Association of Commerce and Tourism

**email**

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**country**

Slovakia

**age**

54

**gender**

male

**questions scope****problem definition**

Yes

**which option**

No change

**recommend option**

The proposal in Option 2 is limiting any potential introduction of new forms of oral tobacco. We believe that any product should be banned only on a basis of scientific research and proper examination. A preemptive ban is against principals of innovation and can be counterproductive. The position of Slovak Association of Commerce and Tourism is unambiguously against the forbidding of exhibit of the tobacco products in the chain retail shops, which would on non requireable way and disserviceable caused the substantial increase of the sale of non legal cigarettes.

**questions smokeless**

**problem definition**

Yes

**which option**

Lifting the ban on snus

**questions consumer****problem definition**

No

**explanations**

Retailers are facing a menace of illicit trade in many goods, but the cigarettes are a prominent case. We believe, that the EC proposal, as mentioned in Options 2 and 3, will create an unprecedented opportunity for organized crime. Plain packaging or even enlarged health warnings will make the manufacturing process of fake cigarettes very simple and will thus put a lot of pressure on law obeying retailers. The ensuing consequences – decrease of the legal market and loss of control over significant size of cigarettes smoked in the EU – will go against declared health objectives and will, in the time of global economical crisis push retailers even more into the corner.

**which option**

No change

**questions on reporting****problem definition**

No

**explanations**

Member states can now use their power and establish a system of penalties for noncompliance with mandatory reporting. This should stay within powers of Member states.

**which option**

Establish a common compulsory reporting format

**regulation of ingredients****problem definition**

No

**explanations**

Ingredients regulation should be based solely on scientific assessment and therefore should operate with measurable criteria, e.g. increased toxicity and/or addictiveness of the tobacco smoke or product. Any measurement of attractiveness is according to our view, impossible and unscientific.

**which option**

No Change

**access to tobacco products****problem definition**

No

**explanations**

The proposed ban or restriction will lead to significant costs for law obeying retailers and potential loss of sales either to illegal sources, or to the pure fact, that an adult consumer will not know, that tobacco products are available in the shop.

**which option**

No change

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**NGO submission****identification****affiliation**

NGO

**name**

Swiss Cigarette

**email**

office@swiss-cigarette.ch

**country**

Switzerland

**questions scope****problem definition**

Yes

**which option**

No change

**recommend option**

The scope of the Directive can be extended to cover other products, but this should not include an automatic ban on one category of product (novel forms of oral tobacco). Any bans should be based on scientific assessments.

**questions smokeless****problem definition**

No

**comments**

Swiss Cigarettes believes that the ban on snus is not justified on scientific grounds and should be lifted.

**which option**

Lifting the ban on snus

**questions consumer**

**problem definition**

No

**explanations**

There is no evidence that bigger warnings are more effective. There is no evidence that plain packaging would improve the functioning of the internal market or have any public health benefits. It would make it easier to copy legitimate brands and would lead to an increase in legal sales of cigarettes.

**which option**

No change

**questions on reporting****problem definition**

No

**explanations**

The focus of ingredients testing should be on whether the ingredients result in increased toxicity of tobacco smoke.

**which option**

No change

**regulation of ingredients****problem definition**

No

**explanations**

The focus of ingredients testing should be on whether the ingredients result in increased toxicity of tobacco smoke

**which option**

No Change

**access to tobacco products****problem definition**

No

**explanations**

There is no clear problem stated as regards either vending machines or point of sale display. There is no evidence provided as to why bans would improve the functioning of the internal Market or advance any public health objectives.

**which option**

No change

---

**NGO submission**

**identification**  
**affiliation**  
NGO

**name**  
Swiss Cigarette

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office@swiss-cigarette.ch

**country**  
Switzerland

**questions scope**  
**problem definition**  
Yes

**which option**  
No change

**recommend option**  
The scope of the Directive can be extended to cover other products, but this should not include an automatic ban on one category of product (novel forms of oral tobacco). Any bans should be based on scientific assessments

**questions smokeless**  
**problem definition**  
Yes

**which option**  
Lifting the ban on snus

**additional option**  
Swiss Cigarette believes that the ban on snus is not justified on scientific grounds and should be lifted.

**questions consumer**  
**problem definition**  
No

**explanations**  
There is no evidence that bigger warnings are more effective. There is no evidence that plain packaging would improve the functioning of the internal market or have any public health benefits. It would make it easier to copy legitimate brands and would lead to an increase in legal sales of cigarettes.

**which option**  
No change

**questions on reporting**

**problem definition**

No

**explanations**

The focus of ingredients testing should be on whether the ingredients result in increased toxicity of tobacco smoke.

**which option**

No change

**regulation of ingredients****problem definition**

No

**explanations**

The focus of ingredients testing should be on whether the ingredients result in increased toxicity of tobacco smoke.

**which option**

No Change

**access to tobacco products****problem definition**

No

**explanations**

There is no clear problem stated as regards either vending machines or point of sale display. There is no evidence provided as to why bans would improve the functioning of the internal market or advance any public health objectives.

**which option**

No change

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**NGO submission****identification****affiliation**

NGO

**name**

Weber Mathias

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deutschland

**questions scope**  
**problem definition**  
Yes

**which option**  
No change

**questions smokeless**  
**problem definition**  
Yes

**which option**  
No change

**questions consumer**  
**problem definition**  
Yes

**which option**  
No change

**questions on reporting**  
**problem definition**  
Yes

**which option**  
No change; Establish a common compulsory reporting format

**regulation of ingredients**  
**problem definition**  
Yes

**which option**  
Introducing the basic criteria on the EU level without a common list

**access to tobacco products**  
**problem definition**  
Yes

**which option**  
No change; Controlled supply and access

**which supply and access**  
Access to vending machines to be restricted to adults

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**NGO submission**

**identification**



**affiliation**  
NGO

**name**  
Max Müller

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**country**  
german

**questions scope**  
**problem definition**  
Yes

**which option**  
No change

**questions smokeless**  
**problem definition**  
Yes

**which option**  
No change

**questions consumer**  
**problem definition**  
Yes

**which option**  
No change

**questions on reporting**  
**problem definition**  
Yes

**which option**  
No change

**regulation of ingredients**  
**problem definition**  
Yes

**which option**  
No Change

**access to tobacco products**  
**problem definition**  
No

**which option**

No change

---

**NGO submission****identification****affiliation**

NGO

**name**

European Pharmaceutical Students' Association (EPSA)

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**country**

Belgium

**age**

23

**gender**

male

**questions scope****problem definition**

Yes

**which option**

Extend the scope of the Directive

**recommend option**

Improve the European support to health NGO's related to health and well being, especially when they are youth-driven, in order to establish larger platforms of awareness among the most sensitive risk groups and to potentiate the outcomes from Public Health campaigns, tobacco control related activities, etc..

**additional comments**

I believe the EC should take more into account the opinions of the youth, especially from the Associations that took part on the HELP EC network and that spent around 4 years raising awareness on tobacco control all over Europe.

**questions smokeless****problem definition**

Yes

**which option**

Ban on all types of smokeless tobacco products

**questions consumer**

**problem definition**

Yes

**which option**

Improve consumer information

**which improvement**

Picture warnings to become mandatory; Tar, nicotine and carbon monoxide levels to be replaced with general information on harmful substances in tobacco products; Information on harmful substances in tobacco products that cannot be placed on the package would be placed inside the package; Health warnings to be put on water pipes

**questions on reporting**

**problem definition**

Yes

**which option**

Establish a common compulsory reporting format; Introduce fees and sanctions

**regulation of ingredients**

**problem definition**

Yes

**which option**

Establish a common list of tobacco ingredients

**which one**

Establish a positive common list of tobacco ingredients; Establish a negative common list of tobacco ingredients

**access to tobacco products**

**problem definition**

Yes

**which option**

Controlled supply and access; Ban

**which supply and access**

Age verification of buyers and other legal conditions to be set for cross-border retail sale; Access to vending machines to be restricted to adults; Tobacco display and promotion at points of sales to be restricted

**which one2**

Cross-border retail sales of tobacco to be banned over the Internet; Vending machines to be banned; Promotion and displays in retail stores to be banned

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## **NGO submission**

### **identification**

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NGO

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### **questions scope**

#### **problem definition**

Yes

#### **which option**

No change

### **additional comments**

pas de changement

### **questions smokeless**

#### **problem definition**

No

### **comments**

il n'y a pas d'études scientifiques efficaces prouvant les risques concernant les produits du tabac sans fumée.

#### **which option**

Lifting the ban on snus

### **questions consumer**

#### **problem definition**

No

### **explanations**

aucune étude ne prouve l'efficacité des paquets neutres. aucune étude ne prouve l'efficacité des photos chocs, ni même de plusgrands avertissements sanitaire sur les paquets. la mise en place de paquets neutres risque d'entraîner une guerre des prix du tabac( puisque cela restera le seul moyen pour les fabricants de se différencier). la mise en place de photos chocs sur les 2 faces des paquets ou depaquets génériques va pousser les consommateurs francais à aller s'approvisionner sur les marchés parallèles du tabac (achats à l'étranger ou de contrebande, ou sur internet. de telles mesures risquent de déstabiliser et penaliser économiquement le réseau des 28000 buralistes francais organisés dans un réseau réglementé et sous tutelle de l'état

**which option**

No change

**questions on reporting****problem definition**

Yes

**which option**

Establish a common compulsory reporting format

**regulation of ingredients****problem definition**

No

**explanations**

cela risque d'entraîner une standardisation de la production avec comme conséquence une diminution de l'offre au fumeur adulte et responsable ,et le risque de voire apparaitre une augmentation des produits de tabac contrefaits.

**which option**

No Change

**access to tobacco products****problem definition**

Yes

**which option**

Controlled supply and access; Ban

**which supply and access**

Age verification of buyers and other legal conditions to be set for cross-border retail sale

**which one2**

Cross-border retail sales of tobacco to be banned over the Internet; Vending machines to be banned

**additional comments**

Il n'y a pas de corrélation prouvée entre la disparition des linéaires tabac et la lutte contre le tabagisme. La France dispose d'un réseau de 28 000 buralistes, préposés de l'administration responsables et professionnels, seuls habilités à vendre du tabac. Ce réseau est fortement réglementé par l'Etat ce qui permet déjà de contrôler efficacement l'accès au produit tabac.

---

**NGO submission****identification****affiliation**

NGO

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USA

**questions scope****problem definition**

Yes

**which option**

No change

**recommend option**

An extension of the scope of the directive to cover the additional products would be a positive step, but the change should not include an automatic ban on "novel forms of oral tobacco." Any and all bans should be based on current, objective, scientific evidence.

**questions smokeless****problem definition**

Yes

**which option**

Lifting the ban on snus

**additional option**

Current scientific evidence does not support the reasoning behind the EU's ban on snus. Not only has snus been found to be much less risky than tobacco products widely available in the EU but snus is a proven effective smoking cessation tool. The EU's own studies conclude that snus use does not result in an increased risk of lung or oral cancer, and the results of these studies were compelling enough that the EU removed the "Causes Cancer" warning from snus packages. Further, the EU maintains the snus ban in contravention of its own free market principles most notably the Four Freedoms. This ban is highly and unfairly discriminatory, does not achieve any meaningful public health objectives and should be lifted.

**questions consumer****problem definition**

No

**explanations**

Available evidence does not support the contention that larger warnings on tobacco product packages or plain packaging of tobacco products discourages the initiation and continuation of tobacco use among people. There is, however, evidence that the proliferation of counterfeit tobacco products leads to an increase in tobacco initiation -- especially among young people - and that plain packaged items are much easier to counterfeit.

**which option**

No change

**questions on reporting****problem definition**

No

**explanations**

Enforcement of the provisions of the Directive should remain the responsibility of EU Member States, which already have the right to introduce relevant fees and sanctions.

**which option**

Establish a common compulsory reporting format

**regulation of ingredients****problem definition**

No

**explanations**

A better use of resources for ingredients testing would be to focus on whether or not the ingredients in question raise the toxicity level of the tobacco smoke.

**which option**

No Change

**access to tobacco products****problem definition**

No

**explanations**

No clear problem is defined with respect to vending machines or point of sale displays. Further, no evidence is offered on how bans would improve the functioning of the internal market or how such bans would aid in the achievement of any public health objectives.

**which option**

No change

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**NGO submission****identification****affiliation**

NGO

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United Kingdom

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**gender**

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**questions scope****problem definition**

No

**explanations**

The problem definition clearly states that new forms of nicotine delivery are a safety concern, that the inclusion of nicotine in some countries means that products should be classed as pharmaceutical. It states the lack of inter-country regulation as a problem.

**which option**

No change

**recommend option**

We see no reason the inclusion of nicotine should mean that a product is classed as pharmaceutical. The only pharmaceutical products containing nicotine are nicotine replacement therapy products, and other developing nicotine devices that attempt to wean people off tobacco. There is no logical reason that anything containing nicotine must be defined as pharmaceutical. As far as inter-country regulation is concerned we do not believe this is in the best interests of consumers. Regulation must be led by scientific research, and too much centralization in regulation will prejudice the quality of research that is commissioned. It must also respond to the views of electorates in respective member states. No centralized policy machine can be responsive to the range of populations included in the EU. Regulation of oral tobacco, herbal cigarettes and other nicotine devices should be at state level. This is where health warnings and lists of ingredients should also be regulated. There should be no banning of oral tobacco, unless recommended at state level.

**questions smokeless****problem definition**

No

**comments**

There seems to be a fine balance between perceiving smokeless tobacco as a harm reduction method (better than smoked tobacco) and seeing it as a gateway to tobacco.

**which option**

Lifting the ban on snus

**additional option**

We support the use of smokeless tobacco as a consumer choice and also one that might enable them to reduce their smoking if that is what they wish to do. We prefer options that give



member states more leeway to respond individually to local problems.

**questions consumer  
problem definition**

No

**explanations**

There is no need for international regulation of tobacco labelling, and disparities between countries are a problem only to advocates of global tobacco control.

**which option**

No change

**additional option**

If water pipes are felt to be an unacknowledged danger, warnings can be required by national governments. The options 2 presented are all undesirable. Picture warnings have long ceased to shock and if anything are used as collectors' items. The replacement of specific information about tar, nicotine and carbon monoxide levels is retrograde; replacing it with a general warning will not provide the specifics that the customer might be interested in. Surely a warning specific to light or mild cigarettes can be devised by individual member states if it is felt to be necessary. The inclusion of identical pieces of paper containing information on harmful substances (why not beneficial substances?) in packs that people buy every day will not be read more than once by most people. This is extremely wasteful. Option 3 is likely to make life much easier for counterfeiters, and is likely to be the subject of court proceedings. We do not see how it will help to lower tobacco consumption, assuming this to be the aim.

**questions on reporting  
problem definition**

No

**explanations**

no pertinent comments to add

**which option**

No change

**regulation of ingredients**

**problem definition**

No

**explanations**

Do not believe the need for a centrally controlled list of ingredients

**which option**

No Change

**access to tobacco products**

**problem definition**

No

**explanations**

No need for uniform regulations across Europe

**which option**

No change

**additional option**

National requirements should be set for age verification. Option 3 is not in any country's national interest.

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NGO

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Costa Rica

**questions scope****problem definition**

Yes

**which option**

No change

**recommend option**

The directive should not include an automatic ban on one category of product. Any bans should and must have a scientific assessments.

**questions smokeless****problem definition**

Yes

**which option**

Lifting the ban on snus

**additional option**

The ban on Snus is not justified because there is no scientific ground. Besides snus, as recognized by many public health advocates, is less harmful than conventional cigarettes

**questions consumer**

**problem definition**

No

**explanations**

There is no evidence that bigger warnings are more effective. Besides blank packages can be taken by criminals to copy, distribute and sell illegal cigarettes.

**which option**

No change

**questions on reporting****problem definition**

No

**explanations**

State Members of the European can already introduce fees and sanctions. The Directive should remain on the level of responsibility of each state member.

**which option**

Establish a common compulsory reporting format

**regulation of ingredients****problem definition**

No

**explanations**

the point is that testing should be on ingredients that can increased toxicity.

**which option**

No Change

**access to tobacco products****problem definition**

No

**explanations**

1. There is no clear problem regarding point of sales or vending machines. 2. There is no evidence of any source that bans may improve the functioning of the markets

**which option**

No change

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**NGO submission****identification****affiliation**

NGO

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**questions scope****problem definition**

No

**explanations**

The problem definition could be improved. The tobacco product directive should state the minimum level of regulations for the tobacco products. Naturally the member states would be allowed impose further regulations as long as those are not in conflict with the free movements of goods. Finland, as well as the European Commission, has ratified the UN Framework Convention on Tobacco Control. It reaffirms the right of all people to the highest standard of health. Furthermore, article 114.3 of the Treaty states that when establishing rules for the functioning of the internal market in the context of health, safety, environmental protection and consumer protection, the Commission “will take as a base a high level of protection, taking account in particular of any new development based on scientific facts.”

**which option**

Extend the scope of the Directive

**recommend option**

Tobacco products are no ordinary commodities. Many compounds of the tobacco products and the smoke are toxic, mutagenic and carcinogenic. There is no safe level of usage. The scope of the Directive should include the regulation of any new tobacco products smoked (such as low emission or nicotine-free cigarettes). The prohibition of oral tobacco, such as snus, should be maintained. Herbal cigarettes are also dangerous and should be included in the scope Tobacco Products Directive with health warnings. Some forms of nicotine based products (such as electronic cigarettes, nicotine gel, drinks, and sweets) are often marketed as alternatives to cigarettes and as quitting aid. This is not based on facts and they should not classified as quitting aids of smoking. There are strictly regulated pharmaceutical products to help smokers in quitting.

**questions smokeless****problem definition**

Yes

**which option**

Ban on all types of smokeless tobacco products

**additional option**

As long as the use of smokeless tobacco products is not very common, we recommend a ban on all types of smokeless tobacco products. We do not support lifting the ban on snus as there is no legitimate reason to introduce any new dangerous product onto the market. Snus is not

an alternative to treat nicotine addiction. There are already available effective treatments for nicotine addiction, including medicinal or 'clean' nicotine (NRT), that do not carry the risks associated with the use of snus.

**questions consumer  
problem definition**

No

**explanations**

The problem definition could be clarified. The current situation, where some Member States have mandatory graphic warnings and others have not, has led to a disparity in labelling. In addition some consumers do not get enough information on the devastating effects of smoking on their health. Tobacco packages are increasingly used as means to promote the products and brand images. The importance of packaging as a marketing channel has increased when other kind of tobacco advertising has been banned or restricted. Packaging as an advertising measure is not covered by the current Directive.

**which option**

Improve consumer information; Introduce generic or plain packaging

**which improvement**

Picture warnings to become mandatory; Health warnings to be put on water pipes

**additional option**

There should be mandatory pictorial health warnings on all tobacco products (including oral and water pipe tobacco) covering at least 80% of the front and the back of the packs towards the top. This should be combined with standardized (size, shape) packaging. It is important to introduce standardised/plain packaging. Tobacco packages are used to attract consumers, especially young people. All branding from the packaging should be removed and the size and shape of the packaging should be standardised. There should be information on a national Quitline on all packs of tobacco products.

**additional comments**

The article 114.3 of the Treaty states that when establishing rules for the functioning of the internal market in the context of health, safety, environmental protection and consumer protection, the Commission "will take as a base a high level of protection, taking account in particular of any new development based on scientific facts."

**questions on reporting  
problem definition**

Yes

**which option**

Establish a common compulsory reporting format; Introduce fees and sanctions

**additional comments**

All tobacco manufacturers and importers should use the same reporting format to facilitate the comparison of data by the authorities. The tobacco companies should pay an annual registration fee to national competent authorities to finance the data collection and analysis. Allowing only registered products on the market would be an effective measure to control

smuggling.

**regulation of ingredients**

**problem definition**

Yes

**which option**

Establish a common list of tobacco ingredients

**which one**

Establish a positive common list of tobacco ingredients

**additional comments**

Flavourings and other additives are an important element of tobacco marketing, particularly to young people. They make the initiation of smoking easier by masking the harshness of tobacco and numbing the mucosal tissues. These compounds should not be allowed in any forms of tobacco products. The ingredients that may create the impression of a health benefit, ingredients associated with energy and vitality (e.g. caffeine), and ingredients with colouring properties (e.g. coloured cigarette paper) should also be banned. The above measures should be compliant with Articles 9 & 10 of the Framework Convention on Tobacco Control (FCTC).

**access to tobacco products**

**problem definition**

Yes

**which option**

Ban

**which one2**

Cross-border retail sales of tobacco to be banned over the Internet; Vending machines to be banned; Promotion and displays in retail stores to be banned

**additional option**

We urge the Commission to call for a ban on the promotion of tobacco products at point of sale and a ban on vending machines. These measures are important for health protection. The Directive should also remind national governments that they should adopt a comprehensive ban on all forms of tobacco advertising, promotion and sponsorship in accordance with Article 13 of the FCTC which calls on Parties to.

**additional comments**

Internet. The principle of preventing cross-border promotion of tobacco products in order to protect public health was highlighted in the Tobacco Advertising directive (2001/0119). Buying tobacco through Internet has become easier and more common. The problem includes the sale of tobacco products to minors, tax evasion and uncontrolled sales promotion of tobacco products. Therefore, we support the prohibition of tobacco sales via the Internet. Vending machines will be banned in Finland in 2015. Point of Sale. There is a growing and already a convincing body of evidence that putting tobacco products out of sight in retail outlets can reduce youth smoking. We support an EU-wide adoption of a ban on the display of tobacco products at the point of sale.

---

## **NGO submission**

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NGO

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#### **gender**

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#### **questions scope**

##### **problem definition**

Yes

#### **which option**

No change

#### **recommend option**

The scope of the directive can be extended to cover these other products, but this should not include an automatic ban on one category of the product. Any bans should be based on scientific assessments.

#### **additional comments**

We always should preserve the vending machines because they protect us against the BAD tobacco traffic and other crimes.

#### **questions smokeless**

##### **problem definition**

Yes

#### **which option**

Lifting the ban on snus

#### **questions consumer**

##### **problem definition**

No

**explanations**

there is no evidence that bigger warnings are more effective. there is no evidence that plain packaging would improve the functioning of the internal market or have any public health benefits. it would make it easier for criminals to copy legitimate brands and increase in illegal sales of cigarettes. Like the sales in vending tobacco machines are much safer than normal sales it prevent us from the criminal tobacco.

**which option**

No change

**questions on reporting****problem definition**

No

**explanations**

members states should be responsible to introduce fees and sanctions.enforcement of the provision of the directive should remain the responsibility of the members states.

**which option**

Establish a common compulsory reporting format

**regulation of ingredients****problem definition**

No

**explanations**

the focus of ingredients testing should be on whether the ingredients result in increase toxicity of tobacco smoke.

**which option**

No Change

**access to tobacco products****problem definition**

No

**explanations**

there is no clear problem stated as regards either vending machines or POSD. There is no evidence provided as to why bans would improve the functioning of the internal market or advance any public health objectives. The ban of vending machines would increase criminal tobacco in normal point of sales because vending machines are controlled by authorities.

**which option**

No change

---

**NGO submission****identification**



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NGO

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**questions scope****problem definition**

Yes

**which option**

Extend the scope of the Directive

**recommend option**

In our view, Option 2 addresses the problem more effectively than Option 1, but is still inadequate as a means of ensuring appropriate, rational and proportionate regulation for nicotine products. Current nicotine product regulation, at both EU and individual Member State level, is irrational and inconsistent. Medicinal nicotine products, which are inherently low hazard (with a safety profile of a similar order of magnitude to caffeine) are tightly regulated, as drugs; smoked tobacco, which kills half of all sustained users, enjoys market freedoms without precedent for any significantly hazardous product; sale of smokeless tobacco, which is much less hazardous than smoking and hence a logical substitute for smokers who cannot or will not quit smoking, is illegal outside Sweden; whilst other forms of nicotine delivery, such as the electronic cigarette, are unregulated and hence allowed on the market with no constraint on nicotine dose, purity or effectiveness. The status quo thus helps to perpetuate smoked tobacco as the least expensive, most easily available and convenient source of nicotine for those addicted to, experimenting with or otherwise using a nicotine product. It allows cigarette manufacturers freedom to launch new cigarette products to circumvent marketing restrictions, drive sales, and imply unsubstantiated reductions in risk to the consumer [1,2,3,4]. The current system of nicotine regulation is thus strongly counterproductive to individual and public health. We therefore recommend more radical reform of the tobacco products directive to include all nicotine products, and hence to provide consistent regulation of price, promotion, availability and freedom of use to ensure that the market freedom allowed for any nicotine product is in direct inverse relation to its hazard to health. More detailed arguments in support of this position are presented elsewhere [1]. Herbal cigarettes that do not contain nicotine are an anomaly which in our view be brought under this same regulatory framework. 1. BAT's CEO interviewed in the Independent, 18

June 2006 2. Euromonitor International. Global Tobacco: New product developments – creativity in adversity. September 2009. 3. Lambat I. Top Dogs. Tobacco Reporter. February 2007. 4. Euromonitor International. Innovation responds to operating environment. In: Global Tobacco – survival strategies for a savage market. 21 Nov 2008. 5. Tobacco Advisory Group of the Royal College of Physicians. Harm reduction in nicotine addiction. London: Royal College of Physicians; 2007. <http://www.rcplondon.ac.uk/pubs/contents/4fc74817-64c5-4105-951e-38239b09c5db.pdf>

### **additional comments**

We believe that the scope of the Directive should also include smoking paraphernalia such as filters, cigarette papers, pipes and water pipes as well as tobacco leaf.

### **questions smokeless**

#### **problem definition**

No

#### **comments**

The problem definition overstates the risk of smokeless tobacco in relation to smoked tobacco, and does not distinguish between the risks of different forms of smokeless tobacco. Both of these considerations were covered in detail by the SCENIHR report cited in the problem definition, which concluded that: (a) The risk profile of smokeless tobacco varies between different products, but appears to be lowest for low nitrosamine Swedish snus. It is therefore important to distinguish between the different products in describing health risks. (b) The majority of deaths caused by smoking are from lung cancer, COPD, and ischaemic heart disease. The SCENIHR report concluded that Swedish snus does not increase the risk of lung cancer or COPD. It also concluded that snus use does not increase the risk of myocardial infarction, though it does increase the proportion of myocardial infarctions that prove fatal. Snus use is associated with an increased risk of pancreas cancer, but to a much lesser extent than smoking [1]. We therefore disagree that for any individual, substitution of smoking by the use of smokeless tobacco products would probably decrease the incidence of some tobacco-related diseases: the outcome would in fact be a substantial reduction in individual and overall population risk [1,2]. Also, whilst we agree that whilst use of smokeless tobacco by young people may well lead to uptake of smoking in some cases, evidence from Sweden, also summarised in the SCENIHR report, indicates that such gateway migration to smoking is far offset by the number of smokers that move from smoked to smokeless tobacco [1]. It is also estimated that in practice, the likelihood that this balance of gateway progression to or from smoking would ever act against the overall public health is extremely low [3]. Furthermore, an appropriate regulatory environment would help balance the risks in favour of public health. 1. Scientific Committee on Emerging and Newly Identified Health Risks. Health effects of smokeless tobacco products. European Commission; 2008. 2. Tobacco Advisory Group of the Royal College of Physicians. Harm reduction in nicotine addiction. London: Royal College of Physicians; 2007. <http://www.rcplondon.ac.uk/pubs/contents/4fc74817-64c5-4105-951e-38239b09c5db.pdf> 3. Gartner C, Hall WD, Vos T, Bertram MY, Wallace AI, Lim SS. Assessment of Swedish snus for tobacco harm reduction: an epidemiological modelling study. *Lancet* 2007;369:2010-2014

#### **which option**

Lifting the ban on snus

#### **additional option**

In fact none of the three options is ideal. We have argued under (1) above that nicotine product regulation needs to change to encourage the use of less hazardous forms of nicotine. We believe that the current ban on snus, while cigarettes remain legal, is illogical when considered in relation to the relative hazard of the two products, and that snus may have a place in a rationally regulated nicotine market, in a context in which smoked cigarettes are far less available and affordable, and medicinal nicotine far more available and affordable, than snus. However we also share the concern expressed in the SCENIHR report that, whilst the availability of snus has probably been to the benefit of public health in Sweden, there is no assurance that the same would apply if snus were introduced widely, without effective regulation, across the EU. Hence our support for consideration of a role for smokeless tobacco in the context of a nicotine market regulated to minimize harm from nicotine use [1]. Since all other smokeless tobacco products that are currently legally available throughout the EU are almost certainly more hazardous than low-nitrosamine Swedish snus, their continued availability is irrational. We would recommend the establishment of standards for maximum acceptable content of nitrosamines and other hazardous constituents of smokeless tobacco, and require compliance with such standards as a condition of market access. 1. Tobacco Advisory Group of the Royal College of Physicians. Harm reduction in nicotine addiction. London: Royal College of Physicians; 2007. <http://www.rcplondon.ac.uk/pubs/contents/4fc74817-64c5-4105-951e-38239b09c5db.pdf>

**questions consumer  
problem definition**

Yes

**which option**

Improve consumer information; Introduce generic or plain packaging

**which improvement**

Picture warnings to become mandatory; Tar, nicotine and carbon monoxide levels to be replaced with general information on harmful substances in tobacco products; Information on harmful substances in tobacco products that cannot be placed on the package would be placed inside the package; Health warnings to be put on water pipes

**additional option**

We support all of the the given options under 2 and 3, in line with previous advice to the EC [1]. We suggest that picture health warnings should cover most of the two largest sides of a pack that should be rectangular in shape, that telephone helpline information, qualitative information on content, and batch labeling to assist tracing of illicit supply be placed elsewhere on the pack, and that the brand name, in generic type, should cover less than 10% of any one side of the pack. These packaging requirements should apply to all tobacco products, smoking devices and paraphernalia. 1. Sambrook Research International. A review of the science base to support the development of health warnings for tobacco packages. European Commission: 2009. [http://ec.europa.eu/health/tobacco/docs/warnings\\_report\\_en.pdf](http://ec.europa.eu/health/tobacco/docs/warnings_report_en.pdf)

**additional comments**

We are also concerned point of sale displays are prohibited, to ensure that aggregates of plain packages are not used as alibi promotions at point of sale.

**questions on reporting  
problem definition**

Yes

**which option**

Establish a common compulsory reporting format; Introduce fees and sanctions

**regulation of ingredients**

**problem definition**

Yes

**which option**

Establish a common list of tobacco ingredients

**which one**

Establish a positive common list of tobacco ingredients

**additional option**

We suggest that additives should be included on the positive list only if proven to be beneficial to health.

**access to tobacco products**

**problem definition**

Yes

**which option**

Ban

**which one2**

Cross-border retail sales of tobacco to be banned over the Internet; Vending machines to be banned; Promotion and displays in retail stores to be banned

**additional option**

Point of sale displays of tobacco products have become de facto promotional displays for tobacco products and brands. We strongly support their removal from view. This applies whether or not plain generic packaging is introduced, since aggregations of tobacco packs in what is in effect alibi marketing will be exploited by tobacco companies to promote the presence of the product. We fully support the proposal to prohibit tobacco vending machines, since these are an important source of cigarettes for children and young people. We also point out that the text of the definition of the problem could state that the Irish point of sale legislation was implemented in 2009, and that similar measures are due to be introduced in Scotland in 2011 for supermarkets and 2013 for large shops.

---

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**questions scope**

**problem definition**

Yes

**which option**

No change

**recommend option**

THE SCOPE OF THE DIRECTIVE CAN BE EXTENDED TO COVER THESE OTHER PRODUCTS, BUT THIS SHOULD NOT INCLUDE AN AUTOMATIC BAN ON ONE CATEGORY OF PRODUCT (NOVEL FORMS OF ORAL TOBACCO) ANY BANS SHOULD BE BASED ON SCIENTIFIC ASSESSMENTS.

**questions smokeless**

**problem definition**

Yes

**which option**

Lifting the ban on snus

**questions consumer**

**problem definition**

No

**explanations**

THERE IS NO EVIDENCE THAT BIGGER WARNINGS ARE MORE EFFECTIVE.THERE IS NO EVIDENCE THAT PAIN PACKAGING WOULD IMPROVE THE FUNCTIONING OF THE INTERNAL MARKET OR HAVE ANY PUBLIC HEALTH BENEFITS. IT WOULD MAKE IT EASIER FOR CRIMINALS TO COPY LEGITIMATE BRANDS AND WOULD LEAD TO AN INCREASE AN ILLEGAL SALES OF CIGARRETTES.

**which option**

No change

**questions on reporting**

**problem definition**

No

**explanations**

MEMBER STATES CAN ALREADY INTRODUCE FEES AND SANCTIONS. ENFORCEMENT AF THE PROVISIONS OF THE DIRECTIVE SHOULD REMAIN THE

RESPONSABILITY OF THE MEMBER STATES.

**which option**

Establish a common compulsory reporting format

**regulation of ingredients**

**problem definition**

No

**explanations**

THE FOCUS OF INGREDIENTS TESTING SHOULD BE ON WHETHER THE INGREDIENTS RESULT IN INCREASED TOXICITY OF TOBACCO SMOKE

**which option**

No Change

**access to tobacco products**

**problem definition**

No

**explanations**

THERE IS NO CLEAR PROBLEM STATED AS REGARDS EITHER VENDINGMACHINES OR POSD. THERE NO EVIDENCEPROVIDED AS TO WHY BANS WOULD IMPROVE THE FUNCTIONING OF THE INTERNAL MARKET OR ADVANCE ANY PUBLIC HEALTH OBJECTIVES. THE BAN IN VENDING MACHINES, WOULD INCREASE CRIMINAL TOBACCO IN NORMAL POINT OF SALES, BECAUSE VENDING MACHINES ARE CONTROLLED BY AUTHORITIES.

**which option**

No change

---

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**questions scope**

**problem definition**

No

**explanations**

We will not take position on this question.

**which option**

No change

**recommend option**

We will not take position on this question.

**questions smokeless**

**problem definition**

No

**comments**

We will not take position on this question.

**which option**

No change

**additional option**

We will not take position on this question.

**questions consumer**

**problem definition**

Yes

**which option**

No change

**additional comments**

In today's world economy trademarks are important proprietary rights and also significant means which ensures that trade is without unnecessary restrictions. Plain packaging would have significant negative impact to the benefits world's economy is gaining from trademarks. Trademarks foster trade, economical efficiency and are important means to ensure competition. The restriction how trademarks could be used on tobacco packages would be unprecedented step in restricting the intellectual property rights, which in long-term may result that similar restrictions are implemented also against other product categories. Trademarks and product get-up play significant role in providing important information for consumer at the moment of making their purchase decisions and thereby provides guidance in distinguishing different products on the market. Plain package would make it more difficult to distinguish different products and therefore would the quality of consumer information would decrease. Trademarks are not only words or logos, but they may be also colours, package shape designs and their get-up. Therefore even if the use of word trademarks would be allowed on the packages, the implementation of plain package would prohibit using these other trademarks on the tobacco product packaging. Based on several international treaties (TRIPS Agreement, Articles 15(4), 20 and 8(1); Paris convention, Articles 6quinquies and 7), EU law and Estonian national laws trademark rights are proprietary rights and trademark owners have legitimate right that these rights are being protected and properly considered. In

the case the plain package is introduced then registration of certain trademarks will be excluded under the Estonian Trademark Law - § 9 section 1 subsection 12 provides that registration is not allowed for a sign which use is prohibited based on other law or international treaty. This would be obvious infringement of Article 15 (4) of the TRIPS Agreement and Article 7 of the Paris Convention. The change would also mean that all combined (word and design) and design trademarks can be invalidated under the current trademark laws as they are not used any more, which may have significant negative effects on trademark owners. As such the introduction of plain pack legislation would amount to an effective expropriation of trade mark rights through legislation, contrary to Article 1 of the First Protocol to the European Convention on Human Rights. Trademarks (words, design, package shape) used on tobacco packaging are important features to distinguish original and legitimate products from counterfeit products. Implementation of plain packaging would make it more difficult to identify counterfeit tobacco products and would endanger the fight against manufacturer's and distributor's of counterfeit tobacco products, as the number of features based on which to distinguish original products from counterfeits is much more smaller. It has because already general knowledge that counterfeit products are not just a trademark owner's concern, but it has become much wider problem – there is tax concern as well as health concern as the infringers do not pay taxes and the quality of the products is low. Introduction of plain package for tobacco products would open the way for similar restrictions for other products and services and is therefore dangerous precedent not only to the trademark owners, but more generally to the freedom of entrepreneurship and consumer's right to information to make an informed purchase decision.

**questions on reporting**

**problem definition**

No

**explanations**

We will not take position on this question.

**which option**

No change

**additional options**

We will not take position on this question.

**regulation of ingredients**

**problem definition**

No

**explanations**

We will not take position on this question.

**which option**

No Change

**additional option**

We will not take position on this question.

**access to tobacco products**



**problem definition**

No

**explanations**

We will not take position on this question.

**which option**

No change

**additional option**

We will not take position on this question.

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**NGO submission****identification****affiliation**

NGO

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24

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**questions scope****problem definition**

No

**explanations**

the problem definition is incorrect,vague and unclear.It fails to provide any scientific basis or evidence for the different options considered in this section

**which option**

No change

**questions smokeless****problem definition**

No

**which option**

Lifting the ban on snus

**questions consumer  
problem definition**

No

**explanations**

the problem is defined overly narrowly and so fails to identify relevant policy options

**which option**

No change

**questions on reporting  
problem definition**

No

**explanations**

no evidence provided for the different options discussed in this section

**which option**

Establish a common compulsory reporting format

**regulation of ingredients  
problem definition**

No

**explanations**

the problem definition incorrectly defines the use of ingredients

**which option**

No Change

**access to tobacco products  
problem definition**

No

**which option**

No change

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**NGO submission**

**identification  
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NGO

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**questions scope****problem definition**

Yes

**which option**

Extend the scope of the Directive

**questions smokeless****problem definition**

Yes

**which option**

Ban on all types of smokeless tobacco products

**questions consumer****problem definition**

Yes

**which option**

Improve consumer information; Introduce generic or plain packaging

**which improvement**

Picture warnings to become mandatory; Tar, nicotine and carbon monoxide levels to be replaced with general information on harmful substances in tobacco products; Information on harmful substances in tobacco products that cannot be placed on the package would be placed inside the package; Health warnings to be put on water pipes

**questions on reporting****problem definition**

Yes

**which option**

Establish a common compulsory reporting format; Introduce fees and sanctions

**regulation of ingredients****problem definition**

Yes

**which option**

Establish a common list of tobacco ingredients

**which one**

Establish a positive common list of tobacco ingredients; Establish a negative common list of

tobacco ingredients

**access to tobacco products**

**problem definition**

Yes

**which option**

Controlled supply and access; Ban

**which supply and access**

Age verification of buyers and other legal conditions to be set for cross-border retail sale; Access to vending machines to be restricted to adults; Tobacco display and promotion at points of sales to be restricted

**which one2**

Cross-border retail sales of tobacco to be banned over the Internet; Vending machines to be banned; Promotion and displays in retail stores to be banned

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**NGO submission**

**identification**

**affiliation**

NGO

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45

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**questions scope**

**problem definition**

Yes

**which option**

Extend the scope of the Directive

**questions smokeless**

**problem definition**

Yes

**which option**

Lifting the ban on snus

**questions consumer**

**problem definition**

Yes

**which option**

Improve consumer information

**which improvement**

Information on harmful substances in tobacco products that cannot be placed on the package would be placed inside the package

**questions on reporting**

**problem definition**

Yes

**which option**

No change

**regulation of ingredients**

**problem definition**

Yes

**which option**

Introducing the basic criteria on the EU level without a common list

**access to tobacco products**

**problem definition**

Yes

**which option**

Controlled supply and access

**which supply and access**

Access to vending machines to be restricted to adults

---

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**questions scope****problem definition**

No

**explanations**

Kein Kommentar

**which option**

No change

**questions smokeless****problem definition**

No

**comments**

kein kommentar

**which option**

No change

**questions consumer****problem definition**

No

**explanations**

kein kommentar

**which option**

No change

**questions on reporting****problem definition**

No

**explanations**

Kein Kommentar

**which option**

No change

**regulation of ingredients****problem definition**

No

**explanations**

Kein Kommentar

**which option**

No Change

**access to tobacco products****problem definition**

No

**explanations**

kein Kommentar

**which option**

No change

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NGO

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Switzerland

**questions scope****problem definition**

Yes

**which option**

No change

**recommend option**

La portée de la Directive peut être étendue afin de couvrir ces autres produits, mais ceci ne devrait pas inclure une interdiction automatique sur l'une ou l'autre catégorie de produit

(nouvelles formes de tabac oral). Toute interdiction devrait être fondée sur des expertises scientifiques.

**questions smokeless**

**problem definition**

Yes

**which option**

Lifting the ban on snus

**additional comments**

Aucune raison n'est fournie quant à une interdiction sur tous les produits non combustibles du tabac. Une interdiction pourrait uniquement être justifiée s'il était prouvé que tous les produits non combustibles du tabac sont plus nocifs que d'autres formes de produits du tabac. Il n'y a pas de preuves qui suggèrent cela.

**questions consumer**

**problem definition**

No

**explanations**

Il n'y a pas de preuves que des mises en garde plus grandes soient plus efficaces. Il n'y a pas de preuves que les emballages génériques amélioreraient le fonctionnement du marché commun européen ou auraient un quelconque effet bénéfique sur la santé publique.

**which option**

No change

**questions on reporting**

**problem definition**

No

**explanations**

Les Etats membres peuvent déjà introduire des émoluments et des sanctions. L'exécution des dispositions de la Directive doivent rester de la responsabilité des Etats membres.

**which option**

Establish a common compulsory reporting format

**regulation of ingredients**

**problem definition**

No

**explanations**

Les tests sur les ingrédients doivent avant tout s'attacher à déterminer si les ingrédients augmentent la toxicité de la fumée du tabac.

**which option**

No Change



**access to tobacco products****problem definition**

No

**explanations**

Aucun problème clair n'est évoqué par rapport aux automates ou à l'exposition sur le point de vente. Aucune preuve n'est fournie expliquant pourquoi les interdictions amélioreraient le fonctionnement du marché intérieur ou comment elles feraient progresser les objectifs de santé publique.

**which option**

No change

---

**NGO submission****identification****affiliation**

NGO

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**questions scope****problem definition**

Yes

**which option**

No change

**questions smokeless****problem definition**

No

**comments**

Il n'y a pas d'études efficaces réalisées prouvant les dangers des tabacs sans fumées

**which option**

Lifting the ban on snus

**questions consumer  
problem definition**

No

**explanations**

Aucune étude prouve l'efficacité des paquets neutres par ailleurs cela pourra entraîner une guerre des prix entre fabricant ( seul moyen de se démarquer à l'avenir). De plus l'apparition des photos chocs va entraîner un déplacement des consommateur français vers des réseaux parallèles de contrebande de tabac où de contrefaçon qui n'auront pas eux de photos chocs sur leur paquet. Il y a en France un réseau de 28000 buralistes organisés et structurés par l'état qui pourrais bien être déstabilisé avec de telle mesure.

**which option**

No change

**questions on reporting  
problem definition**

Yes

**which option**

Establish a common compulsory reporting format

**regulation of ingredients  
problem definition**

No

**explanations**

Cela va entraîner une standardisation et une banalisation des produits du tabacs. Chaque fabricant doit pouvoir se différencier et améliorer ses produits tout en essayant avec la recherche de les rendre moins nocifs pour du consommateur.

**which option**

No Change

**access to tobacco products  
problem definition**

Yes

**which option**

Controlled supply and access; Ban

**which supply and access**

Age verification of buyers and other legal conditions to be set for cross-border retail sale

**which one2**

Cross-border retail sales of tobacco to be banned over the Internet; Vending machines to be banned

---

## **NGO submission**

### **identification**

#### **affiliation**

NGO

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### **questions scope**

#### **problem definition**

Yes

#### **which option**

Extend the scope of the Directive

### **recommend option**

All tobacco products are hazardous to health – there is no safe level of usage. Therefore we recommend that the scope of the Directive includes the regulation of any new smoked tobacco products (such as low emission or nicotine-free cigarettes), while the prohibition of any novel forms of oral tobacco, including snus, should be maintained. As it is the combustion process and inhalation of smoke that causes most of the harm from smoking, it is appropriate that herbal cigarettes, which are used in a similar way as nicotine cigarettes, are regulated in the same way as smoked tobacco products, and should therefore be included in the scope of the Directive. Novel nicotine based products (that is, products containing nicotine but not tobacco products) have the potential to offer a less hazardous alternative to cigarettes. Currently these include e-cigarettes and nicotine gel. However, as such products are generally marketed as alternatives to cigarettes and in some cases as an aid to quitting smoking, it is appropriate for them to be brought under the same regulatory framework as pharmaceutical products rather than under the scope of the tobacco products directive. The question of how nicotine containing products should be controlled is currently under consideration by the UK's Medicines and Healthcare Regulatory Authority (MHRA) following a recent public consultation on whether to extend its remit on the regulation of nicotine replacement therapies to other nicotine containing products. The outcome of this consultation may assist the Commission in developing its policy on these products.

### **additional comments**

ADPH believes that the scope of the Directive should be extended to include smoking paraphernalia such as filters, cigarette paper, pipes, water pipes as well as the tobacco leaf. We would cite the impact assessment study conducted by RAND Europe stating that the primary benefit of extending the scope of the directive to paraphernalia and other non-tobacco nicotine products would be to increase consumers' awareness of the risks of these products. Smokers of roll-your-own cigarettes (RYO), pipes and water pipes often believe that these

products are less harmful than manufactured cigarettes when in fact there is evidence to the contrary. ,

**questions smokeless**

**problem definition**

Yes

**which option**

No change

**additional option**

It is a high priority that the current ban on snus is definitely maintained. Indeed, there is no legitimate reason to introduce a dangerous product on the market, particularly as, from an internal market point of view, we have no idea how snus would be perceived or used in other countries. There is inadequate evidence on the impacts on smoking uptake and quit rates and no evidence to show the effect of introducing snus to a new market. The SCENIHR report notes the difficulties of extrapolating to new markets from experience in existing markets, pointing out different patterns for smoking prevalence and snus use in Sweden and Norway for example. The switching behaviour reported in Swedish men is not reflected in Norway where smoking cessation rates have been similar in Norwegian men and women during the last decade, but increased use of smokeless tobacco is observed only in young men. There is little evidence that smokers in EU countries other than Sweden would find snus to be an acceptable alternative to cigarettes, were it to be legalised. If the ban on snus were to be lifted, it could encourage dual use of cigarettes and smokeless tobacco and discourage total abstinence from tobacco, thus weakening any potential health gains. Therefore, there is no legitimate reason to justify bringing a new hazardous product onto the market. With regard to other smokeless tobacco products, these should be more tightly regulated (in the same way as tobacco products) but we do not support a total ban on such products, as a total ban would likely be counter-productive by facilitating the use of smokeless tobacco products underground and creating an unnecessary illegal market. This would make it more difficult to engage with users and to offer help in quitting.

**questions consumer**

**problem definition**

Yes

**which option**

Improve consumer information; Introduce generic or plain packaging

**which improvement**

Picture warnings to become mandatory; Information on harmful substances in tobacco products that cannot be placed on the package would be placed inside the package; Health warnings to be put on water pipes

**additional option**

Picture Warnings ADPH recommends that picture warnings should be mandatory in all Member States and that they should occupy a minimum of 80% of the front and back surfaces of all tobacco packaging (i.e not just cigarettes). The warnings should be placed on the upper portion of the packs for maximum visibility. Considering the proven weak effects of written health warnings only, it is essential that pictorial warnings are displayed on both sides of the

pack. Evidence clearly supports the need for large pictorial health warnings (80%) showing that increasing the size of warning messages (text only and combined text and picture) increases the effectiveness of the warning amongst both young and adult smokers / non smokers. Research carried out in Canada by Createc on behalf of Health Canada in 2007 showed that young and adult smokers/non smokers are sensitive to the size of health warning messages. Results showed that warning messages that cover 100% of the pack are significantly more effective across all measured effectiveness indicators compared with warning messages that cover only 50% of the pack. There is further evidence to show that health warnings are effective in conveying the dangers of smoking and helping smokers to quit. , They also help deter young people from starting to smoke. Picture warnings are more effective than written warnings. Further, we believe that all warnings should be displayed in rotation so that each message is given equal display to reach its target audience. Generic or plain packaging ADPH recommends the introduction of plain or generic packaging. This should include not only the removal of all branding from the packaging but the size and shape of the packaging should also be standardised. Not only would this prevent the promotion of smoking through branding as occurs presently but it would reinforce the health warning messages. Although the Australian Federal Government has recently announced its intention to introduce plain packaging in 2012 , no other jurisdiction has yet implemented a law requiring plain packaging. Research suggests that it would help deter young people from taking up smoking because smoking would lose its appeal. Tobacco companies invests considerable resources in making tobacco packaging alluring and eye-catching, as this is now one of the few methods currently available to the industry to market its products to new and existing smokers. Tobacco packaging provides a direct link between consumers and manufacturers and is the main marketing channel, particularly in jurisdictions with tobacco advertising bans. Branding gives the misleading impression some cigarettes are safer than others. Information on Tar, nicotine & carbon monoxide (TNCO) Concerning option 2b, to replace levels of tar, nicotine and carbon monoxide (TNCO) with general information on harmful substances in tobacco products, ADPH believes that instead of removing information on the levels of TNCO, they should be completed with qualitative information about the hazardous content and “stop smoking” help lines. Further it should be insured that the data on the quantities of TNCO are accurate. Additional information on harmful substances in tobacco products ADPH supports the proposal to include additional information on the health effects of tobacco consumption on inserts inside the packaging. This should include advice on quitting smoking (see above). Health warnings on water pipes There is a growing body of evidence to show that water pipes are at least as hazardous, if not more so, than other forms of tobacco use. However, there is a common perception that tobacco smoke is ‘cleansed’ by the water and therefore not as dangerous and some users believe flavoured shisha is not in fact tobacco. It is important that these myths are countered by the inclusion of a health warning on water pipes. Warnings should also be included on the packaging of tobacco used in water pipes.

### **additional comments**

There is evidence from around the world to show that the tobacco industry uses branding in general and pack design in particular to: • Target young people • Maximise display space (some members of brand families are virtually indistinguishable on taste alone yet the number of variants has increased dramatically in recent years). • Communicate misleading messages (it would be illegal for manufacturers to claim products were “low tar” “light” or less harmful yet all these are communicated by the colour of sub-brand packaging). , , ADPH is aware of the tobacco industry claims that plain packaging would contravene intellectual property law. However, legal analysis concludes that this is incorrect and there are no international legal

impediments to the implementation of generic packaging.

**questions on reporting**

**problem definition**

Yes

**which option**

Establish a common compulsory reporting format; Introduce fees and sanctions

**additional options**

Tobacco companies should be required to use a standardised reporting format. Additionally the companies should be required to pay a yearly registration fee to cover the costs of administering this data collection. The above measures should be compliant with Articles 9 & 10 of the Framework Convention on Tobacco Control (FCTC).

**regulation of ingredients**

**problem definition**

Yes

**which option**

Establish a common list of tobacco ingredients

**which one**

Establish a positive common list of tobacco ingredients

**additional option**

ADPH supports the response by Smoke Free Partnership Europe of adopting a positive common list of tobacco ingredients. We believe that tobacco products are highly toxic and addictive, and that their content should therefore be closely regulated, in order to achieve high standards of health protection, as stated under article 95.3. There is a need for such a list at EU level since at the moment, consumers in the internal market are not subject to the same level of protection. Some citizens may be using substances that are banned in other Member States. This constitute an obstacle to free movement of goods within the internal market since some countries may be reluctant to import cigarettes from other Member States that do not comply with the national requirements. Regulation of Flavours and Ingredients: Flavourings are an increasingly important part of tobacco industry marketing, particularly to young people. Flavourings enhance attractiveness, encourage youth initiation, and discourage cessation. The prohibition of ingredients that may be used to increase attractiveness, such as sugars and sweeteners, flavouring substances, and spices and herbs, in cigarettes and cigarette-like tobacco products should be introduced. The prohibition of ingredients that may create the impression of a health benefit (e.g. vitamins), ingredients associated with energy and vitality (e.g. caffeine), and ingredients with colouring properties (e.g. pink cigarette paper) should also be banned. Tobacco manufacturers and importers should report sales volume information by brand. This information is essential to help governments ensure that product regulation is effective. The above measures should be compliant with the Guidelines on Art. 9/10, adopted unanimously at the Fourth Conference of the Parties in Uruguay on the 20th November 2010.

**access to tobacco products**

**problem definition**

Yes

**which option**

Ban

**which one2**

Cross-border retail sales of tobacco to be banned over the Internet; Vending machines to be banned; Promotion and displays in retail stores to be banned

**additional option**

Whilst ADPH urges the Commission to call for a ban on the promotion of tobacco products at point of sale and a ban on vending machines, we are aware that these issues do not have cross-border effects. The legal basis for such measures at an EU level is weak. However, these measures are important for health protection and we call on the Commission to include them as non-mandatory measures as part of the Tobacco Products Directive. The Directive should also remind national governments that they should adopt a comprehensive ban on all forms of tobacco advertising, promotion and sponsorship in accordance with Article 13 of the FCTC which calls on Parties to. Further, we recommend that the EU Directive follows the lead set by Finland which, as part of its recently passed Tobacco Act, has set limits on the amount of tobacco that can be imported into Finland where the labelling differs from that of tobacco products sold in Finland. We recommend that similar limits should be set at EU level, that is, that for each Member State the amount of tobacco that may be imported for personal use which does not conform to domestic labelling requirements, should be limited to a maximum of 200 cigarettes, 50 cigars, 100 cigarillos and 250 grams of pipe or cigarette tobacco.

**additional comments**

Internet: The principle of preventing cross-border promotion of tobacco products in order to protect public health was enshrined in the Tobacco Advertising directive (2001/0119). It is logical, therefore, to extend that principle to the sale of tobacco products between member states via the Internet. ADPH supports the prohibition of tobacco sales via the Internet.

Vending machines: The majority of member states (22 out of 27) already prohibit the sale of tobacco products from vending machines in order to deter young people accessing cigarettes from this source. ADPH supports this measure. However, as this does not have cross-border effects, we urge the Commission to make the prohibition of tobacco vending machines a non-mandatory measure as part of the product directive. Point of Sale. Similarly, there is a growing body of evidence to show that putting tobacco products out of sight in retail outlets can reduce youth smoking. To date, this measure has been adopted by Ireland, the UK and Finland. We support an EU-wide adoption of a ban on the display of tobacco products at the point of sale. As with vending machines, ADPH urges the Commission to make the prohibition of tobacco vending machines a non-mandatory measure as part of the product directive.

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**identification**

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NGO

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**questions scope****problem definition**

Yes

**which option**

Extend the scope of the Directive

**recommend option**

We recommend additional directive on herbal cigarettes and on “new” ways of using tobacco. In particular, it is important to indicate on herbal cigarettes and electronic cigarette (“E-cig”) the list of ingredients. The packages of herbal cigarettes should be given the warnings about the dangers of tar and combustion products (Carbone Monoxid).

**questions smokeless****problem definition**

Yes

**which option**

Ban on all types of smokeless tobacco products

**questions consumer****problem definition**

Yes

**which option**

Improve consumer information

**which improvement**

Picture warnings to become mandatory

**additional option**

In additions, governative help-line number should be placed inside the package (in Italy, “numero verde dell’Istituto Superiore di Sanità”).

**questions on reporting****problem definition**

Yes

**which option**

Introduce fees and sanctions



**regulation of ingredients**

**problem definition**

Yes

**which option**

Establish a common list of tobacco ingredients

**which one**

Establish a positive common list of tobacco ingredients

**access to tobacco products**

**problem definition**

Yes

**which option**

Ban

**which one2**

Vending machines to be banned

---

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NGO

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**questions scope**

**problem definition**

Yes

**which option**

Extend the scope of the Directive

**additional comments**

All tobacco products are hazardous to health – there is no safe level of usage. Therefore we recommend that the scope of the Directive includes the regulation of any new smoked tobacco products (such as low emission or nicotine-free cigarettes), while the prohibition of any novel forms of oral tobacco, including snus, should be maintained. Herbal cigarettes are also harmful because it is the combustion and inhalation of smoke that causes most of the harm from smoking. Therefore, herbal cigarettes should be included in the scope Tobacco Products Directive and should also be subject to health warnings requirements. Finally, all forms of nicotine based products (that is, products containing nicotine but which are not tobacco products, such as electronic cigarettes, nicotine gel, drinks, and sweets) are often marketed as alternatives to cigarettes and in some cases as an aid to quitting smoking. Therefore, they should only be sold as quitting aids and comply with specific safety and quality requirements under the same regulatory framework as pharmaceutical products rather than under the scope of the Tobacco Products Directive.

**questions smokeless****problem definition**

Yes

**which option**

No change

**additional comments**

The ban on snus should definitely be maintained. This is high priority. Indeed, there is no legitimate reason to reintroduce a carcinogenic and addictive product onto the EU market. Furthermore, if the ban on snus were to be lifted, it could encourage dual use of cigarettes and smokeless tobacco and discourage total abstinence from tobacco, thus weakening any potential health gains. In this context, we stress that there are already available effective treatments for nicotine addiction, including medicinal or ‘clean’ nicotine (NRT), that do not carry the risks associated with the use of snus. These should be promoted first and foremost. It is clear that the public health interest can be served even more by encouraging a) greater use of these treatments and b) the development of more effective cessation aids, especially those that mimic more closely the nicotine ‘hit’ delivered by cigarettes. Regarding other forms of smokeless tobacco products, ENSP does not believe that they should be “marketed” in all Member States. We recognise that they are as addictive and dangerous as smoked tobacco. As stated in the Opinion of the Scientific Committee on Emerging and Newly Identified Health Risks (SCENIHR), many forms of smokeless tobacco increase the risk of mouth, esophageal, pancreatic and liver cancer, and other conditions including gum and heart disease. However, we also know that these products are mostly consumed in the UK and used by South Asian communities; introducing an EU-wide ban on these products now could lead to the creation of an unnecessary illegal market, pushing consumption underground. This is why we do not recommend an immediate ban on all types of smokeless tobacco products; we do recommend that they should be regulated in the same way as tobacco products.

**questions consumer****problem definition**

No

**explanations**

The problem definition could be improved. We agree with the Commission that the current

situation, whereby some Member States have made graphic warnings compulsory and others not, has led to a disparity in labelling throughout the EU. Consequently, this has an impact on the functioning of the internal market, on consumers' awareness and as a result, on their smoking behaviour. We also agree that packaging as an advertising tool is not covered by the current Directive. Finally, we welcome the acknowledgement that tobacco packaging and product features are increasingly used to attract consumers, to promote products and brand image. In this context, it would have been judicious to highlight the fact that, in the Eurobarometer survey released in 2010, the policy that received the most positive response is that of putting health warnings on all packages of tobacco products (on average, 75% of EU citizens are in favour of mandatory pictorial warnings, and over 54% support plain packaging measures).

#### **which option**

Improve consumer information; Introduce generic or plain packaging

#### **which improvement**

Picture warnings to become mandatory; Tar, nicotine and carbon monoxide levels to be replaced with general information on harmful substances in tobacco products; Health warnings to be put on water pipes

#### **additional option**

Crucial importance of Graphic health warnings: Evidence shows that text only warning messages are not as effective as graphic warnings. Pictures, especially fear inducing pictures, are proven to be effective in getting consumers more engaged with the warning message. Pictures are able to immediately provoke a reaction and prompt people to read the associated text message. The need for graphic health warnings on both sides of the pack: There is also evidence that pictures on both sides of the packaging have a greater impact. The need for LARGE pictorial health warnings (80%): The global trend is towards larger health warnings. Uruguay, for instance, has implemented legislation to make pictorial health warnings obligatory, covering 80% of the front and the back of cigarette packs. Evidence clearly shows that increasing the size of warning messages (text only and combined text and picture) increases the effectiveness of the warning amongst both young and adult smokers / non smokers. Research carried out in Canada by Createc on behalf of Health Canada in 2007 showed that young and adult smokers/non smokers are sensitive to the size of health warning messages. Results showed that warning messages that cover 100% of the pack are significantly more effective across all measured effectiveness indicators compared with warning messages that cover only 50% of the pack. The importance of Rotation: Warning texts and pictures should be displayed on a rotating basis, so that each message is given equal display and can reach its target audience. The proved effectiveness of shocking health warnings & targeted messages: as specified in the Sambrook Research International report, fear inducing warnings (using strong “shocking” images related to health risks such as rotten teeth or throat cancer) and strong emotion inducing warnings (especially involving children and unborn babies) are the most effective way to educate consumers on the health risks of tobacco use and to achieve changes in attitudes and behaviour. These warnings' effectiveness is enhanced if they are used in conjunction with a quit line. Generic or plain packaging: We strongly recommend the introduction of standardised/plain packaging. This should include not only the removal of all branding from the packaging but the size and shape of the packaging should also be standardised. Not only would this prevent the promotion of smoking through branding as occurs presently but it would reinforce the health warning messages. Tobacco packaging provides a direct link between consumers and manufacturers and is the main

marketing channel, particularly in jurisdictions with tobacco advertising bans. Branding gives the misleading impression some cigarettes are safer than others. The tobacco industry claims that plain packaging would contravene intellectual property law. However, legal analysis concludes that this is incorrect and there are no international legal impediments to the implementation of generic packaging. Replace TNCO quantitative labelling with qualitative information on contents, emissions and quit-lines: The inclusion of machine-based tar, nicotine and carbon monoxide yields on cigarette packs promotes the mistaken belief that some cigarette brands are less harmful than others. We support the proposal to replace numerical measurements with descriptive information on the hazardous effects of tobacco constituents and emissions. We stress the importance of putting quit line numbers on the package. As underlined in the Sambrook research (p46), providing a telephone number on the pack is more effective than telling smokers to seek advice from a doctor or pharmacist. P46 Health warnings on water pipes: There is a growing body of evidence to show that water pipes are at least as hazardous, if not more so, than other forms of tobacco use. Warnings should also be included on the packaging of tobacco used in water pipes.

### **additional comments**

Under Article 5.3 of the TPD 2001, Member States have the option to adopt pictorial warnings. This situation emphasised the right of Member States to go further than the Directive to protect public health as set out in Article 30 of the Treaty of the Union (now article 36). Five years after the adoption of the library of 42 pictorial health warnings by the European commission, seven Member States have adopted legislation to introduce pictorial health warnings (Belgium, Romania, United Kingdom, Latvia, Malta, France and Spain). Such measures are in compliance with the current TPD and are welcomed by the tobacco control community. However, their adoption by some Member States necessarily creates growing discrepancies between Member States. As stated above, there is clear evidence that pictorial warnings are much more powerful than written health warnings. Extending the information and protection to all EU Member States would be in harmony with Article 168 of the TFEU and consistent with the objectives of the internal market stated in Article 114.3 of the TFEU and reiterated in Recital 19 of the Directive. A revision of the TPD should, therefore, aim at making pictorial health warnings of tobacco products subject to common rules.

### **questions on reporting problem definition**

Yes

### **which option**

Establish a common compulsory reporting format

### **additional comments**

The current situation which allows different formats and reporting mechanisms is unsatisfactory, making it difficult for authorities to compare and analyse the data. All tobacco manufacturers and importers should be subject to the same reporting requirements. The SFP believes that tobacco products, which are highly harmful, should be subject to an effective reporting system that allows the gathering and analysis of relevant data, including comparison as appropriate, in order to ensure high levels of consumer safety and information. The format already exists (based on the voluntary reporting format developed by the Commission in May 2007) and it would therefore be very easy to adopt this measure and to implement it. We welcome the introduction of yearly registration fees in order to finance the data collection on

ingredients by the national authorities and their analysis work on ingredients. The payment of penalties in case of non-compliance with the requirements of delivery of data on tobacco product ingredients also seems adequate and would contribute to fund the tests conducted on these products. It is crucial that the appropriate toxicological and addictiveness tests are properly conducted. Such tests would allow policy-makers to make more informed decisions in this field, as there would be more scientific evidence. It would enhance the scientific knowledge of the dangers of tobacco products and would contribute to a high protection of health, as stated in Article 95.3 TFEU. Besides, such measures would also have an indirect impact on illicit trade, since only registered products would be allowed on the market.

### **regulation of ingredients**

#### **problem definition**

Yes

#### **which option**

Establish a common list of tobacco ingredients

#### **which one**

Establish a positive common list of tobacco ingredients

#### **additional comments**

We support the adoption of a positive common list of tobacco ingredients. We believe that tobacco products are highly toxic and addictive, and that their content should therefore be closely regulated, in order to achieve high standards of health protection, as stated under article 114.3. There is a need for such a list at EU level since at the moment, consumers in the internal market are not subject to the same level of protection. Some citizens may be using substances that are banned in other Member States. Apart from creating unequal health protection across the EU, this may constitute an obstacle to free movement of goods within the internal market: some countries can refuse access to their markets of cigarettes from Member States that do not comply with the importing Member State's national requirements. Regulation of Flavours and Ingredients: Flavourings are an increasingly important part of tobacco industry marketing, particularly to young people. Flavourings enhance attractiveness, encourage youth initiation, and discourage cessation. The prohibition of ingredients that may be used to increase attractiveness, such as sugars and sweeteners, flavouring substances, and spices and herbs, in cigarettes and cigarette-like tobacco products should be introduced. The prohibition of ingredients that may create the impression of a health benefit (e.g. vitamins), ingredients associated with energy and vitality (e.g. caffeine), and ingredients with colouring properties (e.g. pink cigarette paper) should also be banned. Tobacco manufacturers and importers should report sales volume information by brand. This information is essential to help governments ensure that product regulation is effective. The above measures should be compliant with the Guidelines on Art. 9/10, adopted unanimously at the Fourth Conference of the Parties in Uruguay on the 20th November 2010.

### **access to tobacco products**

#### **problem definition**

Yes

#### **which option**

Ban

**which one2**

Cross-border retail sales of tobacco to be banned over the Internet; Vending machines to be banned; Promotion and displays in retail stores to be banned

**additional option**

European Network for Smoking and Tobacco Prevention urge the Commission to call for a ban on the promotion of tobacco products at point of sale and a ban on vending machines as described in the Art 13 Guidelines of the FCTC.

**additional comments**

Internet. The principle of preventing cross-border promotion of tobacco products in order to protect public health was enshrined in the Tobacco Advertising directive (2001/0119). It is logical, therefore, to extend that principle to the sale of tobacco products between member states via the Internet. We support the prohibition of tobacco sales via the Internet. Vending machines. Considering that only 2 Member States have no legislation on vending machines, we support harmonisation of the legislation on the basis of a prohibition of the sale of tobacco from vending machines . Point of Sale. Evidence shows that a coordinated cross border marketing strategy on the part of the tobacco companies is reflected at point of sale (i.e. point of sale marketing is similar in most EU countries (i.e.: a brand is advertised at point of sale in the same way in Germany and Belgium). There is a growing body of evidence to show that putting tobacco products out of sight in retail outlets can reduce youth smoking. To date, this measure has been adopted by Ireland and Finland (as well as Iceland and Norway). This measure is also official government policy in Scotland, Wales and Northern Ireland and a decision is awaited in England. We strongly support an EU-wide adoption of a ban on the display of tobacco products at the point of sale.

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NGO

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**questions scope****problem definition**

Yes

**which option**

No change

**questions smokeless  
problem definition**

Yes

**which option**

No change

**questions consumer  
problem definition**

No

**explanations**

We disagree with the problem definition and we strongly oppose to the possible policy options addressed (Option 2 & 3) other than Option 1 (No change). In particular the potential policy option of plain packaging enforcement (Option 3) would lead to an unjustified restriction on intellectual property rights and undermine corporate brand and reputation. Such a measure will lead to a “de facto” annulment of trade marks that are clearly protected by national and European law as well as international conventions. At the same time, we strongly believe that plain packaging is most possible to open the door to illicit trade –mainly by the vast explosion of counterfeit products– and restrict fair competition. It is not made sufficiently evident that such an option would lead to a significant reduction of smoking or would increase awareness of consumers on the side effects caused by smoking. Further evidence and research is needed if a potential revision on consumer information rules is considered necessary. Widespread information campaigns on the side effects of smoking , mainly among young people is considered more effective and suitable.

**which option**

No change

**questions on reporting  
problem definition**

Yes

**which option**

No change

**regulation of ingredients  
problem definition**

No

**explanations**

We disagree with the problem definition. Regulatory framework cannot be based on subjective concepts, but only on scientific evidence. The indiscriminately ban of ingredients would devastate the Greek market of tobacco products, since blended cigarettes that use ingredients account for 93% of the market. We recommend that the EU and national authorities conduct scientific assessments and ban only ingredients that are proven to have increased toxicity. Further evidence and research is needed if a potential ban on specific tobacco products is considered necessary.

**which option**

No Change

**access to tobacco products**

**problem definition**

No

**explanations**

We disagree with the proposed problem definition. It is not sufficiently proven that a widespread ban on display of tobacco products at points of sale will reduce smoking and therefore promote public health. In such a case it will most possibly lead to an increase of illicit trade and consumption will not fall with certainty. Furthermore, we believe that Member states should maintain their right to legislate measures of this nature that have a serious effect on state revenue or that lead to market restructuring.

**which option**

No change

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**NGO submission**

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**questions scope**

**problem definition**

No

**explanations**

Mit der Problemdarstellung stimmen wir aus den folgenden Gründen nicht überein: Aus der Sicht des VdR (Verband der deutschen Rauchtabakindustrie e.V.) hat sich der Markt für Tabakprodukte nicht verändert. Von wenigen Ausnahmen, abgesehen sind alle Tabakprodukte, die sich auf dem Markt befinden, auch bereits vor dem Erlass der Tabakproduktrichtlinie (2001/37/EG) auf dem Markt gewesen (Zigaretten, Feinschnitt, Zigarren/Zigarillos, Pfeifentabak, traditioneller Kautabak, Schnupftabak und Snus (letzteres in einem Mitgliedstaat). Der Umstand, dass einzelne Mitgliedstaaten Produkte, die keinen Tabak enthalten, unter andere Gesetze subsumieren, ist grundsätzlich nachvollziehbar. Produkte, die keinen Tabak enthalten, sollten grundsätzlich auch nicht von der Tabakproduktrichtlinie erfasst werden. Nur diejenigen Produkte, die auch tatsächlich Tabak enthalten, fallen unter die Tabakproduktrichtlinie. ENDS und Kräuterzigaretten sind keine tabakhaltigen Produkte und



sollten unterthematisch anderweitige Gesetze subsumiert werden, die deren wesentlichen Produkteigenschaften gerechter werden. Diese Produkte könnten zum Beispiel unter die Arzneimittel-oder Lebensmittelgesetze oder ähnliche Gesetze gefasst werden.

#### **which option**

No change

#### **recommend option**

#### **additional comments**

Der VdR ist der Ansicht, dass alle Tabakprodukte von der Tabakproduktrichtlinie erfasst werden sollten. Dies sollte auch neue Tabakprodukte betreffen, die erst in der Zukunft entwickelt und vermarktet werden. Wir möchten unterstreichen, dass der VdR sich gegen einheitliche Rechtsvorschriften für charakteristisch unterschiedliche Tabakprodukte, wie dies in den geplanten Änderungen der Tabakproduktrichtlinie vorgesehen ist, ausspricht. Dieser Ansatz wird der Produktvielfalt und Unterschiedlichkeit auf dem Markt für Tabakerzeugnisse nicht gerecht. Der VdR vertritt Mitgliedsunternehmen, die Feinschnitt, Pfeifentabak, Kau- und Schnupftabak herstellen oder wie bei Zigarren und Zigarillos aus Drittstaaten importieren. Diese Produkte sind zum Teil sehr unterschiedlich in ihren Produkteigenschaften, in ihrer Geschichte, in ihrer Handhabung und im Konsum. Pfeifentabak enthält beispielsweise Additive, die überhaupt nicht oder in geringen Mengen in anderen Tabakprodukten in der Herstellung zugefügt werden. Des Weiteren möchten wir darauf hinweisen, dass eine beachtliche Anzahl der Mitgliedsunternehmen des VdR kleine und mittelständische Unternehmen (KMU) sind, zumeist familiengeführte Unternehmen mit einer langen Tradition. Diese Unternehmen sind wirtschaftlich weitaus stärker von den geplanten Änderungen betroffen als die internationalen Konzerne. Mit der Umsetzung der geplanten Änderungen der Tabakprodukt-Richtlinie würden die Kosten für die kleinen und mittleren Unternehmen überproportional steigen. Zudem müssten die kleinen und mittleren Unternehmen auf kostenintensive externe Expertisen zurückgreifen. Einige Produkte der Mitgliedsunternehmen des VdR, wie beispielsweise der Schnupftabak, werden ausschließlich regional hergestellt. Diese Produkte sind keine Massen-, sondern Nischenprodukte und werden teilweise für einen bestimmten und sehr überschaubaren Konsumentenkreis hergestellt. Schnupftabake haben nur einen sehr geringen Absatzanteil am Gesamtkonsum von Tabakprodukten auf dem Markt für Tabakerzeugnisse. U.a. auch aus diesem Grund möchte der VdR auf die Besonderheiten und die Spezifikationen der Produkte seiner Mitgliedsunternehmen hinweisen mit geringen Marktanteilen und Nischenprodukten. Bereits heute sieht die Tabakprodukt-Richtlinie aus guten Gründen rechtliche Unterschiede in der Umsetzung vor. Dieses grundsätzliche Tatbestandsmerkmal sollte bei der Änderung der Tabakproduktrichtlinie in jedem Fall nachhaltig berücksichtigt werden.

#### **questions smokeless**

#### **problem definition**

No

#### **comments**

In der Problemdarstellung werden die rauchlosen Tabakprodukte als eine homogene Produktgruppe dargestellt, was allerdings nicht den tatsächlichen Gegebenheiten entspricht. Rauchlose Tabakerzeugnisse unterscheiden sich innerhalb ihrer Produktkategorie durch Herstellung und Konsum. Diese Tatbestandsmerkmale werden auch von der

Weltgesundheitsorganisation nicht in Zweifel gezogen. Vielmehr wird die Unterschiedlichkeit von rauchlosen Tabakerzeugnissen generell anerkannt. Dazu heißt es im Bericht der WHO in Bezug auf die Tabakproduktrichtlinie, dass es wissenschaftlich nicht dienlich ist, rauchlosen Tabak als Grundlage für die Risikobewertung und Politikrichtlinien zugrunde zu legen (The Scientific Basis of Tobacco Product Regulation, Second Report of a WHO Study Group, Seite 9, siehe dazu den Link auf der Seite der Weltgesundheitsorganisation:

[http://www.who.int/tobacco/global\\_interaction/tobreg/publications/9789241209519.pdf](http://www.who.int/tobacco/global_interaction/tobreg/publications/9789241209519.pdf).

Nach unserem Dafürhalten können die rauchlosen Tabakprodukte in die Kategorien: traditioneller Kautabak, Schnupftabak und Snus (Schweden) unterteilt werden. In Schweden fällt der Snus in den Anwendungsbereich des Lebensmittelrechts. Innerhalb der EU sind traditionelle Kau- und Nasenschnupftabake verkehrsfähig. Im SCENIHR-Bericht (2008) werden die Gesundheitsauswirkungen der verschiedenen rauchlosen Tabake bezüglich ihrer gesundheitlichen Auswirkungen untersucht. Zum Teil werden generelle Rückschlüsse für diese Kategorien der rauchlosen Tabake im Vergleich zu den übrigen Tabakprodukten gezogen. Wir möchten unterstreichen, dass die Problemdarstellung des SCENIHR-Berichts nur bestimmte Aussagen in Bezug auf die rauchlosen Tabakprodukte gibt und nur diese als allgemeingültig ansieht. Der VdR möchte die Problemdarstellung dahingehend berichtigen, dass die spezifischen Produktmerkmale dieser Tabakerzeugnisse auch entsprechend zugeordnet werden. Die Problemdarstellung geht sowohl von der suchterzeugenden als auch der krebsverursachenden Wirkung aller Tabakprodukte aus. Wir beziehen uns diesbezüglich auf den SCENIHR-Bericht, der sich mit dem Konsum von Schnupftabak beschäftigt, insbesondere die Seiten 92 und 93 des SCENIHR Berichtes von 2008. In diesen Abschnitten wird hervorgehoben, dass in vielen Regionen der Welt der nasale Konsum von Schnupftabak geringer ist als der orale Konsum. Zudem seien wenige Studien verfügbar, die eine Verbindung zwischen dem Konsum von Schnupftabak und einer karzinogenen Erkrankung herstellen. Tatsächlich beziehen sich 3 der 5 angeführten Studien auf Indien, eine auf Tunesien und eine auf Südafrika, die jedoch bis in das Jahr 1955 zurückreicht. Damit wird deutlich, dass der europäische Nasenschnupftabak inhaltlich nicht Gegenstand einer der zitierten Studien ist, die sich mit den gesundheitlichen Folgen des konsumierten Tabaks in diesen Ländern beschäftigt hat. Zudem möchten wir darauf hinweisen, dass in einer Studie bezüglich der gesundheitlichen Folgen des Schnupftabaks, die im Journal of Laryngology & Otology (2003) veröffentlicht wurde, der Schluss gezogen wird, dass es keinen Beweis für eine Verbindung zwischen Kopf-, Hals oder anderen Malignomen und dem Konsum des europäischen Schnupftabaks gibt. Zusätzlich zu dieser Studie wird in dem „IARC Monographs on the Evaluation of Carcinogenic Risks to Humans, Volume 89“ zu rauchlosem Tabak aus dem Jahre 2004 hervorgehoben, dass die Schnupftabak-Studien keinen Beweis für eine Verbindung zu einer Krebserkrankung hervorgebracht haben. Die Problemdarstellung lässt eine klare tatbestandliche Unterscheidung zwischen den einzelnen rauchlosen Tabaken vermissen, so dass falsche Schlussfolgerungen gezogen werden können. In diesem Zusammenhang verweisen wir auf die Veröffentlichung in Beiträge zur Tabakforschung „Smokeless an overview“ (Beiträge zur Tabakforschung International Volume 23, No. 5 September 2009).

#### **which option**

Lifting the ban on snus

#### **additional comments**

Der VdR möchte darauf hinweisen, dass ein Verbot von Tabakprodukten nicht auf der Grundlage „willkürlicher“ politischer Entscheidungen erfolgen kann. Vielmehr können diese nur auf der Grundlage einer wissenschaftlich validen – international anerkannten - Analyse

erfolgen. Der VdR lehnt aufgrund der vorstehend aufgeführten Gründe die Option 3 ab und spricht sich für eine Erlaubnis aller rauchlosen Tabakprodukte aus, um diese in der EU zu vermarkten.

**questions consumer  
problem definition**

No

**explanations**

Bezüglich der Einführung von Bildwarnhinweisen möchten wir anmerken, dass aus dem Hintergrundpapier nicht eindeutig hervorgeht, inwieweit diese Option auf einer freiwilligen Basis erfolgt. Das Hintergrundpapier bringt nicht klar zum Ausdruck, inwieweit es den Mitgliedstaaten überlassen bleiben soll, festzulegen, welcher Ansatz sich als der Beste erweist. Dabei dürften die Mitgliedstaaten ihre spezifischen Marktbesonderheiten, die Konsumentenstruktur und die Marktbedeutung der unterschiedlichen Tabakprodukte nationalstaatlich berücksichtigen. Daher möchte der VdR darauf hinweisen, dass gerade dies der Grund für die freiwillige Einführung der Bildwarnhinweise ist und war. Aus dieser bei den Mitgliedstaaten freiwillig belassenen Option haben sich in der Folgezeit aufgrund unterschiedlicher kultureller Vorgaben unterschiedliche nationale Regelungen ergeben. Eine homogene Regelung in der EU gibt es nicht. Es ist daher für den VdR nicht nachvollziehbar, aus welchem Grund die selbst verursachten Unterschiede in den Mitgliedstaaten nunmehr zu einer Störung des Binnenmarktes führen. Es ist weiterhin im Ermessen der Mitgliedstaaten, die Bildwarnhinweise für alle oder für einige Tabakproduktkategorien zuzulassen. Der VdR widerspricht den Ausführungen, wonach die Gestaltung der Verpackung von Tabakerzeugnissen dazu dient, die Attraktivität gegenüber Konsumenten zu erhöhen und um das Markenimage und den Absatz zu fördern. Der VdR lehnt bereits die Verwendung des Begriffes „Attraktivität“ als zulässiges regulatorisches Ziel ab, da es sich um subjektive Kriterien handelt, die nicht justiziabel sind. Die Gestaltung der Verpackung von Tabakprodukten führt weder zum Beginn des Tabakkonsums noch hat sie einen entscheidenden Einfluss auf das Absatzvolumen. In diesem Zusammenhang möchten wir darauf hinweisen, dass der wesentliche Anteil der Konsumenten von Feinschnitttabaken älter als 35 der von Pfeifentabaken älter als 40 Jahre ist. Zudem muss sich ein Produkt bereits aus zwingenden markenrechtlichen Gründen von anderen Produkten unterscheiden. Die Packungsgestaltung bei Tabakerzeugnissen dient, wie in allen anderen Produktsegmenten, markenrechtlich der Unterscheidung der Marken und der Unterschiedliche der Tabakerzeugnisse. Die Verpackung und die Marke ermöglichen es dem Konsumenten, sein Produkt zu identifizieren. Der Hersteller bietet dem Kunden mithilfe der Verpackung die Möglichkeit, seine Kaufentscheidung für ein bestimmtes Produkt z.B. Feinschnitt in den verschiedenen Geschmacksvarianten, wie bei Kaffee oder Tee, zu treffen. Tabakprodukte werden in unterschiedlichen Spezifikationen und Qualitäten angeboten. In Deutschland beispielsweise werden 300 verschiedene Feinschnitttabakmarken und Pfeifentabake mit 700 unterschiedlichen Marken angeboten. Diese Vielzahl von unterschiedlichen Produkten werden überwiegend in unterschiedlichen Verpackungsformaten angeboten. Die Verpackungen unterscheiden sich durch unterschiedlich verwendete Verpackungsmaterialien und unterschiedliche Größen der Verpackung. Aufgrund der geringen Umschlagrate im Handel und der langen Verpackungsbevorratung sehen sich die meisten der Mitgliedsunternehmen des VdR erheblichen technischen Schwierigkeiten bei einer Änderung der Warnhinweise ausgesetzt. Der VdR möchte in diesem Zusammenhang darauf hinweisen, dass der Rat schon am 30.11.2009 den juristischen Dienst der Kommission beauftragt hat, Einführung des Plain Packaging juristisch umfassend, unter anderem auch unter Einbeziehung der

Binnenmarktproblematik, zu prüfen. Der VdR unterstreicht in dem Zusammenhang, dass nach wie unklar ist, ob eine solche rechtliche Analyse erfolgt ist oder inwiefern die Ergebnisse veröffentlicht worden sind. Aus diesem Grund regen wir an, die Wirksamkeit, die Rechtmäßigkeit und die Verhältnismäßigkeit näher zu untersuchen bevor Maßnahmen von dieser Reichweite und diesen Auswirkungen ins legislative Verfahren eingebracht werden.

#### **which option**

No change

#### **additional comments**

Grundsätzlich befürwortet der VdR das Bestreben, den präventiven Gesundheitsschutz zu stärken. Dabei sind die Grundsätze einer evidenzbasierten wissenschaftlichen Zielsetzung strikt einzuhalten. Auch hier gilt es die produktspezifischen Eigenschaften der einzelnen Tabakerzeugnisse eindeutig zu deklinieren. Gesundheitsinformationen müssen dem Grundsatz der Verhältnismäßigkeit entsprechen und dürfen nicht zu einer Irreführung des Konsumenten führen. Der VdR ist der Ansicht, dass die derzeitige Größe der Warnhinweise nebst den Sprachhinweisen ausreichend ist und es damit keiner Änderung bedarf. Auch ist uns nicht bekannt, dass wissenschaftlich fundierte Studien für Feinschnitt und Pfeifentabak vorliegen, die unsere Feststellung widerlegen. Der VdR spricht sich daher gegen eine Vergrößerung der Warnhinweise aus. Gleiches gilt für die verpflichtende Einführung von Bildwarnhinweisen, da keine evidenzbasierten Fakten vorliegen. Zudem würde dies zu erheblichen Mehrbelastungen der KMU führen. Der VdR möchte betonen, dass die Vergrößerung der Warnhinweise auf den Verpackungen ebenfalls die Rechte aus dem geistigen Eigentum der Unternehmen beeinträchtigt. Wir sind der Ansicht, dass es die Aufgabe der Gesetzgeber ist, im Rahmen der Tabakprävention insbesondere Jugendliche über den Konsum von Tabakerzeugnissen aufzuklären. Die Einführung von Bildwarnhinweisen hat in den Mitgliedstaaten nicht zu einem signifikanten Konsumrückgang geführt. Alle Literaturquellen beziehen sich ausschließlich auf die Fabrikzigarette und deren Konsumenten. Daher lassen diese Ergebnisse keinen Rückschluss auf den Konsum von Feinschnitt und Pfeifentabak zu. (In Belgien wurden die Bildwarnhinweise verpflichtend ausschließlich für Zigarettenverpackungen eingeführt.) Grundsätzlich wäre auch die Verpflichtung, Inserts beizufügen mit erheblichen Schwierigkeiten verbunden. Dies trifft einerseits die Kleinpäckchen von Kau- und Schnupftabaken, andererseits handelt es sich bei Feinschnitt und Pfeifentabaken um „losen“ Tabak, so dass eine mögliche Reaktion zwischen Insert und Tabak zunächst wissenschaftlich untersucht werden müsste. Unsere Mitgliedsfirmen sind verpflichtet, ihre Rezepturen für Konsumenten unter Wahrung des Geschäftsgeheimnisses offen zu legen; von daher erschließt sich für den VdR der Sinn eines Inserts nicht. Beispielsweise hat das BMELV einen Internetauftritt bereitgestellt, über den sich die Konsumenten hinreichend informieren können: [http://service.ble.de/tabakerzeugnisse/index2.php?site\\_key=153&site\\_key=153](http://service.ble.de/tabakerzeugnisse/index2.php?site_key=153&site_key=153) Der VdR ist der Ansicht, dass die Einführung der Einheitsverpackung (Plain Packaging) unangemessen und ungerechtfertigt ist. Die verpflichtende Einführung einer Einheitsverpackung würde die Verträge der Europäischen Gemeinschaft, die Vorschriften bezüglich der gewerblichen Schutzrechte sowie das deutsche Verfassungsrecht verletzen. Dies gilt insbesondere in Bezug auf die Verpflichtungen aus Artikel 34 AEUV, Artikel 12 GG (Berufsfreiheit), Artikel 14 GG (Eigentum) und Artikel 5 GG (Meinungsfreiheit). Zudem müssen die europarechtlichen Grundsätze der Subsidiarität mit herangezogen werden. Grundsätzlich – und insbesondere im Hinblick auf das Funktionieren des Binnenmarktes – haben die Unternehmen das Recht (und die Pflicht), ihre Produkte von anderen unterscheidbar zu gestalten, um zu gewährleisten, dass erwachsene Konsumenten in angemessener Weise ihre Kaufentscheidung treffen können. Das

die Einführung von Einheitsverpackungen den Zielen des Jugendschutzes gerecht wird, ist aus unserer Sicht nicht verifiziert. Außerdem besteht die Gefahr, dass sich das Schmuggelpotenzial aus Drittstaaten erhöht. Der VdR bittet die Kommission, die Folgen abzuschätzen, die aus der Einführung der Einheitsverpackung in Bezug auf den illegalen Handel entstehen können (auch unter Berücksichtigung sinkender Tabaksteuereinnahmen aufgrund des Schmuggels zu prüfen).

### **questions on reporting**

#### **problem definition**

No

#### **explanations**

Mit Blick auf die Problemstellung fallen die Meldemechanismen von Mitgliedstaat zu Mitgliedstaat tatsächlich unterschiedlich aus. Unklar ist, welche Schwierigkeiten jeder einzelne Mitgliedstaat bei der Analyse der Daten als Folge seines eigenen Meldeformats hat. In der Richtlinie über Tabakerzeugnisse aus dem Jahr 2001 wurde keine spezifische Bewertung der zur Verfügung gestellten Informationen seitens der Herstellern vorgesehen (Dokument zum öffentlichen Konsultationsverfahren, Seite 2, 5. Absatz). Die veröffentlichten Leitlinien nach Verabschiedung der Richtlinie lassen letztendlich offen, wie die Zusatzstoffdaten zu melden sind. Der VdR möchte auch darauf hinweisen, dass die mittelständischen Mitgliedsfirmen nicht nur eine erhebliche wirtschaftliche Belastung durch die Unterschiede in der Berichtspflicht haben, insbesondere dann, wenn entweder keine Leitlinien vorgesehen sind oder wenn EU-weit verschiedene Meldeformate verwendet werden müssen. Das harmonisierte Format zur Mitteilung der Zusatzstoffe kommt nach Angaben des Bundesamtes für Verbraucherschutz und Lebensmittelsicherheit (BVL) von über 90 Prozent der meldepflichtigen Unternehmen zur Anwendung. Allerdings wäre es wünschenswert, eindeutige Definitionen zu verwenden, um den Unternehmen ein deutliches Mehr an Rechtssicherheit im Binnenmarkt zu gewährleisten. Außerdem erachten wir es als dringend geboten, im Rahmen der Offenlegung der Rezepturen, die Wahrung des Geschäftsgeheimnisses (Art. 14 GG) rechtlich eindeutig zu regeln. Insgesamt bewerten wir die Empfehlung der Kommission zu den harmonisierten Meldeformaten als einen ersten richtigen Schritt, der aber der weiteren Modifizierung und Konkretisierung bedarf. Darüber hinaus erscheint es insbesondere mit Blick auf die KMUs notwendig, die Kosten der Meldeverfahren in einer angemessenen Höhe zu begrenzen, unabhängig von der Vorgehensweise der einzelnen Mitgliedstaaten. Die Hersteller von Rauchtobaken haben im Zuge der Beratungen und vor der Verabschiedung der Richtlinie 2001/37/EG auf die bestehende Problematik hingewiesen. Dem wurde auch dadurch Rechnung getragen, dass nur die toxikologischen Daten zu melden sind, die auch verfügbar sind. Der Umfang der Meldungen sollten daher auch in Zukunft die produktspezifischen Unterschiede zwischen den einzelnen Tabakerzeugnissen berücksichtigen.

#### **which option**

Establish a common compulsory reporting format

#### **additional comments**

Option 3 kann seitens des VdR nicht unterstützt werden. Wir weisen darauf hin, dass dies keine "Stand-alone"-Option sein kann. Diese könnte nur eingeführt werden, wenn ein gemeinsames Meldeformat Gültigkeit hätte. Inwieweit Gebühren oder strafbewährte Sanktionen anfallen, sollte dies schon aus Gründen des Rechtsgrundsatzes der Justiziabilität in den Mitgliedstaaten verbleiben. Option 2 wird seitens des VdR unterstützt. Wir

unterstützen das Prinzip der gemeinsamen Meldeformats zur Meldung der Zusatzstoffe sowie den Grundsatz einer nachhaltigen, robusten und sicheren elektronischen Datenbank auf der Basis des derzeit entwickelten EMTOC-Systems. Der VdR würde eine Initiative der Kommission begrüßen, den "Practical Guide" verbindlich für alle Mitgliedstaaten vorzuschreiben sowie das EMTOC-System mit einzubeziehen. Der VdR schlägt daher einen maximalen Harmonisierungsansatz vor. Dabei sollte die Datenübertragung, wie dies freiwillig derzeit über das EMTOC-System erfolgt, auf eine legale und justiziable Rechtsgrundlage gestellt werden. Die Mitgliedsfirmen des VdR sind gerne bereit, beratend an der Fortentwicklung der Meldeformate und der Datenübertragung gegenüber der Kommission mitzuwirken. Der VdR ist der Auffassung, dass das EMTOC-System unter Einbeziehung der Hersteller und Importeure von Tabakerzeugnissen zusammen mit den abgestimmten Dokumenten, wie Instruktionen, Nutzungsbedingungen sowie dem angemessenen Schutz der wettbewerbsrelevanten Geschäftsgeheimnissen, weiter entwickelt werden sollte.

### **regulation of ingredients**

#### **problem definition**

No

#### **explanations**

Der VdR stimmt der Problemdarstellung nicht zu, da die gesundheitlichen Bewertungen der eingesetzten Zusatzstoffe überschätzt werden. Die in Deutschland verwendeten Zusatzstoffe ergeben sich – wie in vielen Mitgliedstaaten – aus einer Positiv-/Negativliste der Tabakverordnung, Anlage 1. In der Problemdarstellung wird darauf hingewiesen, dass „attraktive“ Stoffe den Tabakerzeugnissen zugesetzt werden. Aus grundsätzlichen Erwägungen lehnen wir den Begriff der „Attraktivität“ ab, da es an objektiven, wissenschaftlich validierten Kriterien fehlt, die als Basis für rechtsverbindliche Regelungen zur Produktbeschaffenheit herangezogen werden können. Wie bei anderen Verbrauchsgütern werden Zusatzstoffe bei Tabakerzeugnissen verwendet, um die Vielfalt der Produkte zu gewährleisten. So ist es zum Beispiel für Pfeifenraucher wichtig, die Geschmacksvielfalt sensorisch bewerten zu können. Aus unserer Sicht liegen in der Literatur keine belastbaren Beweise dafür vor, dass Zusatzstoffe in den verwendeten Mengen Substanzen enthalten, die sich krebserzeugend oder erbgutverändernd auswirken. Einzelne Bestandteile der Pyrolyse eines Tabakerzeugnisses sind nicht ausreichend, um einzelne Zusatzstoffe wissenschaftlich objektiv als karzinogen zu beurteilen. International anerkannte Normen für die Bewertung der Rauchbestandteile im Hauptstromrauch bestehen unseres Wissens nach nicht. Jedoch zeigen verfügbare toxikologische und epidemiologischen Daten für Produkte mit und ohne Zusatzstoffe (USA vs Kanada) keinen Unterschied in den Krankheitsbildern. Allerdings ist die Darstellung richtig, dass diejenigen Mitgliedstaaten, die Regelungen für Zusatzstoffe getroffen haben, Zusatzstoffe auf verschiedenen wissenschaftlichen Grundlagen genehmigt haben. Von daher würden wir es begrüßen, wenn einheitliche international anerkannte Bewertungskriterien von der Kommission erarbeitet werden, die auch Rücksicht auf die Kostenstruktur der KMU nehmen.

#### **which option**

No Change

#### **additional option**

Aus unserer Sicht ist keine der Optionen geeignet, die Problemfelder eindeutig zu bewerten und abzubilden. Erst wenn international anerkannte Bewertungskriterien vorliegen, folgt die Frage, ob eine gemeinsame Positiv- und/oder Negativliste das geeignete rechtliche Instrument

der Vorgabe ist. Dabei sollte jede Methode Untersuchungen zu den Auswirkungen von Zusatzstoffen für den jeweiligen Zusatzstoff, aber auch für die Gesamtheit der verwendeten Zusatzstoffe in Tabakerzeugnissen beinhalten. Schließlich möchten wir darauf hinweisen, dass die Toxizität auch dahingehend zu prüfen ist, inwieweit damit die Risiken des Rauchens erhöht werden. Der VdR unterstützt die geltende Definition von Zusatzstoffen in Artikel 2 (5) der Richtlinie 2001/37/EG für " jeder bei der Herstellung oder Zubereitung eines Tabakerzeugnisses verwendete und im Endprodukt, auch in veränderter Form, noch vorhandene Stoff oder Bestandteil einschließlich Papier, Filter, Druckerschwärze und Klebstoffe, jedoch mit Ausnahme des Tabakblatts und anderer natürlicher oder nicht verarbeiteter Teile der Tabakpflanze." Eine gemeinsame Additivliste könnte seitens des VdR unterstützt werden, jedoch sollten vorab die Voraussetzungen der Bewertungsmethode und -kriterien definiert und erfüllt werden. Bezüglich der Beurteilung von Zusatzstoffen ist der VdR der Auffassung, dass jede Entscheidung über ein Verbot der Verwendung eines bestimmten Zusatzstoffes auf eine vollständige wissenschaftliche Beurteilung beruhen muss, nämlich ob der Zusatzstoff die Risiken, die mit dem Rauchen assoziiert werden, erhöht. Um das Verbot eines Zusatzstoffes zu prüfen, ist die Kommission verpflichtet, eine klare Definitionen und wissenschaftliche Grundlagen für ein solches Vorgehen zu entwickeln, gefolgt von einer umfassenden wissenschaftlichen Bewertung. In diesem Zusammenhang sollte die Kommission die wissenschaftlichen Prinzipien, gemeinsam entwickelt von der WHO / FAO Codex Alimentarius Kommission (CAC), berücksichtigen. Der VdR unterstützt die Anwendung des wissenschaftlichen Prinzips der "inhalation threshold of toxicological concern" für die Bewertung der Inhaltsstoffe von Tabakerzeugnissen. Das Prinzip des toxikologisch relevanten Schwellenwerts wird erfolgreich international auf die sicherheitstechnische Beurteilung von vielen chemischen Stoffen und Zusatzstoffen angewendet. Hinsichtlich der Zusatzstoffe und der gesundheitlichen Risiken ist der VdR der Ansicht, dass aufgrund der derzeit verfügbaren Informationen und wissenschaftlichen Belege, die verwendeten Zusatzstoffe, keinen Hinweis auf potentielle Schäden des Tabakkonsums darlegen und auch keine differenzierte Aussage dazu treffen, dass Zusatzstoffe dafür kausal sind, ob Konsumenten mit dem Rauchen beginnen oder aufhören. Es gibt infolge dessen keine wissenschaftlichen Belege dafür, dass das Rauchen von Tabakerzeugnissen mit oder ohne Zusatzstoffe zu unterschiedlichen Gesundheitsrisiken führt. Schließlich gibt es keine zuverlässige wissenschaftliche Grundlage, dass einige Zusatzstoffe die Sucht verstärken können. Aus grundsätzlichen Erwägungen sind wir der Ansicht, dass neue Rechtsvorschriften nur für die Erzeugnisse gelten, die in der EU vermarktet werden, nicht aber auf Tabakerzeugnisse, die in der EU für den Export hergestellt werden. Viele Tabakerzeugnisse, die in unseren Mitgliedsfirmen hergestellt werden, sind für den Export in Drittländer bestimmt. Dabei beachten die Unternehmen die jeweilige Gesetzgebung in diesen Ländern sowie die dort gegebenen Präferenzen der Konsumenten für das jeweilige Tabakprodukt, die im Wesentlichen auch auf kulturelle Unterschiede beruhen. Eine weitergehende Rechtswirkung von EU-Richtlinien – die nicht mit der Gesetzgebung im Exportland kongruent sind, führt de facto zu einem Exportverbot und gefährdet Arbeitsplätze innerhalb der EU. Abschließend möchte der VdR darauf hinweisen, dass sich die Kommission, das Parlament und der Rat auf das Fachwissen unserer Mitgliedsfirmen stützen können.

### **access to tobacco products**

#### **problem definition**

No

#### **explanations**

Im Hinblick auf die grenzüberschreitenden Verkäufe von Tabakprodukten im Internet, weist

der VdR darauf hin, dass dieses Thema bereits von der Richtlinie 2008/118/EG abgedeckt ist. Diese Richtlinie befasst sich mit dem allgemeinen Verbrauchssteuersystem und speziell in Artikel 3 mit den Fernverkäufen. Wir möchten ausdrücklich darauf hinweisen, dass das Präsentationsverbot (Display ban) von Tabakprodukten im Handel mangels Binnenmarktrelevanz nicht in die legislative Zuständigkeit der EU fällt. In dem Zusammenhang dürfen wir daran erinnern, dass die Kommission die Grundsätze der Subsidiarität (Art. 5 Lissabon Vertrag) zu berücksichtigen hat. Ein solches Präsentationsverbot würde daneben auch die legal erworbenen gewerblichen Schutzrechte (Markenrechte) – Verdecken der Marke - unmittelbar verletzen. Auch im Interesse der Kommission erwarten wir eine substantiierte juristische Bewertung der von uns aufgeworfenen Fragen.

### **which option**

No change

### **additional comments**

Der VdR geht von der Mündigkeit Erwachsener aus, persönliche Entscheidungen treffen zu können. Von daher befürworten wir ein Verkaufsverbot von Tabakerzeugnissen an Jugendliche unter 18 Jahren, wie dies bereits in den meisten Mitgliedstaaten gilt. Aufgrund der hoheitlichen Befugnisse der Mitgliedstaaten haben diese die Eingriffsgewalt bei einem Missbrauch. Aufgrund des technischen Fortschritts ist es zum Beispiel in Deutschland möglich, jugendsichere Zigarettensautomaten aufzustellen. Da es sich um nationalstaatliche Entscheidungen handelt, sehen wir die Binnenmarktrelevanz als nicht gegeben an. Vielmehr fällt die Fragestellung in den Bereich der Subsidiarität. Generell ist die Präsentation eines Produktes im Handel ein essentieller Bestandteil des Kaufvorganges. Der Wunsch des Konsumenten, das Produkt in Augenschein nehmen zu können, ist besonders beim Ersterwerb oder bei Neueinführungen von Produkten gegeben. Mit der Präsentation im Handel erhält der Kunde die Möglichkeit, das von ihm gewünschte Produkt zu identifizieren bzw. zu sehen, ob es überhaupt erhältlich ist. Von einem Präsentationsverbot werden insbesondere kleinere Produktgattungen, wie z.B. Pfeifentabake oder Zigarren mit einer Vielzahl unterschiedlicher Marken, betroffen sein. Tabakerzeugnisse sind insbesondere in Mitgliedstaaten, wie in Deutschland, beratungsintensiv. Ein Präsentationsverbot würde letztlich in den derzeit bestehenden Wettbewerb im Handel und auf Hersteller/Importeure eingreifen. Der VdR betrachtet das Präsentationsverbot als eine gravierende Einschränkung des erwachsenen, informierten Konsumenten, eine Kaufentscheidung für ein legales Produkt aus einer breiten Markenvielfalt, verschiedenen Preiskategorien bzw. neuen Produkten zu treffen. Die Folgen hieraus gehen eindeutig zu Lasten der Hersteller /Importeure sowie des Handels. Das teilweise oder gänzliche Präsentationsverbot von Tabakprodukten im Handel bedeutet einen ungerechtfertigten und unangemessenen Eingriff in die Berufsfreiheit der Hersteller und Einzelhändler, einen Eingriff die Meinungsfreiheit und eine Beeinträchtigung des verfassungsrechtlich geschützten Eigentums. Nach einer neueren Studie die vom Institute of Economic Affairs herausgegeben worden ist, führt das Präsentationsverbot nicht zu einem Rückgang des Tabakkonsums (<http://www.iea.org.uk/files/upld-book517pdf?.pdf>.) Erfahrungen in Irland zeigen darüber hinaus, dass der Verkauf illegal gehandelter Produkte zunimmt, mit der Folge von Einnahmeverlusten aus der Tabaksteuer. Zudem sollte nicht außer acht gelassen werden, dass die illegal verbrachten Tabakerzeugnisse nicht den Rechtsvorschriften in den Mitgliedstaaten entsprechen. Der VdR befürchtet, dass das Präsentationsverbot dem verbotenen Handel von Tabakprodukten Vorschub leistet, da die Konsumenten dadurch noch weniger die legalen von den illegalen Produkten unterscheiden



können. Infolge der fehlenden Binnenmarktrelevanz erachten wir die Einführung eines Präsentationsverbots auf EU-Ebene ohnehin nicht als EU-konform.

---

## **NGO submission**

### **identification**

#### **affiliation**

NGO

#### **name**

Cyprus Association of Convenience Stores

#### **email**

andreastheo@netmail.com.cy

#### **country**

Cyprus

### **questions scope**

#### **problem definition**

Yes

#### **which option**

No change

### **questions smokeless**

#### **problem definition**

Yes

#### **which option**

Lifting the ban on snus

### **questions consumer**

#### **problem definition**

No

### **explanations**

We believe that this will increase smuggling, as the illegal selling of the same package becomes easier. Especially in Cyprus, where we already face major problems regarding tobacco products smuggling, derived from the areas that are not under the control of the Republic of Cyprus. We believe that this measure will increase smuggling. We also believe that the same appearance of all the tobacco products will cause delays and difficulties in servicing our customers

#### **which option**

Improve consumer information

#### **which improvement**

Picture warnings to become mandatory

**additional comments**

In addition, we believe that once the product is legal, should not be subject to restrictions on its trade. Otherwise soft drinks, which are also harmful to health, should be under same constrictions

**questions on reporting**

**problem definition**

Yes

**which option**

No change

**regulation of ingredients**

**problem definition**

Yes

**which option**

No Change

**access to tobacco products**

**problem definition**

No

**explanations**

Any introduction of such legislation would impose significant additional cost for our businesses, due to the inevitable rearrangement and creation of new store places for the tobacco products. The members of our Association are small businesses that already face serious problems of survival. The financial crisis and the additional taxes imposed by the government in tobacco products combined with such a measure would be harmful for us. Furthermore, we believe that by creating a new storage place for tobacco products, customer service will be delayed and become more difficult. This is contrary to the philosophy of convenience stores aiming to serve their customers instantly and properly.

**which option**

No change

**additional comments**

These measures were applied in other countries as well and did not contribute to the reduction of smoking. On the contrary, evidence proves that the consumption of tobacco products by minors increased, mainly due the prohibitive way of presenting a product (Canada, Ireland).

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**NGO submission**

**identification**

**affiliation**

NGO

**name**

Forum Rauchfrei

**email**

aktionszentrum@forum-rauchfrei.de

**country**

Germany

**questions scope****problem definition**

Yes

**which option**

Extend the scope of the Directive

**questions smokeless****problem definition**

Yes

**which option**

Ban on all types of smokeless tobacco products

**questions consumer****problem definition**

Yes

**which option**

Improve consumer information; Introduce generic or plain packaging

**which improvement**

Picture warnings to become mandatory; Tar, nicotine and carbon monoxide levels to be replaced with general information on harmful substances in tobacco products; Information on harmful substances in tobacco products that cannot be placed on the package would be placed inside the package; Health warnings to be put on water pipes

**questions on reporting****problem definition**

Yes

**which option**

Establish a common compulsory reporting format; Introduce fees and sanctions

**regulation of ingredients****problem definition**

Yes

**which option**

Establish a common list of tobacco ingredients

**which one**

Establish a negative common list of tobacco ingredients

**access to tobacco products****problem definition**

Yes

**which option**

Ban

**which one2**

Vending machines to be banned; Promotion and displays in retail stores to be banned

---

**NGO submission****identification****affiliation**

NGO

**name**

Stefan gryska

**email**

enigma-b@t-online.de

**country**

Germany

**age**

65

**gender**

male

**questions scope****problem definition**

No

**explanations**

Kein Kommentar

**which option**

Extend the scope of the Directive

**recommend option**

Nicht Verpflichtent

**questions smokeless  
problem definition**  
Yes

**which option**  
No change

**questions consumer  
problem definition**  
No

**explanations**  
Nicht Verpflichtent

**which option**  
No change

**additional option**  
Nicht Verpflichtent

**questions on reporting  
problem definition**  
Yes

**which option**  
Introduce fees and sanctions

**regulation of ingredients  
problem definition**  
Yes

**which option**  
Establish a common list of tobacco ingredients

**which one**  
Establish a negative common list of tobacco ingredients

**access to tobacco products  
problem definition**  
Yes

**which option**  
No change

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**NGO submission**

**identification  
affiliation**

NGO

**name**

Füstölgők Társasága (Smokers' Society)

**email**

info@fustolgotok.eu

**country**

Hungary

**questions scope**

**problem definition**

Yes

**which option**

No change

**recommend option**

Fontosnak tartjuk, hogy tilalmakat csakis tudományosan megalapozott eredmények alapján fogalmazzanak meg!

**questions smokeless**

**problem definition**

Yes

**which option**

Lifting the ban on snus

**questions consumer**

**problem definition**

No

**explanations**

Nincs egyértelmű bizonyíték a hatékonyságra. Aggályos, hogy a feketepiac erősödését hozza magával.

**which option**

No change

**questions on reporting**

**problem definition**

No

**explanations**

Tudomásunk szerint ez a kérdés tagországi szinten szabályozott.

**which option**

Establish a common compulsory reporting format

**regulation of ingredients****problem definition**

No

**explanations**

Az attraktivitás szubjektív kategória. Nincs bizonyíték arra, hogy az összetevők fokoznák a rászakás esélyét.

**which option**

No Change

**access to tobacco products****problem definition**

No

**explanations**

A kereskedelmi szabadságot veszélyezteti. Nem ismerünk olyan tanulmányokat, amelyek igazolnák, hogy egészségügyileg hatásos lenne.

**which option**

No change

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**NGO submission****identification****affiliation**

NGO

**name**

Deutsche Kinderhilfe e.V.

**email**

info@kinderhilfe.de

**country**

Germany

**questions scope****problem definition**

Yes

**which option**

Extend the scope of the Directive

**questions smokeless****problem definition**

Yes

**which option**

Ban on all types of smokeless tobacco products

**questions consumer****problem definition**

Yes

**which option**

Improve consumer information

**which improvement**

Picture warnings to become mandatory; Tar, nicotine and carbon monoxide levels to be replaced with general information on harmful substances in tobacco products; Information on harmful substances in tobacco products that cannot be placed on the package would be placed inside the package; Health warnings to be put on water pipes

**questions on reporting****problem definition**

Yes

**which option**

Introduce fees and sanctions

**regulation of ingredients****problem definition**

Yes

**which option**

Establish a common list of tobacco ingredients

**which one**

Establish a positive common list of tobacco ingredients; Establish a negative common list of tobacco ingredients

**access to tobacco products****problem definition**

Yes

**which option**

Controlled supply and access

**which supply and access**

Age verification of buyers and other legal conditions to be set for cross-border retail sale; Access to vending machines to be restricted to adults

**additional comments**

We recommend further to establish an age verification especially for kids and young adults.

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## **NGO submission**

### **identification**

#### **affiliation**

NGO

#### **name**

Land

#### **email**

k.d.land@gastroland.de

#### **country**

42659 Solingen

#### **gender**

male

#### **questions scope**

#### **problem definition**

Yes

#### **which option**

No change

#### **recommend option**

nein

#### **additional comments**

Nein

#### **questions smokeless**

#### **problem definition**

No

#### **which option**

No change

#### **additional comments**

nein

#### **questions consumer**

#### **problem definition**

No

#### **explanations**

Keine Bevormundung der Bürger!

#### **which option**

No change

**questions on reporting  
problem definition**

No

**explanations**

Keine Bevormundung

**which option**

No change

**regulation of ingredients  
problem definition**

Yes

**which option**

No Change

**access to tobacco products  
problem definition**

Yes

**which option**

No change

---

**NGO submission**

**identification**

**affiliation**

NGO

**name**

Andrea Dickens Acting Director, Smokefree South West

**email**

andrea.dickens@smokefreesouthwest.org.uk

**country**

UK

**questions scope  
problem definition**

Yes

**which option**

Extend the scope of the Directive

**recommend option**

We recommend the following: + Extend the scope of the Directive to include all smoked products including herbal cigarettes. + Do NOT extend the Directive to include electronic nicotine delivery systems (ENDS or E-cigarettes).

**additional comments**

It is the combustion process and inhalation of smoke that causes most of the harm from smoking. Therefore it is appropriate that herbal cigarettes, which are used in a similar way to nicotine cigarettes, are regulated in the same way as smoked tobacco products, and should be included in the scope of the Directive. Therefore we recommend that the scope of the Directive includes the regulation of any new smoked tobacco products (such as low emission or nicotine-free cigarettes). Novel nicotine based products (that is, products containing nicotine but not tobacco products) have the potential to offer a less hazardous alternative to cigarettes. Currently these include e-cigarettes and nicotine gel. However, as such products are generally marketed as alternatives to cigarettes and in some cases as an aid to quitting smoking, it is appropriate for them to be brought under the same regulatory framework as pharmaceutical products rather than under the scope of the tobacco products directive. The question of how nicotine containing products should be controlled is currently under consideration by the UK's Medicines and Healthcare Regulatory Authority (MHRA) following a recent public consultation on whether to extend its remit on the regulation of nicotine replacement therapies to other nicotine containing products. The outcome of this consultation may assist the Commission in developing its policy on these products.

**questions smokeless****problem definition**

Yes

**which option**

No change

**additional comments**

With regard to smokeless products that are not currently illegal, particularly those used by ethnic minority populations, we recommend that they are more tightly regulated but we do not support a total ban on such products. Whilst recognising that such products are harmful, the introduction of an EU-wide ban could create an illegal market that would be more difficult to control than the current situation. Furthermore a ban would make it more difficult to engage with users to offer help in quitting.

**questions consumer****problem definition**

Yes

**which option**

Improve consumer information; Introduce generic or plain packaging

**which improvement**

Picture warnings to become mandatory; Tar, nicotine and carbon monoxide levels to be replaced with general information on harmful substances in tobacco products; Health warnings to be put on water pipes

### **additional option**

The minimum size of health warnings should be increased to 80% of the front and back surfaces of all tobacco packaging.

### **additional comments**

**Picture Warnings** We strongly recommend that picture warnings should be mandatory and that they should occupy a minimum of 80% of the front and back surfaces of all tobacco packaging (i.e. not just cigarettes). The warnings should be placed on the upper portion of the packs for maximum visibility. The current situation with some Member States adopting picture warnings whilst others have not done so has created a discrepancy and uneven health protection across the EU. From an internal market perspective, the differences in rules are contrary to the operation of the single market and may constitute a barrier to trade. These obstacles should therefore be removed and pictorial health warnings should be mandatory to ensure optimum health protection for all EU citizens. There is good evidence to show that health warnings are effective in conveying the dangers of smoking and helping smokers to quit. They also help deter young people from starting to smoke. Picture warnings are more effective than written warnings.<sup>2</sup> All warnings should be displayed in rotation so that each message is given equal display to reach its target audience. There is widespread consumer support for pictorial health warnings. A Eurobarometer survey conducted in October 2009 showed that 78% of respondents supported health warnings. Information on tar, nicotine & carbon monoxide (TNCO) Currently the Directive requires the inclusion of machine-based tar, nicotine and carbon monoxide yields on cigarette packs. This promotes the mistaken beliefs that some cigarette brands are less harmful than others and that nicotine causes disease. The EU should not only remove this requirement from the Directive but should prohibit ISO or any other emissions numbers on the pack. We support the proposal to replace numerical measurements with descriptive information on the hazardous effects of tobacco constituents and emissions. The addition of a quitline telephone service should be included on the packaging. Additional information on harmful substances in tobacco products We support the proposal to include additional information on the health effects of tobacco consumption on inserts inside the packaging. This should include advice on quitting smoking. Health warnings on water pipes There is a growing body of evidence to show that water pipes are at least as hazardous, if not more so, than other forms of tobacco use. However, there is a common perception that tobacco smoke is 'cleansed' by the water and therefore not as dangerous and some users believe flavoured shisha is not in fact tobacco. It is important that these myths are countered by requiring the inclusion of a health warning on all water pipes. Warnings should also be included on the packaging of tobacco used in water pipes. Generic or plain packaging We strongly recommend the introduction of plain or generic packaging. This should include not only the removal of all branding from the packaging but the size and shape of the packaging should also be standardised. Not only would this prevent the promotion of smoking through branding as occurs presently but it would reinforce the health warning messages. The Australian federal government has recently announced its intention to introduce plain packaging in 2012, setting a standard that the EU should follow. Tobacco packaging provides a direct link between consumers and manufacturers and is the main marketing channel, particularly in jurisdictions with tobacco advertising bans. Branding gives the misleading impression some cigarettes are safer than others. The tobacco industry claims that plain packaging would contravene intellectual property law. However, legal analysis for Action on Smoking and Health concludes that this is incorrect and there are no legal impediments to the implementation of generic packaging in the EU.

### **questions on reporting**

**problem definition**

Yes

**which option**

Establish a common compulsory reporting format

**additional comments**

The current situation which allows different formats and reporting mechanisms is unsatisfactory, making it difficult for authorities to compare and analyse the data. Tobacco companies should be required to use a standardised reporting format. Additionally the companies should be required to pay a yearly registration fee to cover the costs of administering this data collection. The above measures should be compliant with Articles 9 & 10 of the Framework Convention on Tobacco Control (FCTC).

**regulation of ingredients****problem definition**

Yes

**which option**

Establish a common list of tobacco ingredients

**which one**

Establish a positive common list of tobacco ingredients

**additional comments**

We support the adoption of a positive common list of tobacco ingredients. Tobacco products are highly toxic and addictive; their contents should therefore be regulated in order to achieve high standards of health protection. A positive common list would ensure that only registered products, with ingredients, flavourings and additives that appear on the positive list would be permitted on the EU market. Currently, EU citizens are not subject to the same level of health protection and a common list of permitted ingredients would go some way towards addressing this anomaly. The tobacco industry uses a range of additives to alter the composition of tobacco products. These can make the product more palatable to children or increase the addictiveness of the product. Therefore any flavourings that may be used to enhance the addictiveness or attractiveness of tobacco products should be banned. The revised Product Directive should be fully compliant with the guidelines on Articles 9 & 10 adopted at the fourth Conference of the Parties of the FCTC on 20th November 2010.

**access to tobacco products****problem definition**

Yes

**which option**

Ban

**which one2**

Cross-border retail sales of tobacco to be banned over the Internet; Vending machines to be banned; Promotion and displays in retail stores to be banned

**additional option**

The EU Directive should follow the lead set by Finland which, as part of its recently passed Tobacco Act, has set limits on the amount of tobacco that can be imported into Finland where the labelling differs from that of tobacco products sold in Finland. We recommend that similar limits should be set at EU level, that is, that for each Member State the amount of tobacco that may be imported for personal use which does not conform to domestic labelling requirements, should be limited to a maximum of 200 cigarettes, 50 cigars, 100 cigarillos and 250 grams of pipe or cigarette tobacco.

### **additional comments**

Internet. The principle of preventing cross-border promotion of tobacco products in order to protect public health was enshrined in the Tobacco Advertising directive (2001/0119). It is logical, therefore, to extend that principle to the sale of tobacco products between member states via the Internet. We support the prohibition of tobacco sales via the Internet. Vending machines. The majority of member states (22 out of 27) already prohibit the sale of tobacco products from vending machines in order to deter young people accessing cigarettes from this source. We support this measure. Point of Sale. We support an EU-wide adoption of a ban on the display of tobacco products at the point of sale. Across the EU, most forms of tobacco advertising are now prohibited but the tobacco industry continues to market its products by the use of attractive packaging. Research shows that point of sale displays of tobacco have a direct impact on young people's intention to smoke. Furthermore, there is a growing body of evidence to show that putting tobacco products out of sight in retail outlets can reduce youth smoking. To date, this measure has been adopted by Ireland and Finland (as well as Iceland and Norway) and is going through the parliamentary process in the UK.

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### **NGO submission**

#### **identification**

##### **affiliation**

NGO

##### **name**

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##### **email**

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##### **country**

Deutschland

#### **questions scope**

##### **problem definition**

No

#### **explanations**

Die Gewerkschaft NGG vertritt sowohl die Interessen der Beschäftigten in der Tabakwirtschaft, wie die der Beschäftigten im Hotel- und Gaststättensektor. Die Gewerkschaft NGG spricht sich dafür aus, dass Nichtraucher vor den Gefahren des Passivrauchens geschützt werden und dass Arbeitnehmer das Recht auf einen rauchfreien Arbeitsplatz haben. Dabei

muss es aber einen vernünftigen Ausgleich zwischen den Interessen geben. Wenn und soweit der Schutz vor den Gefahren des Passivrauchens anders als durch Verbote gewährleistet werden kann, sollten diese (technischen) Möglichkeiten genutzt werden. Der Geltungsbereich der Tabakrichtlinie bedarf, wenn überhaupt, nur einer eingeschränkten Erweiterung. Soweit bestimmte Produkte derzeit von anderen Richtlinien der Europäischen Union geregelt sind (z.B. für Lebensmittel) bedarf es keiner Erweiterung des Anwendungsbereiches der Richtlinie. Die NGG spricht sich allerdings dafür aus, dass neuartige Formen, insbesondere elektronische Zigaretten, denselben Anforderungen unterliegen, wie herkömmliche Zigaretten. Gleiches gilt für sogenannte Kräuterzigaretten. Die NGG tritt ausdrücklich nicht dafür ein, Tabakprodukte zum oralen Gebrauch - wie z.B. Snus - weiterhin zu verbieten.

**which option**

No change

**questions smokeless**

**problem definition**

No

**comments**

Rauchlose Tabakprodukte können nicht einheitlich beurteilt werden. Ein Verbot von rauchlosen Tabakprodukten wäre auch im Hinblick auf den Gesundheitsschutz nicht zielführend. Rauchlose Tabakprodukte können und sind zum Teil weniger gesundheitsschädlich als gerauchte Tabakprodukte. Auch wenn die rauchlosen Tabakprodukte nicht ungefährlich sind, muss ihre Gefährlichkeit jedoch immer im Verhältnis zu gerauchten Tabakprodukten beurteilt werden. Die NGG spricht sich daher dafür aus, dass das Snus-Verbot aufgehoben wird und auf Basis gesicherter wissenschaftlicher Erkenntnisse – Regulierungen für das Produkt selbst erfolgen können. Erwachsene Verbraucher sollten die Freiheit haben selbst über den Konsum zu entscheiden.

**which option**

Lifting the ban on snus

**questions consumer**

**problem definition**

No

**explanations**

Die vorgeschlagene Einheitsverpackung (plain packaging) trägt nach Auffassung der Gewerkschaft NGG in keiner Weise zur Minderung der Gefahren des Rauchens bei. Herstellern von Tabakprodukten muss es auch weiterhin erlaubt sein, für ihre – legalen Produkte – unterschiedliche Verpackungen zu gestalten. Sollte die individuelle Gestaltung von Verpackungen untersagt werden, steht zu befürchten, dass der Wettbewerb zwischen den einzelnen Anbietern hauptsächlich über den Preis stattfinden wird. Der Preis wäre das einzige Differenzierungskriterium. Ein solcher - allein preisgetriebener - Wettbewerb würde aber dem illegalen Handel, insbesondere Fälschungen Vorschub leisten. Der illegale Handel – mit erweiterten Gesundheitsgefahren – ist bereits heute ein nicht unerhebliches Problem für die Tabakindustrie. In Deutschland werden etwa 20 Prozent der in Deutschland konsumierten Tabakwaren nicht in Deutschland versteuert. Plain packaging würde diesen Trend weiter verstärken. Er würde darüber hinaus Produktfälschungen durch die organisierte Kriminalität erweitern. Dieses dient weder dem Verbraucher noch dem Gesundheitsschutz. Legale

Produkte müssen auch den erwachsenen Konsumenten am Verkaufsort präsentiert werden dürfen. Der erwachsene Konsument muss die Möglichkeit der freien Wahl für ein Produkt haben. Ein Verbot der Produktpräsentation und Werbung am Verkaufsort hätte zur Folge, dass erwachsene Konsumenten nicht mehr über Produktinnovationen und/oder neue Marken informiert werden könnten. Darüber hinaus befürchten wir, dass mit derartigen Maßnahmen im Gegensatz zur beabsichtigten Wirkung des Gesundheitsschutzes, falsche Anreize gesetzt werden. Tabakprodukte würden immer mehr den Reiz des Verbotenen haben. Dies würde in bestimmten Konsumentengruppen eher einen Anreiz zum Tabakkonsum verstärken. Darüber hinaus ist die NGG der Meinung, dass das erreichte Aufklärungsniveau über die Gefahren des Tabakrauchs ausreichend ist. Es gibt in der gesamten EU wohl kaum Bürgerinnen und Bürger, die nicht davon überzeugt sind, dass Rauchen gesundheitsschädlich ist. Will man Raucherinnen und Raucher vom gesundheitsschädlichen Rauchen abhalten, sind erweiterte und zielgruppenspezifische Angebote zur Rauchentwöhnung sinnvoller.

**which option**

No change

**questions on reporting**

**problem definition**

No

**explanations**

Die NGG tritt für ein EU-weites gemeinsames Meldeformat ein. Die Meldung von Zusatzstoffen muss jedoch anhand von wissenschaftlich validen Kriterien erfolgen. Die NGG lehnt eine Regulierung auf Basis von "Attraktivität" ab, da dies kein wirklich nachprüfbares Kriterium ist.

**which option**

Establish a common compulsory reporting format

**additional options**

Die NGG tritt für ein EU-weites gemeinsames Meldeformat ein. Die Meldung von Zusatzstoffen muss jedoch anhand von wissenschaftlich validen Kriterien erfolgen. Die NGG lehnt eine Regulierung auf Basis von "Attraktivität" ab, da dies kein wirklich nachprüfbares Kriterium ist.

**regulation of ingredients**

**problem definition**

No

**explanations**

Die Forderung nach einem Verbot von Tabakzusatzstoffen beruht auf drei – nicht überzeugend wissenschaftlich belegten – Argumenten: - Tabakprodukte könnten durch Zusatzstoffe attraktiver für Konsumenten werden - Zusatzstoffe könnten eine „süchtig machende“ Wirkung von Tabakprodukten verstärken - Zusatzstoffe könnten ein erhöhtes gesundheitliches Risiko für Konsumenten bedeuten. Zunächst ist festzuhalten, dass ein umfassendes Verbot von Zusatzstoffen in Tabakprodukten Konsumenten fälschlicherweise suggerieren würde, dass erst Zusatzstoffe die Tabakerzeugnisse schädlich machen und das Tabakerzeugnisse ohne Zusatzstoffe weniger schädlich wären. Ein Verbot oder eine Zulassung eines Zusatzstoffes muss auf einer umfassenden wissenschaftlichen Bewertung



basieren. Die Unternehmen publizieren seit Jahren toxikologische Daten zu Zusatzstoffen. Zudem werden die entsprechenden toxikologischen Daten zu Zusatzstoffen an die nationalen Regulierungsbehörden übermittelt. Es gibt bisher keine Vorgaben, welche Testverfahren für eine toxikologische Bewertung oder eine Sucht verstärkende Wirkung der Zusatzstoffe verwendet werden sollen und wie diese Daten verbindlich bewertet werden könnten. Entscheidend ist dabei die Frage, ob ein Zusatzstoff die gesundheitlichen Risiken, die mit dem Rauchen verbunden sind wirklich erhöht. Die NGG setzt sich aber für eine Sicherheitsbewertung auf Basis eines Ansatzes toxikologisch relevanter Schwellenwerte für die Inhalation ein. Dieser Grundsatz der toxikologisch relevanten Schwellenwerte wird bisher auch in anderen Bereichen, z.B. bei der Sicherheitsbewertung von Chemikalien und Lebensmittelzusatzstoffen erfolgreich angewendet. Solche Prüfkriterien müssen auch für die Beurteilung von neuen Zusatzstoffen in Tabakprodukten Anwendung finden. Sie sollten die Basis bilden für eine europaweite Harmonisierung der Regulierung von Zusatzstoffen. Hierzu ist es nötig, innerhalb der EU für alle Beteiligten (Verbraucher, Regulierungsbehörden und Hersteller) wissenschaftlich anerkannte Kriterien zur Bewertung von Zusatzstoffen und entsprechende harmonisierte Prüfstrategien erarbeitet werden. Diese müssen dann für alle Hersteller verbindlich sein. Ein Verbot von Tabakzusatzstoffen lehnt die Gewerkschaft NGG ab. Dieses würde zu gravierenden Marktverwerfungen führen. Wir befürchten für diesen Fall einen gravierenden Arbeitsplatzverlust und die Verlagerung ganzer Standorte, da ein erheblicher Teil der deutschen Tabakwirtschaft auch für den Export in das Nicht-EU-Ausland produziert.

#### **which option**

No Change

#### **access to tobacco products**

##### **problem definition**

No

##### **explanations**

Die Gewerkschaft NGG ist der festen Überzeugung, dass Tabakprodukte nur von erwachsenen Menschen konsumiert werden sollten. Daraus folgt, dass Jugendliche keinen Zugang zu Tabakprodukten haben dürfen. Gleichzeitig muss der Zugang zu Tabakprodukten für Erwachsene jedoch möglich sein. Die NGG ist daher der Auffassung, dass der Zugang zu Verkaufsautomaten auf Erwachsene beschränkt werden sollte. Dieses ist in Deutschland vorbildlich umgesetzt. Die Alterskontrolle bei Zigarettenautomaten funktioniert. Ein Verbot von Verkaufsautomaten wäre nicht zielführend, sondern würde die Freiheit des erwachsenen, selbstbestimmten Konsumenten einschränken, ohne dass hiermit ein weiterer Schutz von Jugendlichen verbunden wäre. Im Hinblick auf grenzüberschreitende Einzelhandelsverkäufe von Tabakerzeugnissen, insbesondere über das Internet muss der besondere Schutz der Jugendlichen gewährleistet werden. Daher muss dort, ähnlich wie im stationären Tabakverkauf sowie bei Tabakautomaten, für eine Altersverifikation gesorgt werden. Die Gewerkschaft NGG spricht sich ausdrücklich dagegen aus, ein Verbot von Produktpräsentation und Werbung am Verkaufsort einzuführen. Tabakprodukte sind legale Produkte. Sie müssen dem erwachsenen Konsumenten auch präsentiert werden dürfen. Legale Produkte dürfen nicht zur „Bückware“ werden. Darüber hinaus muss es dem erwachsenen Konsumenten selbst überlassen sein, welche Marke von Tabakprodukt er oder sie konsumiert. Hierzu stellen Verpackungsdesign, Werbung und Produktpräsentation am Verkaufsort eine entsprechende Entscheidungshilfe dar. Durch ein solches Verbot von Produktpräsentation und Werbung am Verkaufsort in Verbindung mit plain packaging würde daher der Wettbewerb

nur noch über den Preis stattfinden. Neue Marken könnten kaum oder gar nicht eingeführt werden. Die Gewerkschaft NGG hat sich auch in der Vergangenheit gegen umfassende Werbever-bote für legale Produkte ausgesprochen.

**which option**

No change

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**NGO submission**

**identification**

**affiliation**

NGO

**name**

Slovenska zveza za tobačno kontrolo in javno zdravje, kot koordinator Vsebinske mreže NVO varujejo naše zdravje (usklajeni predlogi 14 nevladnih organizacij)

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nvo.zdravje@tobak-zveza.si

**country**

Slovenija

**questions scope**

**problem definition**

Yes

**which option**

Extend the scope of the Directive

**recommend option**

Obseg obravnave Direktive mora biti povečan. Direktiva mora vključevati obravnavo novih oblik tobaka za oralno uporabo, zeliščnih cigaret, elektronskih cigaret in drugih novih oblik tobačnih izdelkov. Novi tobačni izdelki in oblike tobaka za oralno uporabo bi bili prepovedani kot je to urejeno za „snus“. Področje zeliščnih cigaret (in njim podobnim izdelkov) mora urejati prehranska oz. farmacevtska zakonodaja.

**additional comments**

Obseg obravnave Direktive mora biti povečan. Direktiva mora vključevati obravnavo novih oblik tobaka za oralno uporabo, zeliščnih cigaret, elektronskih cigaret in drugih novih oblik tobačnih izdelkov. Novi tobačni izdelki in oblike tobaka za oralno uporabo bi bili prepovedani kot je to urejeno za „snus“. Področje zeliščnih cigaret (in njim podobnim izdelkov) mora urejati prehranska oz. farmacevtska zakonodaja.

**questions smokeless**

**problem definition**

Yes

**which option**

No change

**questions consumer****problem definition**

Yes

**which option**

Improve consumer information; Introduce generic or plain packaging

**which improvement**

Picture warnings to become mandatory; Information on harmful substances in tobacco products that cannot be placed on the package would be placed inside the package; Health warnings to be put on water pipes

**additional option**

Vsi tobačni izdelki (vključujoč vodno pipo) bi morali imeti obvezno slikovno zdravstveno opozorilo, ki bi pokrivala 80% sprednjega in hrbtnege zgornjega dela embalaže. Slikovna opozorila bi morala biti obvezujoča za vse države članice. Na vsakem posameznem zavitku tobačnih izdelkov mora biti na eni strani zavitka opozorilo o nevarnostih pasivnega kajenja, s čimer so kadilci obveščeni o škodljivosti pasivnega kajenja. Uveljaviti se mora splošna enotna embalaža (angl. „packaging“), kar pomeni: prepoved uporabe logotipov, barv, prepoved uporabe podobe blagovne znamke ali promocijske informacije na embalaži tobačnih izdelkov. Na embalaži je dovoljena uporaba imena blagovne znamke in proizvoda, kar mora biti prikazano v navadnih barvah (npr. siva ali črna) in navadnem slogu pisave. Določiti se mora standardna velikost in oblika embalaže. Tobačne industrije smejo imeti za cigaretno blagovno znamko le eno velikost embalaže in standardno obliko.

**additional comments**

Vsi tobačni izdelki (vključujoč vodno pipo) bi morali imeti obvezno slikovno zdravstveno opozorilo, ki bi pokrivala 80% sprednjega in hrbtnege zgornjega dela embalaže. Slikovna opozorila bi morala biti obvezujoča za vse države članice. Na vsakem posameznem zavitku tobačnih izdelkov mora biti na eni strani zavitka opozorilo o nevarnostih pasivnega kajenja, s čimer so kadilci obveščeni o škodljivosti pasivnega kajenja. Uveljaviti se mora splošna enotna embalaža (angl. „packaging“), kar pomeni: prepoved uporabe logotipov, barv, prepoved uporabe podobe blagovne znamke ali promocijske informacije na embalaži tobačnih izdelkov. Na embalaži je dovoljena uporaba imena blagovne znamke in proizvoda, kar mora biti prikazano v navadnih barvah (npr. siva ali črna) in navadnem slogu pisave. Določiti se mora standardna velikost in oblika embalaže. Tobačne industrije smejo imeti za cigaretno blagovno znamko le eno velikost embalaže in standardno obliko.

**questions on reporting****problem definition**

Yes

**which option**

Establish a common compulsory reporting format; Introduce fees and sanctions

**additional options**

Uvesti se mora usklajen poročevalsk obrazec za poročanje tobačne industrije o vsebnosti

cigaret za vsako vrsto proizvoda cigaretnih izdelkov posamezne blagovne znamke. Tobačna industrija mora letno pristojnim uradom plačati pristojbino, s čimer bi bilo financirano neodvisno zbiranje in analiza podatkov o sestavinah tobačnih izdelkov. Dovoljena bi bila prodaja le registriranih tobačnih izdelkov.

**additional comments**

Uvesti se mora usklajen poročevalsk obrazec za poročanje tobačne industrije o vsebnosti cigaret za vsako vrsto proizvoda cigaretnih izdelkov posamezne blagovne znamke. Tobačna industrija mora letno pristojnim uradom plačati pristojbino, s čimer bi bilo financirano neodvisno zbiranje in analiza podatkov o sestavinah tobačnih izdelkov. Dovoljena bi bila prodaja le registriranih tobačnih izdelkov.

**regulation of ingredients**

**problem definition**

Yes

**which option**

Establish a common list of tobacco ingredients

**which one**

Establish a positive common list of tobacco ingredients

**additional option**

Vzpostavitev „pozitivnega“ enotnega seznama (liste) sestavin tobačnih izdelkov glede na toksičnost, privlačnost in zasvojljivost izdelka, ki se kadi, oziroma je za oralno uporabo. Zgolj sestavine, ki so na seznamu, se lahko uporabijo v proizvodnji tobačnih izdelkov.

**additional comments**

Vzpostavitev „pozitivnega“ enotnega seznama (liste) sestavin tobačnih izdelkov glede na toksičnost, privlačnost in zasvojljivost izdelka, ki se kadi, oziroma je za oralno uporabo. Zgolj sestavine, ki so na seznamu, se lahko uporabijo v proizvodnji tobačnih izdelkov.

**access to tobacco products**

**problem definition**

Yes

**which option**

Controlled supply and access

**which supply and access**

Age verification of buyers and other legal conditions to be set for cross-border retail sale;  
Tobacco display and promotion at points of sales to be restricted

**additional option**

Za vse države članice mora biti prepovedana prodaja tobačnih izdelkov preko interneta. Omejitev bi vključevala tudi prepoved poštne dostave tobaka potrošnikom. Prepoved prikaza (disply) na vseh prodajnih mestih.

**additional comments**

Za vse države članice mora biti prepovedana prodaja tobačnih izdelkov preko interneta.

Omejitev bi vključevala tudi prepoved poštno dostave tobaka potrošnikom. Prepoved prikaza (disply) na vseh prodajnih mestih.

---

## **NGO submission**

### **identification**

#### **affiliation**

NGO

#### **name**

The Irish Cancer Society

#### **email**

Komeara@irishcancer.ie

#### **country**

Ireland

#### **gender**

female

#### **questions scope**

#### **problem definition**

Yes

#### **which option**

Extend the scope of the Directive

#### **additional comments**

The ICS agree with the problem definition but believes that it is incomplete. The directive should also be expanded to include measures which internalise the health costs of tobacco to manufacturers (such as is set out in chapter nine of the DG SANCO report 'Assessing the Impacts of Revising the Tobacco Products Directive'. Smoking causes 30% of all cancers, including 95% of all lung cancers. Overall 6,000 people die in Ireland every year from smoking related illnesses including cancer, heart and respiratory disease. Based on the polluter pays principle, we support the DG SANCO proposal of requiring full liability and payment of the health costs of smoking by the tobacco industry to national health systems. The ICS would also recommend the introduction of a penalty directed at tobacco companies whose products are smuggled. We contend that the tobacco industry is not committed to combating smuggling as it is not in its commercial interest. We propose E.U. wide legislation similar to that which exists in the U.K. The U.K. finance act makes it a legal duty for tobacco manufacturers not to facilitate smuggling. Manufacturers who fail to take sufficient steps to prevent their products being smuggled into the U.K. face fines of up to £5 million. We are aware that this issue is currently being discussed by the WHO as part of the negotiation of Article 15 of the Framework Convention for Tobacco Control (FCTC).

#### **questions smokeless**

#### **problem definition**

Yes

**which option**

Ban on all types of smokeless tobacco products

**additional comments**

Given that all smokeless tobacco products are addictive and can cause cancer, the ICS proposes that the ban on snus should be maintained and extended to include all types of smokeless tobacco products.

**questions consumer**

**problem definition**

Yes

**which option**

Improve consumer information; Introduce generic or plain packaging

**which improvement**

Picture warnings to become mandatory; Tar, nicotine and carbon monoxide levels to be replaced with general information on harmful substances in tobacco products; Information on harmful substances in tobacco products that cannot be placed on the package would be placed inside the package; Health warnings to be put on water pipes

**additional comments**

The ICS wholeheartedly supports mandatory pictorial warnings across all states and would advocate for an even stronger selection of graphic images than that which the E.U. has currently approved. In reference to option 2a, we believe that the minimum size required for combined pictorial/text warnings should be increased to 80% on both the front and back of packs. The use of plain or generic packaging (in addition to pictorial warnings) will increase the prominence of health warnings.

**questions on reporting**

**problem definition**

Yes

**which option**

Introduce fees and sanctions

**additional comments**

Requiring the tobacco industry to finance independent analysis of ingredients and imposing penalties on those who do not supply sufficient data on tobacco product ingredients would seem the most effective means of dealing with the problem.

**regulation of ingredients**

**problem definition**

Yes

**which option**

Establish a common list of tobacco ingredients

**which one**

Establish a positive common list of tobacco ingredients

**additional comments**

The ICS supports the introduction of a positive common list of tobacco ingredients. We also propose the prohibition of all flavours and ingredients which enhance attractiveness, encourage youth initiation, and discouraging cessation. Ingredients which create the impression of a health/energy benefit and ingredients with colouring properties should also be banned.

**access to tobacco products****problem definition**

Yes

**which option**

Ban

**which one2**

Cross-border retail sales of tobacco to be banned over the Internet; Vending machines to be banned; Promotion and displays in retail stores to be banned

**additional comments**

As the Irish government have already placed a ban on vending machines and also on promotions /displays in retail stores, we would now like to see regulation put in place which tackles the issues surrounding cross-border internet sales of tobacco products.

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**NGO submission****identification****affiliation**

NGO

**name**

European Society for Medical Oncology

**email**

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Switzerland

**questions scope****problem definition**

Yes

**which option**

Extend the scope of the Directive

**additional comments**

All tobacco products are hazardous to health – there is no safe level of usage. Therefore we recommend that the scope of the Directive includes the regulation of any new smoked tobacco products (such as low emission or nicotine-free cigarettes), while the prohibition of any novel forms of oral tobacco, including snus, should be maintained. Herbal cigarettes are also harmful because it is the combustion and inhalation of smoke that causes most of the harm from smoking. Therefore, herbal cigarettes should be included in the scope Tobacco Products Directive and should also be subject to health warnings requirements. Finally, all forms of nicotine based products (that is, products containing nicotine but which are not tobacco products, such as electronic cigarettes, nicotine gel, drinks, and sweets) are often marketed as alternatives to cigarettes and in some cases as an aid to quitting smoking. Therefore, they should only be sold as quitting aids and comply with specific safety and quality requirements under the same regulatory framework as pharmaceutical products rather than under the scope of the Tobacco Products Directive.

**questions smokeless  
problem definition**

Yes

**which option**

No change

**additional option**

The ban on snus should definitely be maintained. This is high priority. Indeed, there is no legitimate reason to introduce a dangerous product onto the market, particularly as, from an internal market point of view, we have no idea how snus would be perceived or used in other countries. A small study conducted by the University of Nottingham by Professor Ann McNeil showed that, in the UK, people could not see the point of snus unless it was as a cessation aid (i.e. there is currently no demand). For internal market purposes, it really does not make sense to lift the ban. Furthermore, if the ban on snus were to be lifted, it could encourage dual use of cigarettes and smokeless tobacco and discourage total abstinence from tobacco, thus weakening any potential health gains. In this context, we stress that there are already available effective treatments for nicotine addiction, including medicinal or ‘clean’ nicotine (NRT), that do not carry the risks associated with the use of snus. These should be promoted first and foremost. It is clear that the public health interest can be served even more by encouraging a) greater use of these treatments and b) the development of more effective cessation aids, especially those that mimic more closely the nicotine ‘hit’ delivered by cigarettes. Regarding other forms of smokeless tobacco products, the SFP does not believe that they should be “marketed” in all Member States. We recognise that they are as addictive and dangerous as smoked tobacco. As stated in the Opinion of the Scientific Committee on Emerging and Newly Identified Health Risks (SCENIHR), many forms of smokeless tobacco increase the risk of mouth, esophageal, pancreatic and liver cancer, and other conditions including gum and heart disease. However, we also know that these products are mostly consumed in the UK and used by South Asian communities; introducing an EU-wide ban on these products now could lead to the creation of an unnecessary illegal market, pushing consumption underground. This is why we do not recommend an immediate ban on all types of smokeless tobacco products; we do recommend that they should be regulated in the same way as tobacco products.

**questions consumer**



**problem definition**

No

**explanations**

The problem definition could be improved. We agree with the Commission that the current situation, whereby some Member States have made graphic warnings compulsory and others not, has led to a disparity in labelling throughout the EU. Consequently, this has an impact on the functioning of the internal market, on consumers' awareness and as a result, on their smoking behaviour. We also agree that packaging as an advertising tool is not covered by the current Directive. Finally, we welcome the acknowledgement that tobacco packaging and product features are increasingly used to attract consumers, to promote products and brand image. In this context, it would have been judicious to highlight the fact that, in the Eurobarometer survey released in 2010, the policy that received the most positive response is that of putting health warnings on all packages of tobacco products (on average, 75% of EU citizens are in favour of mandatory pictorial warnings, and over 54% support plain packaging measures).

**which option**

Improve consumer information; Introduce generic or plain packaging

**which improvement**

Picture warnings to become mandatory; Tar, nicotine and carbon monoxide levels to be replaced with general information on harmful substances in tobacco products; Information on harmful substances in tobacco products that cannot be placed on the package would be placed inside the package

**additional option**

Crucial importance of Graphic health warnings: Evidence shows that text only warning messages are not as effective as graphic warnings. Pictures, especially fear inducing pictures, are proven to be effective in getting consumers more engaged with the warning message. Pictures are able to immediately provoke a reaction and prompt people to read the associated text message. (Footnote 2) The need for graphic health warnings on both sides of the pack: There is also evidence that pictures on both sides of the packaging have a greater impact. (3) The need for LARGE pictorial health warnings (80%): Evidence clearly shows that increasing the size of warning messages (text only and combined text and picture) increases the effectiveness of the warning amongst both young and adult smokers / non smokers. Research carried out in Canada by Createc (4) on behalf of Health Canada in 2007 showed that young and adult smokers/non smokers are sensitive to the size of health warning messages. Results showed that warning messages that cover 100% of the pack are significantly more effective across all measured effectiveness indicators compared with warning messages that cover only 50% of the pack. The importance of Rotation: Warning texts and pictures should be displayed on a rotating basis, so that each message is given equal display and can reach its target audience. The proved effectiveness of shocking health warnings & targeted messages: as specified in the Sambrook Research International report, fear inducing warnings (using strong "shocking" images related to health risks such as rotten teeth or throat cancer) and strong emotion inducing warnings (especially involving children and unborn babies) are the most effective way to educate consumers on the health risks of tobacco use and to achieve changes in attitudes and behaviour. These warnings' effectiveness is enhanced if they are used in conjunction with a quit line. Generic or plain packaging: We strongly recommend the introduction of standardised/plain packaging. This should include not only the removal of all

branding from the packaging but the size and shape of the packaging should also be standardised. Not only would this prevent the promotion of smoking through branding as occurs presently but it would reinforce the health warning messages. Tobacco packaging provides a direct link between consumers and manufacturers and is the main marketing channel, particularly in jurisdictions with tobacco advertising bans. Branding gives the misleading impression some cigarettes are safer than others. The tobacco industry claims that plain packaging would contravene intellectual property law. However, legal analysis concludes that this is incorrect and there are no international legal impediments to the implementation of generic packaging.(5) Replace TNCO quantitative labelling with qualitative information on contents, emissions and quit-lines: The inclusion of machine-based tar, nicotine and carbon monoxide yields on cigarette packs promotes the mistaken belief that some cigarette brands are less harmful than others. (6) We support the proposal to replace numerical measurements with descriptive information on the hazardous effects of tobacco constituents and emissions. We stress the importance of putting quit line numbers on the package. As underlined in the Sambrook research (p46), providing a telephone number on the pack is more effective than telling smokers to seek advice from a doctor or pharmacist. P46 Health warnings on water pipes: There is a growing body of evidence to show that water pipes are at least as hazardous, if not more so, than other forms of tobacco use. Warnings should also be included on the packaging of tobacco used in water pipes. Footnotes (2-6) exceed maximum number of characters - to be provide upon request

### **additional comments**

Under Article 5.3 of the TPD 2001, Member States have the option to adopt pictorial warnings. This situation emphasised the right of Member States to go further than the Directive to protect public health as set out in Article 30 of the Treaty of the Union (now article 36). Ten years after the entering into force of the TPD, four countries (the UK, Belgium, Romania and Malta) have adopted the option. More countries such as Spain and France are planning to adopt mandatory pictorial warnings. Such measures are in compliance with the current TPD and are welcomed by the tobacco control community. However, their adoption by some Member States necessarily creates growing discrepancies between Member States. As stated above, there is clear evidence that pictorial warnings are much more powerful than written health warnings. Extending the information and protection to all EU Member States would be in harmony with Article 168 of the TFEU and consistent with the objectives of the internal market stated in Article 114.3 of the TFEU and reiterated in Recital 19 of the Directive. A revision of the TPD should, therefore, aim at making pictorial health warnings of tobacco products subject to common rules. Note: Legislation on labelling, advertising and product regulation put forward by the Commission in the field of tobacco control, has been based on the internal market legislation (Articles 26 and 114 of the TFEU). Article 26 of the TFEU establishes the internal market. Article 114 gives EU institutions the competence to regulate and set rules for the functioning of the internal market. More specifically, article 114.3 also states that when establishing rules for the functioning of the internal market in the context of health, safety, environmental protection and consumer protection, the Commission “will take as a base a high level of protection, taking account in particular of any new development based on scientific facts.” The European Court of Justice (the “ECJ”) made an extensive analysis of Article 95 EC (now Article 114) throughout the years. In *Spain v. Council*, the Court observed that “recourse to Article 100a (now Article 114) as a legal basis is possible if the aim is to prevent the emergence of future obstacles to trade resulting from multifarious development of national laws.” The TPD was adopted on the basis of Article 114 TFEU (ex Article 95). As a result, Recital 19 of the TPD states that “[t]he presentation of warning labels and yields has continued to remain variable in the different

Member States. As a consequence, consumers in one Member State may be better informed as to the risks of tobacco products than in another. Such differences are unacceptable and are liable to constitute a barrier to trade and to impede the operation of the internal market in tobacco products, and should therefore be eliminated.”

**questions on reporting**

**problem definition**

Yes

**which option**

Establish a common compulsory reporting format; Introduce fees and sanctions

**additional comments**

The current situation which allows different formats and reporting mechanisms is unsatisfactory, making it difficult for authorities to compare and analyse the data. All tobacco manufacturers and importers should be subject to the same reporting requirements. The SFP believes that tobacco products, which are highly harmful, should be subject to an effective reporting system that allows the gathering and analysis of relevant data, including comparison as appropriate, in order to ensure high levels of consumer safety and information. The format already exists (based on the voluntary reporting format developed by the Commission in May 2007) and it would therefore be very easy to adopt this measure and to implement it. We welcome the introduction of yearly registration fees in order to finance the data collection on ingredients by the national authorities and their analysis work on ingredients. The payment of penalties in case of non-compliance with the requirements of delivery of data on tobacco product ingredients also seems adequate and would contribute to fund the tests conducted on these products. It is crucial that the appropriate toxicological and addictiveness tests are properly conducted. Such tests would allow policy-makers to make more informed decisions in this field, as there would be more scientific evidence. It would enhance the scientific knowledge of the dangers of tobacco products and would contribute to a high protection of health, as stated in Article 95.3 TFEU. Besides, such measures would also have an indirect impact on illicit trade, since only registered products would be allowed on the market.

**regulation of ingredients**

**problem definition**

Yes

**which option**

Establish a common list of tobacco ingredients

**which one**

Establish a positive common list of tobacco ingredients

**additional comments**

We support the adoption of a positive common list of tobacco ingredients. We believe that tobacco products are highly toxic and addictive, and that their content should therefore be closely regulated, in order to achieve high standards of health protection, as stated under article 114.3. There is a need for such a list at EU level since at the moment, consumers in the internal market are not subject to the same level of protection. Some citizens may be using substances that are banned in other Member States. Apart from creating unequal health protection across the EU, this may constitute an obstacle to free movement of goods within

the internal market: some countries can refuse access to their markets of cigarettes from Member States that do not comply with the importing Member State's national requirements. Regulation of Flavours and Ingredients: Flavourings are an increasingly important part of tobacco industry marketing, particularly to young people. Flavourings enhance attractiveness, encourage youth initiation, and discourage cessation. The prohibition of ingredients that may be used to increase attractiveness, such as sugars and sweeteners, flavouring substances, and spices and herbs, in cigarettes and cigarette-like tobacco products should be introduced. The prohibition of ingredients that may create the impression of a health benefit (e.g. vitamins), ingredients associated with energy and vitality (e.g. caffeine), and ingredients with colouring properties (e.g. pink cigarette paper) should also be banned. Tobacco manufacturers and importers should report sales volume information by brand. This information is essential to help governments ensure that product regulation is effective. The above measures should be compliant with the Guidelines on Art. 9/10, adopted unanimously at the Fourth Conference of the Parties in Uruguay on the 20th November 2010.

### **access to tobacco products**

#### **problem definition**

Yes

#### **which option**

Ban

#### **which one2**

Cross-border retail sales of tobacco to be banned over the Internet; Vending machines to be banned; Promotion and displays in retail stores to be banned

#### **additional option**

We urge the Commission to call for a ban on the promotion of tobacco products at point of sale and a ban on vending machines as described in the Art 13 Guidelines of the FCTC.

#### **additional comments**

Internet. The principle of preventing cross-border promotion of tobacco products in order to protect public health was enshrined in the Tobacco Advertising directive (2001/0119). It is logical, therefore, to extend that principle to the sale of tobacco products between member states via the Internet. We support the prohibition of tobacco sales via the Internet. Vending machines. The majority of member states (22 out of 27) already prohibit the sale of tobacco products from vending machines in order to deter young people accessing cigarettes from this source. We support this measure. Point of Sale. Evidence shows that a coordinated cross border marketing strategy on the part of the tobacco companies is reflected at point of sale (i.e. point of sale marketing is similar in most EU countries (i.e.: a brand is advertised at point of sale in the same way in Germany and Belgium). There is a growing body of evidence to show that putting tobacco products out of sight in retail outlets can reduce youth smoking. To date, this measure has been adopted by Ireland and Finland (as well as Iceland and Norway). This measure is also official government policy in Scotland, Wales and Northern Ireland and a decision is awaited in England. We strongly support an EU-wide adoption of a ban on the display of tobacco products at the point of sale.

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**gender**

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**questions scope****problem definition**

Yes

**which option**

Extend the scope of the Directive

**additional comments**

Extend the scope of the Directive to include all smoked products including herbal cigarettes. Do NOT extend the Directive to include electronic nicotine delivery systems (ENDS or E-cigarettes). It is the combustion process and inhalation of smoke that causes most of the harm from smoking. Therefore it is appropriate that herbal cigarettes, which are used in a similar way to nicotine cigarettes, are regulated in the same way as smoked tobacco products, and should be included in the scope of the Directive. Therefore we recommend that the scope of the Directive includes the regulation of any new smoked tobacco products (such as low emission or nicotine-free cigarettes). Novel nicotine based products (that is, products containing nicotine but not tobacco products) have the potential to offer a less hazardous alternative to cigarettes. Currently these include e-cigarettes and nicotine gel. However, as such products are generally marketed as alternatives to cigarettes and in some cases as an aid to quitting smoking, it is appropriate for them to be brought under the same regulatory framework as pharmaceutical products rather than under the scope of the tobacco products directive. The question of how nicotine containing products should be controlled is currently under consideration by the UK's Medicines and Healthcare Regulatory Authority (MHRA) following a recent public consultation on whether to extend its remit on the regulation of nicotine replacement therapies to other nicotine containing products. The outcome of this consultation may assist the Commission in developing its policy on these products.

**questions smokeless****problem definition**

Yes

**which option**

No change

**additional comments**

With regard to smokeless products that are not currently illegal, particularly those used by ethnic minority populations, we recommend that they are more tightly regulated but we do not support a total ban on such products. Whilst recognising that such products are harmful, the introduction of an EU-wide ban could create an illegal market that would be more difficult to control than the current situation. Furthermore a ban would make it more difficult to engage with users to offer help in quitting.

**questions consumer  
problem definition**

Yes

**which option**

Improve consumer information; Introduce generic or plain packaging

**which improvement**

Picture warnings to become mandatory; Tar, nicotine and carbon monoxide levels to be replaced with general information on harmful substances in tobacco products; Information on harmful substances in tobacco products that cannot be placed on the package would be placed inside the package; Health warnings to be put on water pipes

**additional option**

The minimum size of health warnings should be increased to 80% of the front and back surfaces of all tobacco packaging.

**additional comments**

**Picture Warnings** We strongly recommend that picture warnings should be mandatory and that they should occupy a minimum of 80% of the front and back surfaces of all tobacco packaging (i.e. not just cigarettes). The warnings should be placed on the upper portion of the packs for maximum visibility. The current situation with some Member States adopting picture warnings whilst others have not done so has created a discrepancy and uneven health protection across the EU. From an internal market perspective, the differences in rules are contrary to the operation of the single market and may constitute a barrier to trade. These obstacles should therefore be removed and pictorial health warnings should be mandatory to ensure optimum health protection for all EU citizens. There is good evidence to show that health warnings are effective in conveying the dangers of smoking and helping smokers to quit. They also help deter young people from starting to smoke. Picture warnings are more effective than written warnings.<sup>2</sup> All warnings should be displayed in rotation so that each message is given equal display to reach its target audience. There is widespread consumer support for pictorial health warnings. A Eurobarometer survey conducted in October 2009 showed that 78% of respondents supported health warnings. Information on tar, nicotine & carbon monoxide (TNCO) Currently the Directive requires the inclusion of machine-based tar, nicotine and carbon monoxide yields on cigarette packs. This promotes the mistaken beliefs that some cigarette brands are less harmful than others and that nicotine causes disease. The EU should not only remove this requirement from the Directive but should prohibit ISO or any other emissions numbers on the pack. We support the proposal to replace numerical measurements with descriptive information on the hazardous effects of tobacco constituents and emissions. The addition of a quitline telephone service should be included on the packaging. Additional information on harmful substances in tobacco products We support

the proposal to include additional information on the health effects of tobacco consumption on inserts inside the packaging. This should include advice on quitting smoking. Health warnings on water pipes There is a growing body of evidence to show that water pipes are at least as hazardous, if not more so, than other forms of tobacco use. However, there is a common perception that tobacco smoke is 'cleansed' by the water and therefore not as dangerous and some users believe flavoured shisha is not in fact tobacco. It is important that these myths are countered by requiring the inclusion of a health warning on all water pipes. Warnings should also be included on the packaging of tobacco used in water pipes. Generic or plain packaging We strongly recommend the introduction of plain or generic packaging. This should include not only the removal of all branding from the packaging but the size and shape of the packaging should also be standardised. Not only would this prevent the promotion of smoking through branding as occurs presently but it would reinforce the health warning messages. The Australian federal government has recently announced its intention to introduce plain packaging in 2012, setting a standard that the EU should follow. Tobacco packaging provides a direct link between consumers and manufacturers and is the main marketing channel, particularly in jurisdictions with tobacco advertising bans. Branding gives the misleading impression some cigarettes are safer than others. The tobacco industry claims that plain packaging would contravene intellectual property law. However, legal analysis for Action on Smoking and Health concludes that this is incorrect and there are no legal impediments to the implementation of generic packaging in the EU.

#### **questions on reporting**

##### **problem definition**

Yes

##### **which option**

Establish a common compulsory reporting format; Introduce fees and sanctions

##### **additional comments**

The current situation which allows different formats and reporting mechanisms is unsatisfactory, making it difficult for authorities to compare and analyse the data. Tobacco companies should be required to use a standardised reporting format. Additionally the companies should be required to pay a yearly registration fee to cover the costs of administering this data collection. The above measures should be compliant with Articles 9 & 10 of the Framework Convention on Tobacco Control (FCTC).

#### **regulation of ingredients**

##### **problem definition**

Yes

##### **which option**

Establish a common list of tobacco ingredients

##### **which one**

Establish a positive common list of tobacco ingredients

##### **additional comments**

We support the adoption of a positive common list of tobacco ingredients. Tobacco products are highly toxic and addictive; their contents should therefore be regulated in order to achieve high standards of health protection. A positive common list would ensure that only registered

products, with ingredients, flavourings and additives that appear on the positive list would be permitted on the EU market. Currently, EU citizens are not subject to the same level of health protection and a common list of permitted ingredients would go some way towards addressing this anomaly. The tobacco industry uses a range of additives to alter the composition of tobacco products. These can make the product more palatable to children or increase the addictiveness of the product. Therefore any flavourings that may be used to enhance the addictiveness or attractiveness of tobacco products should be banned. The revised Product Directive should be fully compliant with the guidelines on Articles 9 & 10 adopted at the fourth Conference of the Parties of the FCTC on 20th November 2010.

### **access to tobacco products**

#### **problem definition**

Yes

#### **which option**

Ban

#### **which one2**

Cross-border retail sales of tobacco to be banned over the Internet; Vending machines to be banned; Promotion and displays in retail stores to be banned

#### **additional option**

The EU Directive should follow the lead set by Finland which, as part of its recently passed Tobacco Act, has set limits on the amount of tobacco that can be imported into Finland where the labelling differs from that of tobacco products sold in Finland. We recommend that similar limits should be set at EU level, that is, that for each Member State the amount of tobacco that may be imported for personal use which does not conform to domestic labelling requirements, should be limited to a maximum of 200 cigarettes, 50 cigars, 100 cigarillos and 250 grams of pipe or cigarette tobacco.

#### **additional comments**

Internet. The principle of preventing cross-border promotion of tobacco products in order to protect public health was enshrined in the Tobacco Advertising directive (2001/0119). It is logical, therefore, to extend that principle to the sale of tobacco products between member states via the Internet. We support the prohibition of tobacco sales via the Internet. Vending machines. The majority of member states (22 out of 27) already prohibit the sale of tobacco products from vending machines in order to deter young people accessing cigarettes from this source. We support this measure. Point of Sale. We support an EU-wide adoption of a ban on the display of tobacco products at the point of sale. Across the EU, most forms of tobacco advertising are now prohibited but the tobacco industry continues to market its products by the use of attractive packaging. Research shows that point of sale displays of tobacco have a direct impact on young people's intention to smoke. Furthermore, there is a growing body of evidence to show that putting tobacco products out of sight in retail outlets can reduce youth smoking. To date, this measure has been adopted by Ireland and Finland (as well as Iceland and Norway) and is going through the parliamentary process in the UK. Medicines and Healthcare Regulatory Authority. Public consultation (MLX 364): The regulation of nicotine containing products (NCPs). June 2010

<http://www.mhra.gov.uk/Publications/Consultations/Medicinesconsultations/MLXs/CON065>  
617 Borland R, Wilson N, Fong GT. et al. Impact of graphic and text warnings on cigarette packs: findings from four countries over five years. *Tob Control* 2009;18:358–64.



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## **NGO submission**

### **identification**

#### **affiliation**

NGO

#### **name**

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#### **country**

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#### **questions scope**

#### **problem definition**

Yes

#### **which option**

Extend the scope of the Directive

#### **recommend option**

The above check mark does NOT indicate a full agreement with Option 2. While all nicotine delivery products and smoking material should be included in the scope of the Directive, the component of the description of Option 2 saying “Novel forms of oral tobacco would be banned similarly to snus.” is clearly inappropriate. Rules regarding banning or allowing different types of oral tobacco should be differentiated with respect to the widely differing characteristics of individual products in this heterogeneous category so as pointed out in various scientific reports, for example the second and third reports of WHO study group on tobacco product regulation. Further comments will be given in following sections.

**questions smokeless  
problem definition**

No

**comments**

The problem definition is fundamentally flawed in that it presupposes that all smokeless tobacco products could be dealt with in a uniform manner. The evidence on a wide continuum of risk in this field is neglected although strongly emphasized in many scientific reports, for example the second and third reports of the WHO study group on tobacco product regulation. The importance and implications of this evidence has also been highlighted by a letter from 15 scientists in 7 countries that was recently published in the scientific journal *Addiction* and is available at <http://onlinelibrary.wiley.com/doi/10.1111/j.1360-0443.2010.03250.x/full> . The second paragraph of the problem definition gives an one-sided and overall misleading impression of health risks of smokeless tobacco products, particularly as far as low-toxicity types such as Swedish snus are concerned. For example, there is no mentioning of the illustrative fact that Sweden's incidence and mortality rates for all tobacco-related forms of cancer are the lowest or among the lowest in Europe in spite of the record high consumption of snus in Sweden. Further, the problem definition gives an impression that the SCENIHR report presents an overall negative picture of snus although the SCENIHR report actually presents a balanced view as illustrated by statements like these: "Complete substitution of STP for tobacco smoking would thus ultimately prevent nearly all deaths from respiratory disease currently caused by smoking, which in total represent nearly half of all deaths caused by smoking." (page 113). "It is therefore reasonable to draw a conservative conclusion that substitution of smoking by snus use would, in due course, reduce the cardiovascular mortality that currently arises from tobacco use by at least 50%." (page 114). "Thus it is evident that the risk of pancreatic cancer associated with snus use is less than that of smoking, and for oral cancer substantially so. Since the numbers of deaths from these diseases is relatively small, the public health impact of this reduced risk, if snus were to replace smoking, would also be modest." (page 114). Another example of bias is the statement that there is not sufficient scientific evidence on the efficacy of snus as quitting aid. As a matter of fact there is solid such evidence. Some of the most important pieces of published evidence on these matters can be found at: <http://www.ncbi.nlm.nih.gov/pmc/articles/PMC2564662/?tool=pubmed>  
<http://www.ncbi.nlm.nih.gov/pmc/articles/PMC2910876/?tool=pubmed>  
<http://onlinelibrary.wiley.com/doi/10.1111/j.1360-0443.2010.03122.x/pdf>  
<http://onlinelibrary.wiley.com/doi/10.1111/j.1360-0443.2010.03180.x/full> While the usefulness of snus as an aid to quit smoking is questioned by some parties with vested interests, it is well recognized by independent and authoritative scientific bodies such as The Royal College of Physicians, RCP, London, as illustrated by statements in several reports from there, for example: "In Sweden, the availability and use by men of an oral tobacco product called snus, one of the less hazardous smokeless tobacco products, is widely recognised to have contributed to the low prevalence of smoking in Swedish men and consequent low rates of lung cancer." (From page 4 in: *Ending tobacco smoking in Britain*; RCP, 2008.) Another example of bias in the problem definition is the one-sided mentioning of claims that the use of smokeless tobacco products may lead to subsequent cigarette smoking, while there is no mentioning of the Swedish evidence on the opposite. The SCENIHR Committee reports a number of the Swedish studies and concludes (page 111): "The Swedish data, with its prospective and long-term follow-up do not lend much support to the theory that smokeless tobacco (i.e. Swedish snus) is a gateway to future smoking."

## **which option**

Lifting the ban on snus

## **additional option**

The above check mark for option 2 indicates that option 1 and option 3 are the least acceptable ones, but it still does NOT indicate a full support of option 2 as it is described, since it does not address the full width of the objective of the Directive. A maximum effective option could be developed along the following lines. The objective of the Tobacco products Directive is to ensure “a high level of protection to public health”. With respect to the properties of different smokeless tobacco products there are two tracks where regulatory measures can contribute to the attainment of that objective. Track 1: Protecting consumers from such smokeless tobacco products that entail almost as serious health risks as cigarettes. Track 2: Letting smokers have access to such minimum harmful smokeless tobacco products that can help to abandon smoking (and eventually all tobacco use). The rationale of Track 1 refers to the current availability in EU of such smokeless tobacco products, mainly from South East Asia and Africa, which have been shown to be almost as harmful as cigarettes, particularly as far as non-respiratory cancers are concerned. Removing these products from the market would represent protection of public health. The rationale of Track 2 refers to the current unavailability in EU (outside Sweden) of such smokeless tobacco products which are just slightly more harmful than medicinal nicotine products (patch, chewing gum) but more effective as smoking cessation aids than those products. Since many smokers fail to quit by using medicinal nicotine products, it would be beneficial for smokers to have access to these types of smokeless tobacco products as a means to maximize smoking cessation success. This would represent protection of public health. The above two tracks could be merged in such a system of evidence-based product regulation that has already been presented by the WHO study group on tobacco product regulation. In its third report (WHO technical report series; no. 955. WHO, Geneva, 2009) this expert group concludes that: “Smokeless tobacco products should be regulated by controlling the contents of the products.” The recommended regulation focuses on two categories of toxicants, tobacco-specific N-nitrosamines (TSNA) and polycyclic aromatic hydrocarbons (PAH). Based on reviews of the scientific literature the study group recommends upper limits for the content of these substances. If these recommendations were adopted in a future EU regulation, the health risks of the very harmful smokeless tobacco products would be eliminated at the same time as the potential public health benefits of the least harmful smokeless tobacco products would be attainable.

**SUMMARY CONCLUSION REGARDING AN EFFECTIVE OPTION** The relevant question is NOT simply a matter of lifting or not lifting the current ban on snus. In order to effectively address the public health questions around smokeless tobacco products the most effective option would be to replace the current ban by a regulatory regime that encompasses all kind of smokeless tobacco products taking into account the wide variation of properties between different smokeless tobacco products.

## **additional comments**

Matters regarding smokeless tobacco products should be seen in a wide context of strategies for minimizing tobacco-induced morbidity and mortality. Conventional measures focus entirely on preventing uptake of smoking and helping smokers to quit smoking. This approach will be ineffective for the millions of smokers who, despite best efforts to persuade and help them to quit, will carry on smoking. Half of these smokers, representing many millions in the EU, will die as a result. Tobacco control policy needs to be radically extended to address the needs of these smokers with implementation of effective harm reduction strategies. Harm reduction in smoking can be achieved by providing smokers with safer sources of nicotine

that are acceptable and effective cigarette substitutes. There is a moral and ethical duty to provide these products to addicted smokers. Current systems of regulation of nicotine products perpetuate the use of the most dangerous nicotine products. This is unjust, irrational and immoral. When discussing these matters the 2007 report by the Tobacco Advisory Group of the Royal College of Physicians, London, "Harm Reduction in Nicotine Addiction. Helping People Who Can't Quit." concludes: - Nicotine product regulation must therefore be reformed. - Low nitrosamine smokeless tobacco products may have a positive role to play in a coordinated and regulated harm reduction strategy which maximises public health benefit and protects against commercial market exploitation. These statements illustrate the solid support from authoritative scientific bodies for a regulatory option along the lines outlined here above. At the same time, concerns that have been raised that widespread use of snus could entail unintended side-effects that would reduce or eliminate the beneficial effects. One such concern is about snus users' continued nicotine dependence. There are even concerns that snus users would get strengthened nicotine dependence. But, smokers who switch to snus will most probably have less strong nicotine dependence than before. Whereas average nicotine intake by snus use is about the same as by smoking, the uptake is much slower from snus (in the mouth) than from smoke (in the lungs), and strength of dependence is primarily related to uptake speed. Another concern deals with the question if the possibility to use snus when or where smoking is forbidden might weaken the quit-motivating power of non-smoking environments and thereby make some smokers more prone to abstain from quitting smoking. But this concern does not seem to be warranted. Research data from Sweden show that virtually all (88%) of the smokers who take up snus use do abandon smoking, and a substantial proportion, around 32%, do eventually stop all tobacco use.

**questions consumer  
problem definition**

Yes

**which option**

Improve consumer information; Introduce generic or plain packaging

**which improvement**

Tar, nicotine and carbon monoxide levels to be replaced with general information on harmful substances in tobacco products; Information on harmful substances in tobacco products that cannot be placed on the package would be placed inside the package

**additional comments**

As suggested in the descriptions of options 2b and 2c the information on inserts should contain general information on harmful substances. This should include clarification that nicotine, although addictive, is NOT a major cause of somatic diseases whereas disease risks come from the combustion products that are present in the smoke but not in smokeless tobacco products.

**questions on reporting  
problem definition**

Yes

**which option**

Establish a common compulsory reporting format

**regulation of ingredients****problem definition**

Yes

**which option**

Introducing the basic criteria on the EU level without a common list

**access to tobacco products****problem definition**

Yes

**which option**

No change

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**NGO submission****identification****affiliation**

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**questions scope****problem definition**

Yes

**which option**

Extend the scope of the Directive

**recommend option**

L'élargissement du champ d'application est nécessaire dès lors que l'apparition d'une catégorie de nouveaux produits et de nouvelles formes de consommation peuvent avoir une incidence sur l'application des autres dispositions en matière de réglementation du tabac. (cf. La cigarette électronique et l'utilisation de pipes à eau/narguilé mettent à mal l'application de l'interdiction de fumer dans les lieux à usage collectif). La directive doit inclure des

dispositions relatives à l'ensemble des nouveaux produits du tabac, sans exceptions, destinés à être fumés. La portée de cette directive doit inclure l'interdiction de toute nouvelle forme de tabac à usage oral. L'interdiction faite à la commercialisation du «Snus» devra donc être maintenue. Eu égard à la commercialisation « sauvage » de nouvelles formes de tabac, y compris des cigarettes électroniques, il est essentiel de fixer un cadre plus strict permettant de définir à la fois des exigences de sécurité, de qualité, voire d'autorisation de mise sur le marché, notamment pour les produits susceptibles d'entrer dans la catégorie des substituts nicotiques. Les cigarettes et autres produits destinés à être fumés mais qui ne contiennent pas de tabac (cf. cigarettes aux herbes) sont également nuisibles, même s'ils ne contiennent pas de tabac car les gaz et particules dégagés par la combustion sont nocifs tant pour le fumeur que pour son environnement et particulièrement pour le non-fumeur qui vit dans cet environnement. La consommation de ces produits rend difficile le respect des dispositions adoptées par les Etats membres afin d'interdire de fumer dans les lieux à usage collectif. Il a été constaté que les mesures visant à assurer l'application de l'interdiction de fumer dans les lieux à usage collectif peuvent être compromises par l'utilisation de ces produits, dont certains utilisent les apparences « traditionnelles » des produits du tabac (à titre d'exemple, certaines cigarettes électroniques sont équipées de diodes électroluminescentes rouges qui s'allument à l'inhalation. Elles produisent également, à l'inhalation et à l'expiration, un halo parfaitement identique à la fumée de tabac). Ainsi, les cigarettes et produits destinés à être fumés, même sans tabac, devraient être inclus dans la directive. Il serait nécessaire de prévoir que ces produits, si leur mise sur le marché est autorisée, comportent des avertissements sanitaires. Tous les produits qui contiennent de la nicotine (des produits ne contenant pas du tabac ou des produits du tabac, mais de la nicotine, tels que les cigarettes électroniques, le gel à la nicotine, les boissons à la nicotine et les bonbons à la nicotine) sont souvent vendus comme des solutions de substitution au tabac et, dans certains cas, comme un produit d'aide pour arrêter de fumer. Cependant, la plupart de ces produits ne respectent pas les conditions de mise sur le marché exigées pour les produits de substitution nicotinique : Ils devraient être exclusivement vendus sous l'appellation « produits de substitution ». Il serait nécessaire de préciser dans la directive qu'en matière de SEDN, c'est la réglementation des produits pharmaceutiques, avec ses exigences particulières en matière de sécurité et de qualité qui devrait être appliquée. La consommation de ces produits dans les lieux concernés par l'interdiction de fumer devrait être aussi interdite, afin d'éviter d'entraver les actions de contrôles des agents chargés de faire respecter la législation et des personnes responsables de lieux dans lesquels il est interdit de fumer.

### **questions smokeless**

#### **problem definition**

Yes

#### **which option**

Ban on all types of smokeless tobacco products

#### **additional option**

Aucune raison ne justifie l'introduction, au sein du marché d'un Etat membre ou d'un pays tiers, de produits du tabac sans fumée, tels que le Snus. La libre commercialisation des produits du tabac sans fumée tels que le snus pourrait au contraire favoriser une augmentation de la consommation du tabac (orale et à fumer) et mettre à mal les efforts menés par les Etats pour diminuer la demande de tabac, et, en conséquence, jouer un rôle néfaste dans les objectifs visant à promouvoir la santé de la population. L'interdiction de ce type de produit est d'autant plus pertinente qu'il existe déjà des traitements de substitution nicotinique (TSN) et

des thérapies cognitives d'aide à l'arrêt, qui ne présentent pas les risques associés à l'utilisation des produits du tabac sans fumée. Si le but est de diminuer la consommation des produits du tabac, il est plutôt nécessaire d'encourager l'utilisation de traitements et de thérapies reconnues pour faciliter l'arrêt, au lieu de permettre l'utilisation des produits du tabac sans fumée, dont l'efficacité en termes d'aide à l'arrêt n'est pas démontrée. Enfin, l'hypothèse de l'introduction du tabac oral porte le risque d'effets négatifs pour la santé des plus jeunes, qui pourraient considérer le Snus comme un produit moins dangereux que la tabac à fumer, ou l'utiliser comme « porte d'entrée » dans la consommation d'autres produits du tabac.

### **questions consumer**

#### **problem definition**

Yes

#### **which option**

Improve consumer information

#### **which improvement**

Picture warnings to become mandatory; Tar, nicotine and carbon monoxide levels to be replaced with general information on harmful substances in tobacco products; Information on harmful substances in tobacco products that cannot be placed on the package would be placed inside the package; Health warnings to be put on water pipes

#### **additional option**

Il est nécessaire de rendre obligatoires les avertissements sanitaires graphiques. Les études démontrent que les avertissements seulement composés d'un texte ne sont pas suffisamment efficaces, notamment parce que de nombreux consommateurs ne les lisent pas. Les photos, surtout celles induisant la peur, se sont révélées être efficaces pour captiver davantage les consommateurs. Les photos sont en mesure de provoquer une réaction rapide et d'amener les gens à lire le message texte associé. • Il est fondamental d'introduire des avertissements graphiques sur les deux côtés du paquet. Il est également prouvé que les images des deux côtés de l'emballage, couvrant au moins 80% de la surface, auraient un impact plus important que sur un seul côté. L'augmentation de la taille des avertissements augmente l'efficacité de l'avertissement à la fois parmi les adultes et les jeunes fumeurs. Enfin, cela a des effets sur les non-fumeurs, en particulier l'incitation de ne pas commencer à fumer. • Les avertissements devront être imprimés de manière alternée, de sorte que chaque message soit montré autant de fois qu'un autre et qu'il puisse atteindre à un moment son public cible. • Prendre en compte l'efficacité des avertissements sanitaires choquants : la peur liée à des risques pour la santé (images telles que membres gangrénés ou cancer de la gorge) et à l'émotion (images impliquant des enfants et les bébés à naître) sont des moyens efficaces pour sensibiliser les consommateurs sur les risques liés à l'usage du tabac et pour obtenir des changements dans leurs comportements. L'efficacité de ces messages est renforcée avec la proposition d'aide à l'arrêt, par exemple les lignes téléphoniques pour arrêter de fumer. • Mise en place du paquet neutre à savoir : élimination de toutes les marques de l'emballage, standardisation de la taille et de la forme du paquet. L'emballage du tabac fournit un lien direct entre les consommateurs, les fabricants et les circuits de commercialisation principaux, particulièrement dans les pays qui interdisent la publicité en faveur du tabac. L'instauration des paquets neutres, sur le modèle de la future réglementation australienne, vise à mettre un terme à un marketing dont l'objet principal est de fausser, pour les consommateurs, l'image réelle du tabac. Les contraintes liées à l'instauration d'une telle mesure, notamment en matière de droit de la

propriété intellectuelle, peuvent être dépassées par les objectifs généraux de santé publique de la lutte contre le tabac. • Introduire des informations qualitatives sur les ingrédients entrant dans la composition du produit et sur le contenu des émissions au moment de la combustion: remplacer les informations numériques sur les taux de goudron, nicotine et CO, qui peuvent induire des croyances fausses quant à la dangerosité du produit. Introduire plutôt des informations descriptives des effets dangereux des constituants du tabac et de la fumée. • Avertissements sanitaires sur les pipes à eau: Il existe un nombre croissant de preuves montrant que les pipes à eau ou narguilé constituent des formes de consommation du tabac également dangereuses (cf. rapport OMS). Des avertissements devraient donc figurer sur l'emballage de tabac utilisé dans les pipes à eau.

### **additional comments**

Certains États membres ont introduit des avertissements sanitaires graphiques obligatoires et d'autres non, ce qui crée une disparité dans l'étiquetage des produits du tabac disponibles dans toute l'UE. Toute la législation sur l'étiquetage, la publicité et la réglementation des produits mis en avant par la Commission dans le domaine de la lutte antitabac, a été fondée sur la législation concernant le bon fonctionnement du marché intérieur (article 26 et 114 TFUE). L'article 95.3 du TFUE énonce également que pour les règles de fonctionnement du marché intérieur dans le contexte de la santé, la sécurité, la protection de l'environnement et la protection des consommateurs, la Commission prendra pour base « un niveau élevé de protection » en tenant compte notamment de toute nouvelle évolution basée sur des faits scientifiques. La Cour de justice de l'Union Européenne (la «CJUE») a fait une analyse approfondie de l'article 95 du traité de la communauté Européenne au fil des ans. Dans l'affaire Espagne v. Conseil, la Cour a observé que "le recours à l'article 100 comme base juridique est possible si l'objectif est de prévenir l'apparition d'obstacles futurs aux échanges résultant de l'évolution hétérogène des législations nationales." La directive des produits du tabac a été adoptée sur la base de l'article 114 du TFUE. Ce lien s'explique mieux à la lecture du considérant 19 de la directive « La diversité dans la présentation des avertissements et l'indication des teneurs a été maintenue dans les différents États membres. Par conséquent, les consommateurs sont informés différemment des risques liés aux produits du tabac selon l'Etat membre dans lequel ils résident. De telles disparités sont inacceptables et sont de nature à créer des entraves aux échanges et à faire obstacle au fonctionnement du marché intérieur des produits du tabac et devraient par conséquent être éliminées». L'article 5.3 de la directive et la décision de la Commission sur l'utilisation des photographies en couleurs ou autres illustrations en tant qu'avertissements sanitaires donnent aux États membres la possibilité d'adopter des avertissements graphiques sous forme de photographies en couleurs ou autres illustrations. Presque dix ans plus tard, seuls quatre pays (le Royaume-Uni, la Belgique, la Roumanie et Malte) ont introduit de tels avertissements, alors que l'Espagne et la France prévoient de le faire prochainement. Bien que de telles mesures soient en conformité avec la directive en vigueur et bien accueillies par la communauté du contrôle du tabac, leur adoption par un nombre restreint d'États membres crée nécessairement des écarts grandissants en matière d'information pour les citoyens de l'UE. Les consommateurs au Royaume-Uni sont mieux informés sur les risques inhérents aux produits du tabac que les consommateurs en Allemagne (par exemple). Cette disparité est incompatible avec les objectifs du marché intérieur en vertu de l'article 114.3 du TFUE, objectifs réitérés dans le considérant 19 de la directive. La disparité des législations crée des inégalités au niveau de l'information donnée aux consommateurs dans les différents États membres, et en conséquence, des inégalités quant à la protection de la santé dans toute l'Union européenne. Du point de vue du marché intérieur, ces différences dans les règles concernant les avertissements graphiques sont susceptibles de constituer des entraves aux échanges et à faire obstacle au bon fonctionnement



du marché intérieur. Ces obstacles et les divergences doivent donc être éliminés et, à cette fin, l'obligation d'introduire des avertissements graphiques sur les produits du tabac devrait être soumise à des règles communes à tous les Etats membres. En outre, il existe des compétences partagées entre l'UE et les Etats membres notamment en matière de santé ; afin de ne pas entraver ces compétences partagées, il est nécessaire d'harmoniser la réglementation des produits du tabac.

### **questions on reporting**

#### **problem definition**

Yes

#### **which option**

Establish a common compulsory reporting format; Introduce fees and sanctions

#### **additional options**

La situation actuelle qui autorise différents formats et mécanismes de rapport rend difficile l'analyse et la comparaison des données par les autorités. Tous les fabricants et les importateurs devraient être soumis aux mêmes exigences en termes de déclaration des composants et ingrédients et des effets en termes de toxicité et de dépendance. Etant donné la nocivité des produits du tabac, le rapport fourni par les fabricants aux autorités doit permettre la collecte et l'analyse de données pertinentes, le but étant d'assurer un niveau élevé de sécurité des consommateurs par une amélioration de l'information. Un format commun existe déjà (basé sur le format des rapports volontaires mis au point par la Commission en mai 2007) et il serait donc très facile d'adopter cette mesure.

#### **additional comments**

Il est nécessaire d'étudier la possibilité d'introduire des redevances annuelles pour financer la collecte de données sur les composants et faciliter ainsi les travaux de comparaison et d'analyse des ingrédients par les autorités compétentes. Le paiement des amendes en cas de non-conformité avec les exigences de communication de données sur les ingrédients des produits du tabac semble également indispensable et pourrait contribuer à financer les tests effectués sur ces produits. Il est fondamental d'introduire des évaluations toxicologique et de dépendance de ces produits par des essais cliniques appropriés. Ces tests permettraient aux décideurs de prendre des dispositions plus élaborées dans ce domaine, en donnant accès à des preuves scientifiques supplémentaires. En outre, ces mesures auraient également un impact indirect sur le commerce illicite, puisque seuls les produits homologués seraient autorisés sur le marché.

### **regulation of ingredients**

#### **problem definition**

Yes

#### **which option**

Establish a common list of tobacco ingredients

#### **which one**

Establish a positive common list of tobacco ingredients

#### **additional comments**

Les produits du tabac sont très toxiques, ainsi leur composition doit être étroitement

réglementée afin d'atteindre des normes élevées de protection de la santé. Il est nécessaire d'établir une liste commune au niveau de l'UE afin que les consommateurs puissent profiter du même niveau de protection dans le marché intérieur. Actuellement, certains citoyens européens encourent le risque de consommer des substances interdites dans d'autres Etats membres. De plus, l'inégalité en termes de protection de la santé et d'information des consommateurs constitue aussi un obstacle à la libre circulation des marchandises dans le marché intérieur, car certains pays pourraient être réticents à importer des cigarettes d'autres États membres lorsque celles-ci ne sont pas conformes aux exigences nationales. Les arômes et additifs de goût sont des outils de marketing de l'industrie du tabac et sont mis en place à l'attention particulière des jeunes. Les arômes permettent de renforcer l'attractivité, d'encourager l'initiation des jeunes et de décourager l'arrêt. L'interdiction des ingrédients qui peuvent être utilisés pour augmenter l'attractivité -comme les sucres et les édulcorants, les substances aromatisées, les épices et les herbes- devrait être introduite. L'interdiction des ingrédients qui peuvent donner l'impression d'être bon pour la santé (vitamines par exemple), des ingrédients associés au regain d'énergie et à la vitalité (par exemple, la caféine), et des ingrédients avec des propriétés colorantes (par exemple le papier à cigarette coloré) devrait également être introduite. Enfin, les fabricants de tabac et les importateurs doivent communiquer des informations sur le volume des ventes par marque. Cette information est essentielle pour permettre aux gouvernements de s'assurer que la réglementation des produits est respectée et efficace. Les mesures ci-dessus doivent prendre en compte les dispositions des articles 9 et 10 de la Convention-cadre pour la lutte antitabac (CCLAT) et de ses lignes directrices.

#### **access to tobacco products**

##### **problem definition**

Yes

##### **which option**

Ban

##### **which one2**

Cross-border retail sales of tobacco to be banned over the Internet; Vending machines to be banned; Promotion and displays in retail stores to be banned

##### **additional option**

L'interdiction de la promotion des produits du tabac sur le point de vente et l'interdiction des distributeurs automatiques ont une finalité différente des contrôles des ventes transfrontalières. L'interdiction de la vente sur Internet est une disposition additionnelle permettant de lutter contre la contrebande et la contrefaçon des produits du tabac, mais aussi contre la vente de tabac aux mineurs. La directive devrait également rappeler aux gouvernements nationaux qu'ils doivent adopter une interdiction globale de toutes les formes de publicité pour le tabac, la promotion et le parrainage des produits du tabac conformément à l'article 13 de la CCLAT .

##### **additional comments**

Afin de protéger la santé publique, le principe du contrôle de la promotion et la publicité transfrontalière de produits du tabac a été inscrit dans la directive publicité pour le tabac (2001/0119). Il est donc logique d'étendre ce principe à la vente des produits du tabac entre les États membres via Internet. Un nombre croissant de preuves montre que la mise des produits du tabac hors de la vue des consommateurs chez les détaillants est une mesure

permettant de réduire le tabagisme chez les jeunes. À ce jour, cette mesure a été adoptée par l'Irlande, le Royaume-Uni et la Finlande. L'adoption à l'échelle européenne d'une interdiction de l'étalage des produits du tabac au point de vente permettrait de renforcer le dispositif de protection de la santé au bénéfice de l'ensemble des européens.

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## **NGO submission**

### **identification**

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### **questions scope**

#### **problem definition**

No

### **explanations**

We do not agree with the definition of the problem. The problem is defined incorrectly and vaguely. There are mixed questions of tobacco products and no- tobacco products containing nicotine, which shows a lack of understanding of the tobacco sector. Defining the problem does not present the best scientific basis for the various options considered in this poll.

### **which option**

No change

### **questions smokeless**

#### **problem definition**

No

### **which option**

Lifting the ban on snus

### **questions consumer**

#### **problem definition**

No

### **explanations**

Definition of the problem is based on several erroneous assumptions, which result in that the whole discussion on consumer information is poorly defined. Communication with the consumer can take place in many different ways and using multiple media. This section focuses exclusively on the packaging. The problem is defined too narrowly and therefore does not identify all possible to use solutions. Way of defining the problem does not permit an objective discussion because: a) the packaging is described as a factor in encouraging young people to smoke, despite the many studies conducted which have failed to establish such a relationship b) the package is presented as an advertisement - and yet the packaging of any product is primarily a key factor distinguishing one from the other devices, enabling consumer choice c) refer to the "attractiveness" as an indicator of one or another shape of regulation is inherently a very subjective and arbitrary.

**which option**

No change

**additional option**

This is the current state of market regulation of tobacco and tobacco products should be primarily used there to inform consumers about the risks associated with smoking, rather than proposing new solutions. Using the current legal situation should occur, e. g. through a fuller and more rigorous enforcement of existing regulations aimed at preventing underage smoking. Member countries should also consider pro-health education campaigns.

**questions on reporting**

**problem definition**

No

**explanations**

There is no justification for the various options proposed in this section. Commission has not developed a framework or forum for discussion of issues in terms of scientific ingredients. The definition of the problem also does not mention SCENIHR opinion on the use of additives and the attractiveness of products and their conclusion that no evidence was found that the components of increasing the level of dependence on tobacco products.

**which option**

Establish a common compulsory reporting format

**regulation of ingredients**

**problem definition**

No

**explanations**

Definition of the problem describes how to use components in a way that is completely invalid. The ingredients are used because they are essential in the production process from a technological point of view (to be able to produce a tobacco product), or in order to distinguish products. There are added there to attract people not smoking. SCENIHR opinion says that there is no evidence that the ingredients increase the level of addiction to tobacco products either by themselves are addictive. In our view it is inappropriate to refer to the "attractiveness" as an indicator of one or another shape of regulation because it is by nature a very subjective and arbitrary.

**which option**

No Change

**access to tobacco products****problem definition**

No

**explanations**

Possibility to display the products is very important for the normal operation of a market economy. It allows the consumer to first make an informed choice. The law should always be on the basis of positive evidence that it will be effective. There is no evidence of a causal relationship between exposure and the start of smoking by minors. Denormalization of tobacco products is not sufficient reason to examine or introduce new legislation.

**which option**

No change

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**NGO submission****identification****affiliation**

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**questions scope****problem definition**

Yes

**which option**

No change

**questions smokeless****problem definition**

Yes

**which option**

Lifting the ban on snus

**questions consumer**

**problem definition**

No

**explanations**

.

**which option**

No change

**questions on reporting**

**problem definition**

No

**explanations**

.

**which option**

Establish a common compulsory reporting format

**regulation of ingredients**

**problem definition**

No

**explanations**

.

**which option**

No Change

**access to tobacco products**

**problem definition**

No

**which option**

No change

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**questions scope**

**problem definition**

Yes

**which option**

Extend the scope of the Directive

**recommend option**

Extend the scope of the Directive to include all smoked products including herbal cigarettes. Do NOT extend the Directive to include electronic nicotine delivery systems (ENDS or E-cigarettes). It is the combustion process and inhalation of smoke that causes most of the harm from smoking. Therefore it is appropriate that herbal cigarettes, which are used in a similar way to nicotine cigarettes, are regulated in the same way as smoked tobacco products, and should be included in the scope of the Directive. Therefore we recommend that the scope of the Directive includes the regulation of any new smoked tobacco products (such as low emission or nicotine-free cigarettes). Novel nicotine based products (that is, products containing nicotine but not tobacco products) have the potential to offer a less hazardous alternative to cigarettes. Currently these include e-cigarettes and nicotine gel. However, as such products are generally marketed as alternatives to cigarettes and in some cases as an aid to quitting smoking, it is appropriate for them to be brought under the same regulatory framework as pharmaceutical products rather than under the scope of the tobacco products directive. The question of how nicotine containing products should be controlled is currently under consideration by the UK's Medicines and Healthcare Regulatory Authority (MHRA) following a recent public consultation on whether to extend its remit on the regulation of nicotine replacement therapies to other nicotine containing products. The outcome of this consultation may assist the Commission in developing its policy on these products.

**questions smokeless**

**problem definition**

Yes

**which option**

No change

**additional option**

With regard to smokeless products that are not currently illegal, particularly those used by ethnic minority populations, we recommend that they are more tightly regulated but we do not support a total ban on such products. Whilst recognising that such products are harmful, the introduction of an EU-wide ban could create an illegal market that would be more difficult to control than the current situation. Furthermore a ban would make it more difficult to engage with users to offer help in quitting

**questions consumer  
problem definition**

Yes

**which option**

Improve consumer information; Introduce generic or plain packaging

**which improvement**

Picture warnings to become mandatory; Tar, nicotine and carbon monoxide levels to be replaced with general information on harmful substances in tobacco products; Information on harmful substances in tobacco products that cannot be placed on the package would be placed inside the package; Health warnings to be put on water pipes

**additional option**

The minimum size of health warnings should be increased to 80% of the front and back surfaces of all tobacco packaging.

**additional comments**

Picture Warnings We strongly recommend that picture warnings should be mandatory and that they should occupy a minimum of 80% of the front and back surfaces of all tobacco packaging (i.e. not just cigarettes). The warnings should be placed on the upper portion of the packs for maximum visibility. The current situation with some Member States adopting picture warnings whilst others have not done so has created a discrepancy and uneven health protection across the EU. From an internal market perspective, the differences in rules are contrary to the operation of the single market and may constitute a barrier to trade. These obstacles should therefore be removed and pictorial health warnings should be mandatory to ensure optimum health protection for all EU citizens. There is good evidence to show that health warnings are effective in conveying the dangers of smoking and helping smokers to quit. They also help deter young people from starting to smoke. Picture warnings are more effective than written warnings.<sup>2</sup> All warnings should be displayed in rotation so that each message is given equal display to reach its target audience. There is widespread consumer support for pictorial health warnings. A Eurobarometer survey conducted in October 2009 showed that 78% of respondents supported health warnings. Information on tar, nicotine & carbon monoxide (TNCO) Currently the Directive requires the inclusion of machine-based tar, nicotine and carbon monoxide yields on cigarette packs. This promotes the mistaken beliefs that some cigarette brands are less harmful than others and that nicotine causes disease. The EU should not only remove this requirement from the Directive but should prohibit ISO or any other emissions numbers on the pack. We support the proposal to replace numerical measurements with descriptive information on the hazardous effects of tobacco constituents and emissions. The addition of a quitline telephone service should be included on the packaging. Additional information on harmful substances in tobacco products We support the proposal to include additional information on the health effects of tobacco consumption on inserts inside the packaging. This should include advice on quitting smoking. Health warnings on water pipes There is a growing body of evidence to show that water pipes are at least as hazardous, if not more so, than other forms of tobacco use. However, there is a common perception that tobacco smoke is 'cleansed' by the water and therefore not as dangerous and some users believe flavoured shisha is not in fact tobacco. It is important that these myths are countered by requiring the inclusion of a health warning on all water pipes. Warnings should also be included on the packaging of tobacco used in water pipes. Generic or plain packaging We strongly recommend the introduction of plain or generic packaging. This should include



not only the removal of all branding from the packaging but the size and shape of the packaging should also be standardised. Not only would this prevent the promotion of smoking through branding as occurs presently but it would reinforce the health warning messages. The Australian federal government has recently announced its intention to introduce plain packaging in 2012, setting a standard that the EU should follow. Tobacco packaging provides a direct link between consumers and manufacturers and is the main marketing channel, particularly in jurisdictions with tobacco advertising bans. Branding gives the misleading impression some cigarettes are safer than others. The tobacco industry claims that plain packaging would contravene intellectual property law. However, legal analysis for Action on Smoking and Health concludes that this is incorrect and there are no legal impediments to the implementation of generic packaging in the EU.

### **questions on reporting**

#### **problem definition**

Yes

#### **which option**

Establish a common compulsory reporting format; Introduce fees and sanctions

#### **additional options**

The current situation which allows different formats and reporting mechanisms is unsatisfactory, making it difficult for authorities to compare and analyse the data. Tobacco companies should be required to use a standardised reporting format. Additionally the companies should be required to pay a yearly registration fee to cover the costs of administering this data collection. The above measures should be compliant with Articles 9 & 10 of the Framework Convention on Tobacco Control (FCTC).

### **regulation of ingredients**

#### **problem definition**

Yes

#### **which option**

Establish a common list of tobacco ingredients

#### **which one**

Establish a positive common list of tobacco ingredients

#### **additional comments**

We support the adoption of a positive common list of tobacco ingredients. Tobacco products are highly toxic and addictive; their contents should therefore be regulated in order to achieve high standards of health protection. A positive common list would ensure that only registered products, with ingredients, flavourings and additives that appear on the positive list would be permitted on the EU market. Currently, EU citizens are not subject to the same level of health protection and a common list of permitted ingredients would go some way towards addressing this anomaly. The tobacco industry uses a range of additives to alter the composition of tobacco products. These can make the product more palatable to children or increase the addictiveness of the product. Therefore any flavourings that may be used to enhance the addictiveness or attractiveness of tobacco products should be banned. The revised Product Directive should be fully compliant with the guidelines on Articles 9 & 10 adopted at the fourth Conference of the Parties of the FCTC on 20th November 2010.

**access to tobacco products****problem definition**

Yes

**which option**

Ban

**which one2**

Cross-border retail sales of tobacco to be banned over the Internet; Vending machines to be banned; Promotion and displays in retail stores to be banned

**additional option**

The EU Directive should follow the lead set by Finland which, as part of its recently passed Tobacco Act, has set limits on the amount of tobacco that can be imported into Finland where the labelling differs from that of tobacco products sold in Finland. We recommend that similar limits should be set at EU level, that is, that for each Member State the amount of tobacco that may be imported for personal use which does not conform to domestic labelling requirements, should be limited to a maximum of 200 cigarettes, 50 cigars, 100 cigarillos and 250 grams of pipe or cigarette tobacco.

**additional comments**

Internet. The principle of preventing cross-border promotion of tobacco products in order to protect public health was enshrined in the Tobacco Advertising directive (2001/0119). It is logical, therefore, to extend that principle to the sale of tobacco products between member states via the Internet. We support the prohibition of tobacco sales via the Internet. Vending machines. The majority of member states (22 out of 27) already prohibit the sale of tobacco products from vending machines in order to deter young people accessing cigarettes from this source. We support this measure. Point of Sale. We support an EU-wide adoption of a ban on the display of tobacco products at the point of sale. Across the EU, most forms of tobacco advertising are now prohibited but the tobacco industry continues to market its products by the use of attractive packaging. Research shows that point of sale displays of tobacco have a direct impact on young people's intention to smoke. Furthermore, there is a growing body of evidence to show that putting tobacco products out of sight in retail outlets can reduce youth smoking. To date, this measure has been adopted by Ireland and Finland (as well as Iceland and Norway) and is going through the parliamentary process in the UK.

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**questions scope**

**problem definition**

Yes

**which option**

Extend the scope of the Directive

**questions smokeless**

**problem definition**

Yes

**which option**

Ban on all types of smokeless tobacco products

**questions consumer**

**problem definition**

Yes

**which option**

Improve consumer information; Introduce generic or plain packaging

**which improvement**

Picture warnings to become mandatory; Tar, nicotine and carbon monoxide levels to be replaced with general information on harmful substances in tobacco products; Information on harmful substances in tobacco products that cannot be placed on the package would be placed inside the package; Health warnings to be put on water pipes

**questions on reporting**

**problem definition**

Yes

**which option**

Introduce fees and sanctions

**regulation of ingredients**

**problem definition**

Yes

**which option**

Establish a common list of tobacco ingredients

**which one**

Establish a positive common list of tobacco ingredients

**access to tobacco products**

**problem definition**

Yes

**which option**

Ban

**which one2**

Cross-border retail sales of tobacco to be banned over the Internet; Vending machines to be banned; Promotion and displays in retail stores to be banned

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**NGO submission**

**identification**

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**questions scope**

**problem definition**

Yes

**which option**

Extend the scope of the Directive

**additional comments**

Tous les produits du tabac sont toxiques à la santé et il n'existe pas de seuil de risque. Le champ d'application de la directive doit dès lors concerner l'ensemble de ces produits et veiller à ce qu'en l'état, de nouvelles formes de produits tels que le snus ou autres tabacs non fumés ne soient pas introduits sur le marché, susceptibles d'accroître encore la consommation. Il est à noter que les produits de la nicotine utilisés dans une optique thérapeutique font actuellement, et de manière légitime, l'objet de réglementations sanitaires extrêmement strictes. En revanche la réglementation et l'information imposées à l'égard des produits du tabac demeurent comparativement inversement proportionnelles à la toxicité de ces produits. Dans cette perspective, il incombe de renforcer considérablement le contrôle sur la composition de ces produits ainsi que l'information sur le caractère toxique, addictif et nuisible sur le plan sanitaire mais aussi économique, social et environnemental des produits du tabac.

**questions smokeless**

**problem definition**

Yes

**which option**

No change

**additional comments**

L'interdiction concernant le snus doit être en l'état maintenue. Il s'agit d'une priorité essentielle. L'introduction d'un nouveau produit comme le snus aujourd'hui risque d'induire une augmentation de la consommation de tabac par l'accroissement de l'offre et dissuader des fumeurs d'arrêter complètement de consommer des produits du tabac. En effet, les conditions d'introduction du snus dans une optique de réduction de risques, à la fois pour l'individu et pour la société, ne sont pas réunies. En l'absence de consensus au sein de la communauté de santé publique et d'études expérimentales réalisées à son initiative, dans différents Etats membres de l'Union Européenne, en vue de déterminer si le snus pourrait s'inscrire dans une optique de protocole de prise en charge de fumeurs qui ne parviennent pas à arrêter de fumer ou qui ne veulent pas à l'instant T, la demande de snus aujourd'hui, dans l'hypothèse d'une levée de son interdiction, serait uniquement développée à l'initiative des opérations de marketing des fabricants de tabac. En revanche, il serait nécessaire que la communauté scientifique et de santé se saisisse sereinement de cette problématique de la réduction de risques. Des études prospectives devraient être réalisées visant à la possible introduction du snus dans la seule optique de réduction de risques pour des fumeurs qui ne parviennent pas à arrêter de fumer des cigarettes et avec une absence de toute promotion de ces produits au niveau de l'initiation. Une telle démarche s'inscrit dans un contrôle nécessaire de l'ensemble des produits du tabac et de la nicotine, dans le cadre d'une agence européenne de réglementation, réunissant des représentants des autorités sanitaires, des scientifiques, des représentants de la société civile impliqués dans le contrôle du tabac et le sevrage tabagique. Cela devrait exclure très clairement toute représentation des fabricants de tabac dont les intérêts ont été démontrés comme inconciliables avec ceux de la santé publique. Cette disposition serait une application des engagements pris par la Commission Européenne et la quasi-totalité des Etats membres, qui ont ratifié la Convention Cadre de l'OMS pour la Lutte Anti-tabac, notamment son article 5.3.

**questions consumer****problem definition**

No

**explanations**

La définition du problème pourrait être améliorée. Nous partageons l'analyse de la Commission selon laquelle la situation actuelle induit des différences majeures entre les Etats Membres selon qu'ils ont adopté ou pas l'apposition d'avertissements graphiques sur les emballages des produits du tabac. Cette différence signifie une distorsion de qualité d'information en direction des consommateurs et citoyens européens, les avertissements graphiques ayant également une vertu préventive majeure. Par ailleurs, les dispositions de la directive sont sensiblement en deçà aujourd'hui des recommandations internationales fondées sur les évidences scientifiques qui préconisent une surface beaucoup plus importante dédiée aux avertissements sanitaires. (Lignes directrices de l'article 11 de la CCLAT). Ces dispositions ont été adoptées, notamment par la Commission Européenne et la quasi-totalité des Etats Membres en novembre 2008. Les Etats membres qui souhaitent apposer des avertissements sanitaires comme la France à partir de 2011 ont été contraints de limiter la surface pour ces avertissements graphiques en raison du caractère obsolète de la directive. Il est indispensable que la directive soit donc modifiée pour se mettre en conformité avec les

prescriptions adoptées dans le cadre de la CCLAT. Nous partageons également l'analyse que l'utilisation des packagings des produits du tabac en tant que supports publicitaires n'est pas couverte par la présente directive relative aux produits. Il apparaît bien cependant que les produits du tabac et leur conditionnement sont inextricablement liés et conçus pour attirer les consommateurs, notamment les jeunes. En France, les différents fabricants de tabac sont condamnés définitivement chaque année par les Tribunaux pour violation des législations en vigueur et l'on a constaté au cours de cette dernière décennie une envolée de l'utilisation d'arômes et de parfums associées à des packagings évocateurs visant à faire oublier la dangerosité des produits et à assimiler les produits du tabac à des confiseries, parfums, accessoires ... Dans cette perspective, il importe d'envisager de manière concomitante l'obligation d'apposer des avertissements graphiques et l'instauration de paquets neutres standardisés (ou paquets génériques). Non fumeurs comme fumeurs sont favorables à l'instauration de packagings susceptibles de leur donner des informations sur les ingrédients et sur les risques. Dans cette perspective, ils soutiennent tout particulièrement l'instauration de paquets neutres standardisés : 68 % des 18 ans et plus se déclarent favorables en France à l'introduction de ces paquets . Cette proportion croît de manière encore plus massive (87, dont 59% de très favorables ) lorsqu'il apparaît qu'une telle disposition est susceptible de dissuader les jeunes de commencer à fumer. Par ailleurs, des études scientifiques ont montré l'efficacité des paquets neutres standardisés pour dénormaliser le tabac, inciter à ne pas commencer à fumer et à arrêter .

#### **which option**

Improve consumer information; Introduce generic or plain packaging

#### **which improvement**

Picture warnings to become mandatory; Tar, nicotine and carbon monoxide levels to be replaced with general information on harmful substances in tobacco products; Information on harmful substances in tobacco products that cannot be placed on the package would be placed inside the package; Health warnings to be put on water pipes

#### **additional option**

L'importance majeure des avertissements : L'industrie a développé au fil des décennies toute une imagerie glamour, ludique, rebelle, et séduisante autour du packaging de son produit. Afin de casser ce marketing et de montrer aux consommateurs la réelle dangerosité du tabac, il faut apposer sur les paquets des produits du tabac des avertissements graphiques illustrant les dégâts causés par le tabagisme actif et passif. Ces images sont plus efficaces que de simples mots. Instauration de paquets neutres standardisés ou paquets génériques : Le CNCT soutient fortement l'introduction de paquets neutres standardisés pour l'ensemble des produits du tabac par la suppression de toute référence à l'univers publicitaire de la marque et l'apposition du nom de celle-ci de manière générique. La définition d'une taille et d'une forme standardisée du paquet est également requise. L'objectif est de supprimer les packagings comme supports publicitaires mais également de parvenir à une meilleure mise en exergue des avertissements apposés sur les conditionnements et enfin de mettre un terme aux pratiques actuelles de détournement des dispositions de la directive en vigueur qui interdit l'apposition de descriptifs mensongers tels que douce, légères ... et qui sont remplacées par les cigarettiers par des codes couleurs. Le CNCT insiste sur la nécessité de réglementer de manière positive les packagings des produits du tabac en raison notamment de la permanence d'une fraude à la loi de la part de l'ensemble des fabricants de tabac. Le CNCT à l'instar d'autres organisations internationales, a réalisé plusieurs études sur l'opportunité et la faisabilité juridique et pratique des paquets neutres concluent clairement à l'intérêt de cette

mesure et à sa faisabilité juridique. Remplacer les informations quantitatives relatives aux goudrons, nicotine et monoxyde de carbone par des informations qualitatives sur les ingrédients, les teneurs et apposer un numéro de téléphone pour les lignes téléphoniques d'aide à l'arrêt. Les rendements indiqués sur les packagings sont ceux définis par des machines à fumer et ne sont pas fidèles de la manière de fumer des fumeurs. Les données quantitatives n'apportent aucune information aux consommateurs, elles sont même susceptibles de les induire en erreur en leur laissant croire que certaines cigarettes sont moins dangereuses que d'autres. La France a banni l'utilisation des descriptifs tels que légers. Pourtant une étude révèle que près d'un Français sur 2 croit prendre moins de risque pour sa santé avec des cigarettes moins « chargée » en nicotine. Le dispositif d'information qualitative sur les ingrédients en substitution des données quantitatives était très apprécié de même que l'instauration d'un dispositif complémentaire d'information notamment au travers de l'insertion de vignette à l'intérieur des paquets.

### **additional comments**

Plus d'une trentaine d'études ont montré que cette disposition contribue à réduire la consommation et à dénormaliser les produits du tabac. Elle : - améliore le niveau de connaissance sur les méfaits; - a un impact sur l'envie d'arrêter de fumer; - motive les non fumeurs et ex fumeurs à le rester ; - dissuade les jeunes d'entrer dans le tabagisme ; - renforce la lisibilité, visibilité et compréhension des messages sanitaires, en particulier sur les populations défavorisées ; - réduit significativement l'attractivité du paquet de cigarettes et incite moins les jeunes à commencer à fumer. Sur un plan pratique et pour optimiser leur efficacité, les avertissements visuels doivent être: • segmentés • apposés sur le devant et le derrière du paquet , • en haut du paquet , • les plus grands possibles (80% de la surface comme en Uruguay) , • avec des images en couleur , • alternés et renouvelés régulièrement (un changement au minimum tous les deux ans) , • associés à des fiches d'information sur les aides à l'arrêt du tabac (qui peuvent être glissés à l'intérieur du paquet de cigarettes comme au Canada) afin de rassurer les fumeurs sur leur capacité à arrêter de fumer .

### **questions on reporting**

#### **problem definition**

Yes

#### **which option**

Establish a common compulsory reporting format; Introduce fees and sanctions

### **additional comments**

La situation actuelle qui se caractérise par l'existence de plusieurs formats et des mécanismes de notification différents induit des difficultés majeures pour les autorités publiques en vue d'analyser et de comparer ces données. Elle est préjudiciable au bon fonctionnement du marché intérieur et elle va à l'encontre de la nécessaire transparence requise dans le cadre des articles 9 et 10 du traité de la CCLAT pour communiquer et définir une réglementation des produits du tabac particulièrement toxiques mais aujourd'hui très peu réglementés. Tous les fabricants et importateurs doivent être soumis aux mêmes exigences de notification. Compte tenu du caractère extrêmement toxique des produits du tabac, ces derniers devraient être soumis à une obligation de diffusion des données les plus complètes possibles, en vue d'accroître la connaissance scientifique sur ces produits dans une optique sanitaire et de réduction de la consommation et en vue également de permettre des comparaisons. Cette démarche s'inscrit ainsi également dans une optique de lutte contre le commerce illicite des produits du tabac au travers d'un contrôle de l'offre. Un tel format de notification existe déjà,

développé par la Commission en mai 2007, et devrait donc être généralisé. Cette généralisation apparaît en effet aisée et peu coûteuse à mettre en œuvre. L'introduction de droits annuels d'enregistrements afin de financer la collecte des données sur les ingrédients par les autorités nationales ainsi que le travail d'analyse de ces ingrédients est une bonne disposition. Il importe que la valeur du montant soit déterminé et révisé de telle manière que ce travail n'induisse pas de prélèvement sur les budgets de financements du contrôle du tabac qui sont par ailleurs, très limités et sont indispensables pour mettre en œuvre d'autres politiques publiques de réduction de la consommation de tabac.

### **regulation of ingredients**

#### **problem definition**

Yes

#### **which option**

Establish a common list of tobacco ingredients

#### **which one**

Establish a positive common list of tobacco ingredients

#### **additional comments**

Le CNCT soutient l'adoption d'une liste positive d'ingrédient du tabac . Compte tenu de la haute toxicité de ces produits et de leur caractère addictif, la composition de ceux-ci devrait être étroitement réglementée. Une telle liste positive est nécessaire au niveau européen car selon les Etats Membres, les informations transmises aux consommateurs peuvent différer sensiblement ce qui constitue un dysfonctionnement du marché intérieur et l'instauration de discrimination entre les différents consommateurs et citoyens de l'Union Européenne. Certains sont ainsi exposés à certaines substances tandis que d'autres en sont préservés ... Le CNCT soutient l'interdiction de l'utilisation de tout arôme et de tout élément susceptible d'accroître l'attractivité du produit. L'utilisation des arômes n'est pas une nouveauté ainsi que l'attestent les documents internes de l'industrie du tabac. Le fabricant RJ Reyndolds (JTI) indiquait ainsi en 1972 dans une note à propos de l'utilisation des arômes que «Le goût des fraises connaît une forte acceptabilité parmi le marché des jeunes » L'élément nouveau dans nombre de marchés, et notamment celui de la France, est le développement exponentiel de l'utilisation des arômes au cours de ces dernières décennies. Une étude réalisée par le Comité National Contre le Tabagisme - CNCT en France met en exergue la progression de l'utilisation des arômes en 10 ans entre 1998 et 2008 avec aujourd'hui un recours dorénavant généralisé à l'ensemble des produits du tabac. 11 parfums étaient utilisés en 1998 v/ près de 50 ans 2008, le nombre de produits par marque est passé de 28 à près de 300 pendant la même période. L'évolution des catégories d'arômes reflètent également les cibles visées par les fabricants à savoir : 1. les enfants et adolescents au travers de l'adjonction d'arômes de fruits, souvent acidulés : fraise, mangue, Ou encore d'arômes traditionnels pour les produits de confiserie : caramel, chocolat, vanille, miel, choco-mint, bubble gum, café, réglisse, nougat, ... On constate également que le prix de ces produits aromatisés conçus comme des paquets enfants - paquets bonbons est adapté pour les petits budgets car ces paquets sont moins chers que les produits « classiques ». 2. les femmes sont également ciblées avec le recours à des parfums et des épices tels que le jasmin, le lilas, la rose, l'anis, la cannelle, le clou de girofle,...) 3. Enfin, une autre catégorie renvoie à un public mixte au travers de l'utilisation d'alcools, en particulier Cognac, Pina Colada, Champagne, Bourbon, Martini, Gin, Kir, .... S'agissant des arômes les plus acidulés, les objectifs poursuivis par les fabricants de tabac sont de masquer l'âcreté du produit pour les plus jeunes, de proposer ainsi un produit



d'initiation permettant de capter l'intérêt des enfants et de les faire évoluer vers d'autres produits de la gamme au fur et à mesure qu'ils grandissent. Globalement l'utilisation de ces arômes conduit à une banalisation et à une altération de la perception des produits du tabac comme des produits dangereux. L'acte de fumer est assimilé à un simple geste de gourmandise ou encore à un accessoire de type parfum pour les produits aux arômes de fleurs ... alors que ces produits sont tout aussi dangereux que les autres. Il est donc essentiel de contrôler l'offre des produits en interdisant l'utilisation de tels arômes, conformément aux lignes directrices des articles 9 et 10 adoptées à la 4ème Conférence des Parties de la CCLAT à Punta del Este en novembre 2010 et en interdisant également qu'une présentation attractive des packagings permettent une association à des produits de confiserie, parfums et autres accessoires. Par ailleurs, le produit en tant que tel est de plus en plus conçu de manière attractive via notamment l'utilisation de papier de couleur ou de papier à cigarettes illustrées par de grands designers. (ex paquets Vogue jour, Vogue Nuit ou Pink Elephant ...)

### **access to tobacco products**

#### **problem definition**

Yes

#### **which option**

Ban

#### **which one2**

Cross-border retail sales of tobacco to be banned over the Internet; Vending machines to be banned; Promotion and displays in retail stores to be banned

#### **additional option**

Nous demandons à la Commission l'instauration d'une interdiction de toute publicité et promotion sur le lieu de vente conformément aux engagements pris à Durban, lors de la 3ème Conférence des Parties à la CCLAT en novembre 2008.

#### **additional comments**

Internet. La France prévoit un dispositif d'interdiction d'achat des produits du tabac sur internet ou à distance "Les débiteurs ne peuvent vendre du tabac qu'aux clients présents dans l'enceinte du débit. Il leur est interdit de vendre du tabac par correspondance ou par réseaux informatiques". En l'absence d'harmonisation des législations, en particulier au niveau des différents Etats Membres de l'Union Européenne, cette disposition protectrice trouve néanmoins son efficacité réduite. Un observatoire internet réalisé par le CNCT pour le Ministère de la Santé en 2007-2008 soulignait notamment la nécessité de généraliser ce principe avec les dispositions de contrôle et de sanctions associés vis-à-vis des sites sources mais également des fournisseurs de contenus pouvant être poursuivis pour complicité. En limitant les possibilités d'accès aux produits, on restreint non seulement l'offre et également la demande, et par ailleurs, on est davantage en mesure de contrôler cette offre et de lutter contre toute forme de commerce illicite des produits du tabac. Distributeurs automatiques : La France interdit de tels distributeurs automatiques préservant notamment les plus jeunes de l'accessibilité à ces produits. Point de vente : En France, les produits du tabac sont vendus dans les débits de tabac et il existe une exception au principe d'interdiction de toute publicité dans ces lieux, cette exception est cependant strictement encadrée et était initialement justifiée par un souci d'information en direction des consommateurs. Ainsi la publicité : - ne doit pas être visible de l'extérieur du débit ; - doit être exclusivement sous la forme d'une affichette d'un format maximal de 60 x 80 cm ; - cette affichette ne peut comporter d'autres mentions

que la dénomination du produit, sa composition, ses caractéristiques et conditions de vente, à l'exception du prix, le nom et l'adresse du fabricant et, le cas échéant, du distributeur ; - cette affiche ne doit avoir aucune autre représentation graphique ou photographique que celle du produit, de son emballage et de l'emblème de la marque ; - l'affiche doit également comporter un avertissement sanitaire, lui-même apposé selon des règles de taille, emplacement, formulation, bien précises. Une évaluation de cette réglementation en France vient d'être rendue publique et met en exergue que plus de 80 % des débits de tabac violent la réglementation en vigueur. Sur l'ensemble des PLV recensées, 88 % des publicités étaient illicites sur la forme (format affiche non respecté) ou sur le contenu (présence d'un slogan publicitaire, mention du prix, visuel autre que le produit du tabac etc..). De plus, il apparaît que ces supports sont conçus pour faire oublier la nature dangereuse du tabac en utilisant les codes publicitaires d'autres produits inoffensifs (bonbons, musique, jeux, produits high-tech...) souvent consommés par les jeunes. L'exception conçue à des fins d'information se trouve totalement détournée et a conduit les fabricants à développer toute une désinformation et une promotion de leurs produits. Cette évaluation met clairement en exergue la nécessité d'interdire strictement toute publicité sur le lieu de vente y compris au niveau de l'étal en raison de la permanence des détournements et des violations qui sont systématiquement faits dans le cas d'exception. Le CNCT soutient fortement l'instauration du dispositif de vente sous le comptoir (ou assimilé) susceptible de limiter l'accessibilité et la promotion des produits, notamment en direction des plus jeunes et le CNCT préconise un nouveau dispositif d'information en direction des consommateurs.

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## **NGO submission**

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### **questions scope**

#### **problem definition**

No

### **explanations**

The problem definition could be improved. It should be clearly stated that the tobacco product directive sets the minimum limits to regulate the tobacco products. To ensure the high-level health protection of their citizens the member states would be allowed impose further

regulations as long as those do not restrict the free movements of goods. Finland, as well as the European Commission, has ratified Framework Convention on Tobacco Control. It reaffirms the right of all people to the highest standard of health. Furthermore, article 114.3 of the Treaty states that when establishing rules for the functioning of the internal market in the context of health, safety, environmental protection and consumer protection, the Commission “will take as a base a high level of protection, taking account in particular of any new development based on scientific facts.”

**which option**

Extend the scope of the Directive

**recommend option**

Tobacco products are no ordinary commodities. Many compounds of the tobacco products contain and the smoke they produce is pharmacologically active, toxic, mutagenic and carcinogenic. There is no safe level of usage. Therefore we recommend that the scope of the Directive includes the regulation of any new smoked tobacco products (such as low emission or nicotine-free cigarettes). The prohibition of snus, should be maintained. Herbal cigarettes are also dangerous, and therefore they should be included in the scope Tobacco Products Directive and have health warnings. Some forms of nicotine based products (such as electronic cigarettes, nicotine gel, drinks, and sweets) are often marketed as alternatives to cigarettes and as quitting aid. In our opinion they should in no circumstances to be considered as an aid to quitting smoking. There are strictly regulated pharmaceutical products to help smokers in quitting.

**questions smokeless**

**problem definition**

Yes

**which option**

Ban on all types of smokeless tobacco products

**additional option**

The International Agency for Research on Cancer (IARC) in their Monographs Vol 6 (IARC Monographs on the Evaluation of Carcinogenic Risks to Humans Volume 89 (2007), Smokeless Tobacco and Some Tobacco-specific N-Nitrosamine) represent as a scientific conclusion that “there is sufficient evidence in humans for the carcinogenicity of smokeless tobacco. Smokeless tobacco causes cancers of the oral cavity and pancreas. There is sufficient evidence in experimental animals for the carcinogenicity of moist snuff.” As an overall evaluation they declare that smokeless tobacco is carcinogenic to humans (Group 1). Now that the use of smokeless tobacco products is not widely spread we recommend a ban on all types of smokeless tobacco products. We do not support lifting the ban of snus as there is no legitimate reason to introduce any new dangerous product onto the market. Finland is Sweden's neighbouring country, and was a part of Sweden for about 600 years. However, we have not get used to use snus. In Finland, due to our comprehensive tobacco control policy daily smoking has been declining constantly. Nowadays, the prevalence of daily smoking is among the lowest in the EU: 22 % men and 16 % women were daily smokers in 2009. The use of snus is minimal. Snus is not an alternative to treat nicotine addiction. There are already available effective treatments for nicotine addiction, including medicinal or ‘clean’ nicotine (NRT), that do not carry the risks associated with the use of snus.

**questions consumer  
problem definition**

No

**explanations**

The problem definition could be clarified. The current situation, where some Member States have mandatory graphic warnings and others have not, has led to a disparity in labelling. In addition some consumers do not get enough information on the devastating effects of smoking on their health. Indeed, tobacco packaging and product features are increasingly used to attract consumers, to promote products and brand image. The importance of packaging as a marketing channel has increased when other kind of tobacco advertising has been banned or restricted. Packaging as an advertising measure is not covered by the current Directive.

**which option**

Improve consumer information; Introduce generic or plain packaging

**which improvement**

Picture warnings to become mandatory; Health warnings to be put on water pipes

**additional option**

There should be mandatory pictorial health warnings on all tobacco products (including oral and water pipe tobacco) covering 80% of the front and the back of the packs towards the top, in combination with standardized packaging. Pictures are able to create interest and make people to read the associated text message. We find it important to introduce standardised/plain packaging. Tobacco packaging and product features are used to attract consumers, especially young people. All branding from the packaging should be removed and the size and shape of the packaging should be standardised. In addition, tobacco companies should only be allowed to have one standardized package size per cigarette brand. There should be information on Quit line, preferably the number, on all packs of tobacco products.

**additional comments**

The article 114.3 of the Treaty states that when establishing rules for the functioning of the internal market in the context of health, safety, environmental protection and consumer protection, the Commission “will take as a base a high level of protection, taking account in particular of any new development based on scientific facts.”

**questions on reporting**

**problem definition**

Yes

**which option**

Establish a common compulsory reporting format; Introduce fees and sanctions

**additional comments**

The current system makes it difficult for authorities to compare and analyse the data. All tobacco manufacturers and importers should have the same reporting requirements. We welcome a yearly registration fee paid by the tobacco companies to national competent authorities in order to finance their data collection and analysis work on ingredients. To control smuggling it is extremely important that only registered products would be allowed on the market.

**regulation of ingredients****problem definition**

Yes

**which option**

Establish a common list of tobacco ingredients

**which one**

Establish a positive common list of tobacco ingredients

**additional comments**

Cigarettes and some other products containing tobacco are highly engineered to create and maintain dependence. Many of the compounds they contain and the smoke they produce are pharmacologically active, toxic, mutagenic and carcinogenic. Flavourings are an increasingly important element of tobacco marketing, particularly to young people. Flavourings, such as sugars and sweeteners, flavouring substances, and spices and herbs enhance attractiveness, encourage youth initiation, and discourage cessation. The prohibition of these kinds of ingredients in cigarettes and cigarette-like tobacco products should be introduced. The ingredients that may create the impression of a health benefit, ingredients associated with energy and vitality (e.g. caffeine), and ingredients with colouring properties (e.g. coloured cigarette paper) should also be banned. The above measures should be compliant with Articles 9 & 10 of the Framework Convention on Tobacco Control (FCTC).

**access to tobacco products****problem definition**

Yes

**which option**

Ban

**which one2**

Cross-border retail sales of tobacco to be banned over the Internet; Vending machines to be banned; Promotion and displays in retail stores to be banned

**additional option**

We urge the Commission to call for a ban on the promotion of tobacco products at point of sale and a ban on vending machines. These measures are important for health protection. The Directive should also remind national governments that they should adopt a comprehensive ban on all forms of tobacco advertising, promotion and sponsorship in accordance with Article 13 of the FCTC which calls on Parties to.

**additional comments**

Internet. The principle of preventing cross-border promotion of tobacco products in order to protect public health was highlighted in the Tobacco Advertising directive (2001/0119). Buying tobacco through Internet has become easier and more common. The problem includes the sale of tobacco products to minors, tax evasion and uncontrolled sales promotion of tobacco products. Therefore, we support the prohibition of tobacco sales via the Internet. Vending machines. In Finland vending machines will be banned in 2015. Point of Sale. In the EU member states the tobacco companies' marketing strategy is to advertise their products by

making them very visible at point of sale. In Finland tobacco displays are banned on 1st January 2012. The measure has also been adopted by Ireland, and there are some other member states planning to do so. There is a growing body of evidence to show that putting tobacco products out of sight in retail outlets can reduce youth smoking. We support an EU-wide adoption of a ban on the display of tobacco products at the point of sale.

---

## **NGO submission**

### **identification**

#### **affiliation**

NGO

#### **name**

Gerhard Krykalla

#### **email**

gergard@krykalla.de

#### **country**

Deutschland

#### **age**

62

#### **gender**

male

#### **questions scope**

##### **problem definition**

Yes

##### **which option**

No change

#### **questions smokeless**

##### **problem definition**

Yes

##### **which option**

No change

#### **questions consumer**

##### **problem definition**

Yes

##### **which option**

No change

**questions on reporting  
problem definition**

Yes

**which option**

No change

**regulation of ingredients  
problem definition**

Yes

**which option**

No Change

**access to tobacco products  
problem definition**

Yes

**which option**

No change

---

**NGO submission**

**identification**

**affiliation**

NGO

**name**

horatiu eisgeth

**email**

h.eisgeth@vgda.aponet.de

**country**

deutschland

**age**

39

**questions scope  
problem definition**

Yes

**which option**

No change

**questions smokeless  
problem definition**

Yes

**which option**

No change

**questions consumer**

**problem definition**

Yes

**which option**

No change

**questions on reporting**

**problem definition**

Yes

**which option**

No change

**regulation of ingredients**

**problem definition**

Yes

**which option**

No Change

**access to tobacco products**

**problem definition**

Yes

**which option**

No change

---

**NGO submission**

**identification**

**affiliation**

NGO

**name**

Kämke

**email**

retap2008@web.de

**country**

Hamburg



**gender**  
male

**questions scope**  
**problem definition**  
Yes

**which option**  
No change

**recommend option**  
Keine Änderungen keine weitere Diskriminierung der Raucher

**questions smokeless**  
**problem definition**  
Yes

**which option**  
No change

**questions consumer**  
**problem definition**  
Yes

**which option**  
No change

**questions on reporting**  
**problem definition**  
Yes

**which option**  
No change

**regulation of ingredients**  
**problem definition**  
Yes

**which option**  
No Change

**access to tobacco products**  
**problem definition**  
Yes

**which option**  
No change

---

## **NGO submission**

### **identification**

#### **affiliation**

NGO

#### **name**

AHRESP - Associação da Hotelaria, Restauração e Similares de Portugal

#### **email**

Portugal

#### **gender**

No

### **questions scope**

#### **problem definition**

Ensuring high levels public health protection should be a goal for all of us, however, is not justified, to ban products without any proof or scientific evidence regarding their potential harm.

#### **explanations**

No change

---

## **NGO submission**

### **identification**

#### **affiliation**

NGO

#### **name**

ASSOUTENTI Vicolo Orbetelli 10 00186, Roma

#### **email**

Italia

#### **gender**

Yes

#### **explanations**

No change

### **recommend option**

Appare a nostro avviso ingiustificato un ampliamento dell'ambito applicativo della Direttiva ai prodotti simili al tabacco. Riteniamo, infatti, che l'attuale esclusione di alcuni prodotti dalla Direttiva in esame trovi la sua ratio principale nel fatto che tali prodotti sono già oggetto di regolamentazione in altri settori legislativi, in particolare in ambito alimentare e farmaceutico.

Si tratta, ad esempio, delle caramelle alla nicotina, delle sigarette alle erbe o quelle elettroniche, prodotti per i quali, si aggiunge, non esiste alcuna prova scientifica che ne dimostri il carattere non nocivo per la salute. Al più, per estremo scrupolo, per tali prodotti solo simili al tabacco si potrebbero prevedere delle indicazioni in merito al contenuto dei medesimi e ai possibili rischi che il loro uso comporta per la salute.

---

### **NGO submission**

#### **identification**

##### **affiliation**

NGO

##### **name**

Håkan Karlsson

##### **email**

Sweden

##### **country**

41

##### **age**

male

##### **gender**

Yes

##### **explanations**

No change

##### **recommend option**

Due to the health problems it should be prohibited in the future but this scope is a reasonable way to start. The icehockey club I represent have only young boys and girls active and in the ages 16- and up we have some problems with people using tobacco in different ways because it is "tough".

---

### **NGO submission**

#### **identification**

##### **affiliation**

NGO

##### **name**

QUIT and European Network of Quitlines

##### **email**

UK

**gender**

Yes

**explanations**

Extend the scope of the Directive

**recommend option**

The US supreme court ruling in *FDA v Brown & Williamson*, 529 US 120 (2000), reaffirmed in *Sottera v FDA* 10-5032 (2010) has created a problem in the US that the EU can avoid as nicotine for pleasure is now treated as tobacco (and as such part of the World Trade Organisation rules and WHO FCTC) and nicotine with therapeutic effects as treated as a medicines and medical devices matter (an FDA matter). WTO may overrule WHO FCTC if a dispute arises between the EU and US/ China over nicotine products and devices. All nicotine and tobacco products are hazardous to health – there is no safe level of usage. Therefore we recommend that the scope of the Directive includes the regulation of any new smoked tobacco products (such as low emission or nicotine-free cigarettes), while the prohibition of any novel forms of oral tobacco, including snus, should be maintained. Herbal cigarettes are also harmful because it is the combustion and inhalation of smoke that causes most of the harm from smoking. Therefore, herbal cigarettes should be included in the scope Tobacco Products Directive and should also be subject to health warnings requirements. Finally, all forms of nicotine based products (that is, products containing nicotine but which are not tobacco products, such as electronic cigarettes, nicotine gel, drinks, and sweets) are often marketed as alternatives to cigarettes and in some cases as an aid to quitting smoking. Therefore, they should only be sold as quitting aids and comply with specific safety and quality requirements under the same regulatory framework as pharmaceutical products rather than under the scope of the Tobacco Products Directive.

---

**NGO submission****identification****affiliation**

NGO

**name**

Asian Quitline

**email**

UK

**gender**

Yes

**explanations**

Extend the scope of the Directive

**which option**

To merge the Medical Devices Directive (93/42/EEC) with Tobacco Products Directive

2001/37/EC and avoid the jurisprudence problem that the *Sottera, Inc. v. FDA*, No. 10-5032 (2010) affirming *FDA v. Brown & Williamson*, 529 U.S. 120 (2000) that has created a chimera in that nicotine sold for enjoyment (e-cigarettes and maybe many other such products to come) is treated as tobacco (weakly regulated), while nicotine sold with therapeutic (NRT cessation products) is treated as a medicine and devices issue and severely regulated. Also, to include Ghutka from India as an oral tobacco. Indian Supreme Court has ruled creatively using the Plastics (Manufacture, Usage and Waste Management) Rules, 2009 to ban Indian Smokeless Tobacco (Ghutka) sold in plastic sachets. Gutkha should be covered in Tobacco Products Directive 2001/37/EC as well as Snus.

---

## **NGO submission**

### **identification**

#### **affiliation**

NGO

#### **name**

Goedert

#### **email**

Luxembourg

#### **gender**

No

### **questions scope**

#### **problem definition**

Le champ d'application de la directive doit couvrir tous les produits du tabac tout en prenant en compte les spécificités de chacun des différents produits présents sur le marché. Il nous semble également important d'éviter que ne soit imposé aux opérateurs européens de taille modeste de nouvelles contraintes administratives ou réglementaires qui pourraient conduire à une discrimination envers les petites structures. Le développement de nouveaux produits au sein du marché européen doit également être garanti.

#### **explanations**

No change

#### **recommend option**

La description du marché ne nous semble pas refléter la réalité actuelle dans la mesure où hormis en matière d'emballages, d'unités de vente et de la multiplication des marques au sein d'une même catégorie de produits, le marché ne s'est pas diversifié depuis l'adoption de la directive 2001/37/CE. Nous répétons que tous les produits du tabac peuvent être englobés dans le processus de révision de la directive. Toutefois, les produits tels que les cigarettes aux herbes, les boissons et bonbons contenant de la nicotine ou les cigarettes électroniques ne doivent pas être inclus dans ce processus de révision.

---

## **NGO submission**

**identification****affiliation**

NGO

**name**

Goedert

**email**

Luxembourg

**gender**

No

**questions scope****problem definition**

Le champ d'application de la directive doit couvrir tous les produits du tabac tout en prenant en compte les spécificités de chacun des différents produits présents sur le marché. Il nous semble également important d'éviter que ne soit imposé aux opérateurs européens de taille modeste de nouvelles contraintes administratives ou réglementaires qui pourraient conduire à une discrimination envers les petites structures. Le développement de nouveaux produits au sein du marché européen doit également être garanti.

**explanations**

No change

**recommend option**

La description du marché ne nous semble pas refléter la réalité actuelle dans la mesure où hormis en matière d'emballages, d'unités de vente et de la multiplication des marques au sein d'une même catégorie de produits, le marché ne s'est pas diversifié depuis l'adoption de la directive 2001/37/CE. Nous répétons que tous les produits du tabac peuvent être englobés dans le processus de révision de la directive. Toutefois, les produits tels que les cigarettes aux herbes, les boissons et bonbons contenant de la nicotine ou les cigarettes électroniques ne doivent pas être inclus dans ce processus de révision.

---

**NGO submission****identification****affiliation**

NGO

**name**

EPA - European Parents' Association

**email**

europe

**gender**

Yes

**explanations**

No change

---

**NGO submission**

**identification**

**affiliation**

NGO

**name**

FOOX Groothandelsorganisatie

**email**

Nederland

**gender**

No

**questions scope**

**problem definition**

Any form of regulation of „tobacco products“ must be based on scientific findings as well as on unequivocally given legislative competence of the EU. This also applies to any possible regulations or even prohibitions on nicotine-containing products that do not contain tobacco or cigarette-like products (herbal cigarettes).

**explanations**

No change

---

**NGO submission**

**identification**

**affiliation**

NGO

**name**

Groothandel Bergsma / S.B. Van der Zee

**email**

Nederland

**country**

39

**age**

male

**gender**

No

**questions scope****problem definition**

Any form of regulation of „tobacco products“ must be based on scientific findings as well as on unequivocally given legislative competence of the EU. This also applies to any possible regulations or even prohibitions on nicotine-containing products that do not contain tobacco or cigarette-like products (herbal cigarettes).

**explanations**

No change

---

**NGO submission****identification****affiliation**

NGO

**name**

G.W. de Vries, director of Lekkerland Nederland BV, the largest wholesaler of tobacco products in Holland

**email**

Netherlands

**age**

male

**gender**

No

**questions scope****problem definition**

Any form of regulation of „tobacco products“ must be based on scientific findings as well as on unequivocally given legislative competence of the EU. This also applies to any possible regulations or even prohibitions on nicotine-containing products that do not contain tobacco or cigarette-like products (herbal cigarettes).

**explanations**

No change

---

**NGO submission****identification****affiliation**



NGO

**name**

René van der Steeg

**email**

NL

**country**

44

**age**

male

**gender**

No

**questions scope**

**problem definition**

Any form of regulation of „tobacco products“ must be based on scientific findings as well as on unequivocally given legislative competence of the EU. This also applies to any possible regulations or even prohibitions on nicotine-containing products that do not contain tobacco or cigarette-like products (herbal cigarettes).

**explanations**

No change

---

**NGO submission**

**identification**

**affiliation**

NGO

**name**

René van der Steeg

**email**

NL

**country**

44

**age**

male

**gender**

No

**questions scope****problem definition**

Any form of regulation of „tobacco products“ must be based on scientific findings as well as on unequivocally given legislative competence of the EU. This also applies to any possible regulations or even prohibitions on nicotine-containing products that do not contain tobacco or cigarette-like products (herbal cigarettes).

**explanations**

No change

---

**NGO submission****identification****affiliation**

NGO

**name**

Chris Christodoulou, President of the Cyprus American Business Association (Cyprus AmCham)

**email**

Cyprus

**gender**

Yes

**explanations**

No change

**which option**

Other tobacco products, such as herbal cigarettes should be in the scope of the directive. However, any bans on tobacco products should be based on scientific evidence.

---

**NGO submission****identification****affiliation**

NGO

**name**

dhrr

**email**

bali

**gender**

Yes

**explanations**

No change

---

**NGO submission****identification****affiliation**

NGO

**name**

Per Kim Nielsen Danish Cancer Society

**email**

Denmark

**country**

54

**age**

male

**gender**

No

**questions scope****problem definition**

i. We agree that the defined problem exists, but we also see a corresponding problem area which is not covered by this definition: When a product contains tobacco, it is included in this directive where there are not many possibilities of regulating and controlling new products. This means that the producers of problematic products may have them legalised by adding a little bit of tobacco, e.g. electronic cigarettes and nicotine products. This also means that it is possible to produce tobacco products with very large contents of additives, e.g. sugar, which contributes to causing new smokers by attraction to the product as well as increasing the addiction (SCENIHR 2010). Some kind of prohibition on new products and control of product development will be significant in the administration of the market.

**explanations**

No change

**which option**

A clear definition of what a tobacco product is must be introduced. This must be done in order to limit the development of new and alternative products containing small amounts of tobacco and large amounts of substances causing attraction, which particularly have children and adolescents as target group. We recommend that a tobacco products must contain minimum 90 % tobacco in order to be a tobacco product, and that all other products containing smaller amounts of tobacco must be prohibited.

**recommend option**

Also ensuring that the products that are not included in the directive will be handled in relation to each country's requirements to approval as pharmaceuticals and foods. This will mean that nicotine products must be approved as pharmaceuticals to be used in connection with smoking cessation, and other products like e.g. herbal cigarettes will be handled according to the legislation for foods. They will be prohibited because they develop carcinogenic and other health hazardous substances and therefore cannot be approved as foods (Jorgensen ED et al 2010, Gan Q et al, Chinese 2009, Chen A et al 2007, Manning and Feyerabend 1976).

---

**NGO submission****identification****affiliation**

NGO

**name**

BOVAG

**email**

Nederland

**country**

33

**age**

male

**gender**

Yes

**explanations**

No change

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**NGO submission****identification****affiliation**

NGO

**name**

juan manuel galindo hernandez

**email**

Benalua, Granada.

**country**

41

**age**  
male

**gender**  
Yes

**explanations**  
Extend the scope of the Directive

---

**NGO submission**

**identification**  
**affiliation**  
NGO

**name**  
Cyprus Employers and Industrialists Federation (OEB)

**email**  
Cyprus

**gender**  
Yes

**explanations**  
No change

**which option**

Η διεύρυνση του πεδίου εφαρμογής της Οδηγίας προκειμένου να συμπεριλαμβάνει προϊόντα όπως τα 'φυτικά' (herbal) τσιγάρα είναι εύλογη δεδομένου ότι ομοειδή προϊόντα πρέπει να ρυθμίζονται κατά τον ίδιο τρόπο προκειμένου να μην δημιουργούνται συνθήκες αθέμιτου ανταγωνισμού. Ωστόσο, η α priori απαγόρευση κάποιων προϊόντων καπνού χωρίς καμία επιστημονική τεκμηρίωση είναι λανθασμένη. Κατά συνέπεια τασσόμαστε εναντίον της διεύρυνσης του πεδίου εφαρμογής της Οδηγίας.

---

**NGO submission**

**identification**  
**affiliation**  
NGO

**name**  
vbw Vereinigung der Bayerischen Wirtschaft e. V. , München

**email**

Germany

**gender**

Yes

**explanations**

No change

**which option**

Der Geltungsbereich der Richtlinie könnte erweitert werden um diese Produkte einzuschließen. Allerdings sollte dies kein automatisches Verbot für bestimmte Formen neuartiger Tabakprodukte enthalten. Verbote müssen auf wissenschaftlichen Prüfstrategien beruhen.

---

**NGO submission**

**identification**

**affiliation**

NGO

**name**

Jörg Bähr

**email**

Germany

**country**

42

**age**

male

**gender**

No

**questions scope**

**problem definition**

Mündige bürger können selbst entscheiden welche Produkte sie konsumieren. Aufklärung ist wichtig, aber eine Bevormundung oder weitere Gesetze sind nicht im sinne eines freiheitlichen Bürgers.

**explanations**

No change

**which option**

Aufklärung ja / Reglementierung und Bevormundung nein/ die Freiheit sich selbst ein Bild von einem legalen Produkt zu machen und auch entsprechende Produktinformationen zu erhalten muss gewahrt bleiben.

---

**NGO submission**

**identification**

**affiliation**

NGO

**name**

MOIGE - Movimento Italiano Genitori

**email**

italy

**gender**

Yes

**explanations**

No change

---

**NGO submission**

**identification**

**affiliation**

NGO

**name**

ERMURI Einkaufsverband eG Am Brommerfeld 11 D - 32758 Detmold

**email**

Germany

**gender**

Yes

**explanations**

Extend the scope of the Directive

**which option**

Eine offizielle Freigabe der ENDS mit Nikotin-Höchstkonzentrations-Begrenzungen für die Depots ist sinnvoll. Bei der ENDS handelt es sich in seiner Wirkung um ein zigarettenähnliches Produkt, das es dem Konsumenten erlaubt, in Rauchverbotszonen ohne Beeinträchtigung der Nichtraucher zu genießen. Hinzu kommt, dass heutzutage derartige Produkte hauptsächlich im Internet vertrieben werden und dieses Medium kaum nachhaltig eingeschränkt werden kann.

---

**NGO submission**

**identification****affiliation**

NGO

**name**

Latvian Traders Association

**email**

Latvia

**gender**

Yes

**explanations**

No change

**recommend option**

Piekrītot, ka Direktīvas regulējums būtu jāattiecina uz jauna tipa produktiem kā e-cigaretēm vai augu cigaretēm un citiem produktiem, šim regulējumam nevajadzētu būt automātiskam aizliegumam, uz ko vedina konsultāciju dokumenta komentārs par jaunajiem tabakas izstrādājumiem orālai lietošanai. Lēmums par aizliegumiem var tikt pieņemts, tikai zinātniski izvērtējot jaunus produktus. Iespējams, to vidū patiešām ir samazināta riska produkti, kas patērētājiem spēj piedāvāt mazāk kaitīgu alternatīvu cigarešu smēķēšanai.

---

**NGO submission****identification****affiliation**

NGO

**name**

Nordic Travel Retail Group

**email**

Denmark

**additional comments**

No

**questions smokeless****problem definition**

The problem as defined is largely misrepresented. 1. The current Tobacco Products Directive bans one smokeless tobacco product while leaving the rest unregulated. 2. The problem definition fails to address the implications of article 8 (snus ban) in the TPD on the functioning of the internal market. There are several negative economic and societal consequences that are not in proportion with the established health risks associated with the usage of Swedish snus. Most notable for us is the distortion on the internal market that the ban



creates. 3. Snus is essential as revenue needed in the shipping/travel retail industry to keep Baltic Sea trade alive. Therefore we must stress that a stop to this trade at the Baltic Sea would lead to significant problems for the Finnish shipping industry, for the economy at Åland (the semi autonomous island of Finland) and all involved in travel retailing in the area. Therefore, we urged the Commission and DG Sanco to correct this in the Final Impact Assessment by including a proper economic and societal assessment in this matter.

**comments**

Lifting the ban on snus

**which option**

All tobacco and nicotine products should be regulated with a non-competitive product regulation based on product quality, and consumer protection.

---

**NGO submission**

**identification**

**affiliation**

NGO

**name**

Danish Lung Association

**email**

Denmark

**additional comments**

Yes

**comments**

No change

**which option**

We believe, that option 3 would be the ideal, but we doubt that it would be possible to carry out, since some countries are not interested, or it may be difficult to enforce such a prohibition. We agree therefore on option 1.

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**NGO submission**

**identification**

**affiliation**

NGO

**name**

Claus Boegelund K. Nielsen, vicepresident Independent Grocers Association, Denmark

**email**

Denmark

**additional comments**

Yes

**comments**

Lifting the ban on snus

**which option**

Generally it seems unreasonable to ban certain retailers from the nordic countries from selling a product while others are allowed to. Danish citizens are bringing home snus from Sweden for use in Denmark. This practice is contributing to the existing problem of cross border trade. Since other forms of tobacco are allowed for sale to persons over 18 years it is very hard to see the purpose of such a ban.

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**NGO submission**

**identification**

**affiliation**

NGO

**name**

Goedert

**email**

luxembourg

**additional comments**

No

**questions smokeless**

**problem definition**

La définition du problème regroupe les produits du tabac 'smokeless' en un groupe homogène qui en fait ne l'est pas. Les produits de cette catégorie sont produits de façon différentes et sont consommés différemment par les utilisateurs. La catégorie des produits 'smokeless' peut être divisée entre le tabac à chiquer, le tabac à priser et le 'snus'. Les tabacs à chiquer et à priser sont autorisés sur le marché au sein de l'UE. La mise sur le marché du 'snus' est interdit dans l'UE à l'exception de la Suède.

**comments**

Lifting the ban on snus

**additional option**

Les fabricants de produits du tabac veulent répondre à la demande des consommateurs existants qui souhaitent bénéficier d'un large choix de produits afin de choisir leur type de produits/marques. L'interdiction de « commercialisation » frappant le snus - à l'exception de la Suède - fut introduite sans base et preuve scientifique. Les règles de bon fonctionnement du marché intérieur ne justifient aucunement le maintien de cette interdiction.

---

**NGO submission**

**identification**

**affiliation**

NGO

**name**

Rodrigo Cordoba Garcia, Spanish Society of Family and Community Medicine

**email**

Spain

**country**

57

**age**

male

**additional comments**

Yes

**comments**

Ban on all types of smokeless tobacco products

**which option**

smokeless tobacco products must be banned in UE but drugs to quit smoking dependence must be financed by Public health Services

**additional option**

Smokeless tobacco don't help people to break nicotine addiction

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**NGO submission**

**identification**

**affiliation**

NGO

**name**

EPA - European Parents' Association

**email**

Europe

**additional comments**

Yes

**comments**

Lifting the ban on snus

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**NGO submission****identification****affiliation**

NGO

**name**

G.W. de Vries, director of Lekkerland Nederland BV, the largest wholesaler of tobacco products in Holland

**email**

Netherlands

**age**

male

**additional comments**

Yes

**comments**

Lifting the ban on snus

**additional option**

No scientifically sound basis can be derived from the Commission`s problem definition on which an EU-wide ban on snus (except in Sweden) or other smokeless products seems to be justified. The consumption of smokeless tobacco products by adult and educated people neither harms the health of Thirds nor does the consumption of these products restrict other persons in their habits of living. The consumption of these products lies within the own responsibility of the individual. Advertising and selling these products must therefore be possible. The EU-wide ban on snus (except in Sweden) therefore is a massive incapacitation of citizens. For the adult consumers have the right to make the choice even concerning stimulants with health risks and to take responsible decisions on their own.

---

**NGO submission****identification****affiliation**

NGO

**name**

René van der Steeg

**email**

NL

**country**

44

**age**

male

**additional comments**

Yes

**comments**

Lifting the ban on snus

**additional option**

No scientifically sound basis can be derived from the Commission`s problem definition on which an EU-wide ban on snus (except in Sweden) or other smokeless products seems to be justified. The consumption of smokeless tobacco products by adult and educated people neither harms the health of Thirds nor does the consumption of these products restrict other persons in their habits of living. The consumption of these products lies within the own responsibility of the individual. Advertising and selling these products must therefore be possible. The EU-wide ban on snus (except in Sweden) therefore is a massive incapacitation of citizens. For the adult consumers have the right to make the choice even concerning stimulants with health risks and to take responsible decisions on their own.

---

**NGO submission****identification****affiliation**

NGO

**name**

René van der Steeg

**email**

NL

**country**

44

**age**

male

**additional comments**

Yes

**comments**

Lifting the ban on snus

**additional option**

No scientifically sound basis can be derived from the Commission`s problem definition on which an EU-wide ban on snus (except in Sweden) or other smokeless products seems to be justified. The consumption of smokeless tobacco products by adult and educated people neither harms the health of Thirds nor does the consumption of these products restrict other persons in their habits of living. The consumption of these products lies within the own responsibility of the individual. Advertising and selling these products must therefore be possible. The EU-wide ban on snus (except in Sweden) therefore is a massive incapacitation of citizens. For the adult consumers have the right to make the choice even concerning stimulants with health risks and to take responsible decisions on their own.

---

**NGO submission****identification****affiliation**

NGO

**name**

Harf

**email**

France

**additional comments**

Yes

**comments**

Lifting the ban on snus

**which option**

any way to use tobacco or nicotine should be authorized except those which produce smoke (e cigarettes should be authorized as well as snus.

**additional option**

If tobacco users wouldn't consume it by burning, the health consequences would be so low that it wouldn't be longer a major health problem. People who have banned snus from the european market are responsible of thousands of deaths!

---

**NGO submission****identification****affiliation**

NGO

**name**

Per Kim Nielsen Danish Cancer Society

**email**

Denmark

**country**

54

**age**

male

**additional comments**

Yes

**comments**

No change

**which option**

We agree to option 1, but option 3 would be the ideal, but doubtful to carry out, since a few countries are not interested, or it may be difficult to enforce such a prohibition.

---

**NGO submission****identification****affiliation**

NGO

**name**

BOVAG

**email**

Nederland

**country**

33

**age**

male

**additional comments**

Yes

**comments**

Lifting the ban on snus

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**NGO submission****identification****affiliation**

NGO

**name**

ΠΡΟΕΔΡΟΣ ΙΝΚΑ(ΓΕΝΙΚΗ ΟΜΟΣΠΟΝΔΙΑ ΚΑΤΑΝΑΛΩΝ ΕΛΛΑΔΟΣ)

**email**

greece

**country**

56

**age**

male

**additional comments**

Yes

**comments**

Lifting the ban on snus

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**NGO submission**

**identification**

**affiliation**

NGO

**name**

Iida-Leena

**email**

Estonia

**country**

22

**age**

female

**additional comments**

Yes

**comments**

Lifting the ban on snus

**which option**

I don't get the bans. Real choice is the choice one makes in his mind and you can't charge for making a choice...you can only help or not help. So why the bans? Give people a real chance to care for themselves, educate, love...



**additional option**

Mm..yes, I already said what I think.

---

**NGO submission****identification****affiliation**

NGO

**name**

vbw Vereinigung der Bayerischen Wirtschaft e. V., München

**email**

Germany

**additional comments**

Yes

**comments**

Lifting the ban on snus

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**NGO submission****identification****affiliation**

NGO

**name**

Jörg Bähr

**email**

Germany

**country**

42

**age**

male

**additional comments**

No

**questions smokeless****problem definition**

Legale produkte müssen auch legal verkauft werden dürfen.

**comments**

Lifting the ban on snus

**which option**

Kein kommentar

**additional option**

Kein Kommentar

---

**NGO submission****identification****affiliation**

NGO

**name**

Jarle Hammerstad

**email**

Norway

**country**

43

**age**

male

**additional comments**

No

**questions smokeless****problem definition**

In Norway efforts are made by health authorities and NGOs to limit smoking. Snus is considered a substitute to smoking tobacco and in many cases a way to cut smoking.

**comments**

Lifting the ban on snus

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**NGO submission****identification****affiliation**

NGO

**name**

Stefan Gustavsson. West Sweden Chamber of commerce and industry

**email**  
Sweden

**additional comments**  
No

**questions smokeless  
problem definition**

Huruvida frågeställningen harmonierar med funktionen av den interna marknaden inom EU saknas. Eftersom snus enligt The SCENIHR report är betydligt mindre skadligt än cigaretter men cigaretter är tillåtet och snus är förbjudet, är det inte en hälsofråga utan en handelsfråga. Då handlar det om protektionism och i dagsläget diskrimineras snus.

**comments**  
Lifting the ban on snus

**which option**

Eftersom snus enligt EU:s egna undersökning (SCENIHR report) har visats sig mindre skadligt än cigaretter och andra rökfria tobaksprodukter anser vi att likabehandlingsprincipen bör gälla. Dvs man bör inte särskilja snus från andra tobaksprodukter i den här frågan. Om övrig skadligare tobak är tillåten bör också snus vara det.

---

**NGO submission**

**identification  
affiliation**  
NGO

**name**  
ERMURI Einkaufsverband eG Am Brommerfeld 11 D - 32758 Detmold

**email**  
Germany

**additional comments**  
No

**comments**  
Lifting the ban on snus

**additional option**

Schweden hat europaweit den geringsten Anteil an Zigarettenrauchern, da dort Snus erlaubt ist. Oral oder nasal zu sich genommene Genussmittel dienen zusätzlich dem Nichtraucherschutz. Gesundheitspolitisch sollten derartige Produkte nicht eingeschränkt werden. Theoretisch ist es sicherlich möglich, dass ein Snus-Genießer nach einem wie auch immer verursachten Herzinfarkt beim weiteren Frönen seiner Leidenschaft evtl. mit einer Steigerung des Todesrisikos leben muss. Dieses trifft aber sicherlich dann auch zu, wenn er in eine ganz normale Stresssituation kommt. Es ist allgemein wohl bekannt, dass man nach

einem Herzinfarkt mit allen Dingen, die man tut, vorsichtig sein muss bzw. das eine oder andere auch lassen sollte. So etwas rechtfertigt aber kein Verbot.

---

**NGO submission**

**identification**

**affiliation**

NGO

**name**

Juha Makkonen

**email**

Finland

**country**

26

**age**

male

**additional comments**

Yes

**comments**

Lifting the ban on snus

---

**NGO submission**

**identification**

**affiliation**

NGO

**name**

ANA PAULA ALVES

**email**

PORTUGAL

**country**

45

**age**

male

**additional comments**

Yes

**explanations**

No change

---

**NGO submission****identification****affiliation**

NGO

**name**

NFRN Ireland

**email**

Ireland

**additional comments**

No

**questions consumer****problem definition**

We do not agree that this measure will curb the number of smokers or the number of people taking up smoking. This measure will only help criminals reproduce counterfeit packaging.

**explanations**

No change

**which improvement**

Evidence from other jurisdictions where generic tobacco packaging legislation has been proposed has shown it not to be effective. In 2009, the UK Minister for State (Public Health) acknowledged that there have been no studies undertaken to show that plain packaging of tobacco products would cut the smoking uptake of young people or enable those who want to quit to do so.[14] Furthermore, in March 2010, the Lithuanian parliament rejected a plain packaging proposal, considering it to be contrary to fundamental principles of intellectual property embodied in the Lithuanian Constitution.[15]

**additional option**

It is our contention that the introduction of generic packaging will not lead to a reduction in the prevalence of smoking but will rather put retailers in Ireland and across the EU under severe pressure in a time of difficult economic conditions. We believe that such legislation will directly contribute to an increase in the illicit tobacco trade and will place our industry under significant pressure. Moreover, there is evidence from other countries where similar measures have been proposed that raises questions about the effectiveness and legality of generic packaging. There is much evidence from Ireland to suggest that increased government tobacco legislation, which has concealed access or visibility of tobacco products, has led to an increase in tobacco smuggling. Since the introduction of the Point of Sale Display Ban in 2009 in Ireland, there have been over a quarter of a billion cigarettes seized recovering €85 million of lost tax revenue.[16] Retailers, and in particular small independent shopkeepers,

rely heavily on the sale of tobacco products and can account for up to 30% of overall turnover[17]. In 2009, the UK Minister for State (Public Health) acknowledged that there have been no studies undertaken to show that plain packaging of tobacco products would cut the smoking uptake of young people or enable those who want to quit to do so.[18] In February of 2010 the Department of Health indicated that until further information was known about the consequences of generic packaging, with particular regards to its effectiveness in reducing smoking rates and the legality of such legislation, no plain packaging legislation would be introduced.[19] It is our view that the EU Commission should adopt a similarly cautious approach to the introduction of legislation which we believe could drastically increase the illicit cigarette trade in the EU. In addition, it is likely that the introduction of generic packaging throughout all 27 EU Member States would lead to a number of legal challenges. For example, following the proposal of generic legislation by a Lithuanian MP in January 2010, a parliamentary legal affairs committee found that the proposals infringed on domestic intellectual property rights, Lithuania's obligations under Article 10(2)(3)(1) of the Paris Convention for the Protection of Industrial Property, and the free movement of goods under Article 34 of the Treaty on the Functioning of the European Union.[20]

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## **NGO submission**

### **identification**

#### **affiliation**

NGO

#### **name**

AHRESP - Associação da Hotelaria, Restauração e Similares de Portugal

#### **email**

Portugal

### **additional comments**

No

### **questions consumer**

#### **problem definition**

It is said that the larger the health warnings, the greater its effectiveness, without knowing exactly in which studies are based to make such a statement. On one hand it is said that we should enlarge the warnings, but on the other hand we must hide the packages that should not be seen. It doesn't make any sense. We are talking about a product whose use is not illegal, therefore its promotion it's not illegal either. For that reason, such restrictions should not be imposed at a EU level. The national legislation of each country should have jurisdiction, according to each reality, to establish the appropriate measures. By several orders of reasons, mainly because it will encourage the illegal trade, but also because it appears to be an inadmissible interference in the tobacco trade, we do not agree with the imposition of "generic" or "white" packages, which will only facilitate the work of counterfeiters. We believe that, nowadays, consumers are properly informed and they smoke because that is their free will.

**explanations**

No change

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**NGO submission****identification****affiliation**

NGO

**name**

Nick Hayns - Institute of Economic Affairs

**email**

UK

**additional comments**

Yes

**explanations**

No change

**which improvement**

The Commission has sought comments on a wide range of proposed tobacco control measures. This submission provides comment on three of the proposals: banning point-of-sale tobacco displays; requiring all tobacco products to be sold in plain packages; and the use of graphic health warnings on tobacco products. The submission is based on two factors. First, clear criteria of what constitutes acceptable tobacco control policy and, second, a careful examination of the empirical evidence for both of these tobacco control measures. With respect to the first, we believe that acceptable tobacco control policy is policy that results in 1) reductions in tobacco initiation, prevalence, and consumption and 2) increases in both quit attempts and successful quit attempts. Policies that cannot promise these results are not acceptable instances of tobacco control. With respect to the second we believe, as the evidence outlined below demonstrates, that there is no compelling scientific evidence that establishes that either tobacco display bans or plain packaging or graphic health warnings will result in substantial reductions in tobacco initiation, prevalence, and consumption, or increases in both quit attempts and successful quit attempts. In short, none of these regulatory measures can demonstrate an effect in preventing smoking uptake or reducing current levels of smoking. Consequently, none of these policies meets the crucial test of legitimate tobacco control policy.

**additional option**

A full pdf submission was sent, attached to an email from [nhayns@iea.org.uk](mailto:nhayns@iea.org.uk), at 13:57 GMT on 17.12.2010.

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**NGO submission****identification**

**affiliation**

NGO

**name**

ASSOUTENTI Vicolo Orbetelli 10 00186, Roma

**email**

Italia

**additional comments**

No

**questions consumer****problem definition**

Assoutenti, interessata alle sorti del consumatore a vantaggio del quale opera, ambisce ad una protezione più alta del soggetto fumatore. Pertanto, essa è particolarmente interessata a questa sezione, ed intende indicare le ragioni a sostegno della necessità di una modifica della Direttiva sul punto. In particolare, anche a seguito dell'esame delle opzioni proposte all'interno della consultazione, si ritiene efficace ed utile che le attuali dettagliate informazioni sui livelli di catrame, nicotina e monossido di carbonio siano anche accompagnate da informazioni di carattere più generale sulle sostanze nocive. Qualora tutte queste informazioni non possano essere apposte sul pacchetto, per motivi evidenti di spazio, si potrebbe inserirle, ad esempio, sui siti internet delle manifatture o del Ministero della Salute o nel pack insert. In effetti, qualora venissero poste troppe informazioni sull'esterno del pacchetto, il rischio potrebbe essere quello di abbassare il livello di attenzione del consumatore sul pacchetto in generale, con l'effetto dannoso di far perdere di vista le informazioni davvero rilevanti, che non si riuscirebbero più ad individuare e a distinguere dalle altre. Appare, invece, poco utile per innalzare il livello di corretta informazione sui prodotti del tabacco e per disincentivare l'uso di tali prodotti l'uso di immagini come avvertenze sanitarie (i c.d. pictorial health warnings) sui rischi legati all'uso dei prodotti del tabacco, oggi comunicati, in Italia, attraverso i c.d. textual health warnings, dunque attraverso frasi già perfettamente chiare (es.: "Il fumo nuoce gravemente alla salute"). La consapevolezza dei rischi legati al consumo dei prodotti da fumo sembra non crescere, infatti, proporzionalmente all'aumento delle dimensioni delle avvertenze sanitarie sui pacchetti. Si è visto, infatti, come in Paesi quali l'Inghilterra e il Belgio, dove l'uso di tali immagini è obbligatorio, tale misura non abbia affatto comportato una diminuzione del consumo di tabacco. In effetti, il fumatore è ormai ben conscio che il fumo nuoce alla salute, dunque non sarebbe gran che impressionato da immagini che glielo rammentino con maggiore crudezza degli attuali textual health warnings, che già assolvono di per sé allo scopo informativo di indicare i rischi per la salute derivanti l'uso del tabacco. Meglio catalizzare la sua attenzione su ulteriori informazioni sul prodotto e permettergli una scelta informata.

**explanations**

Improve consumer information

**which option**

Tar, nicotine and carbon monoxide levels to be replaced with general information on harmful substances in tobacco products; Information on harmful substances in tobacco products that cannot be placed on the package would be placed inside the package



### **which improvement**

Il consumatore potrebbe essere interessato a ricevere dati più specifici sui prodotti acquistati. Ad esempio, le informazioni concernenti il contenuto dei prodotti da fumo ed in particolare gli ingredienti dei medesimi (ivi inclusi i coloranti e gli additivi) potrebbero essere comunicati e resi disponibili attraverso i siti web istituzionali o siti web dedicati delle diverse società produttrici o anche tramite linee telefoniche appositamente preposte.

### **additional option**

Non sembra condivisibile l'adozione della proposta di introdurre il cosiddetto pacchetto generico ("generic or plain packaging"). Tale misura costituisce, a nostro avviso, uno strumento del tutto inefficace per la tutela della salute dei consumatori, anzi potrebbe, per molti versi, rivelarsi un boomerang. In primo luogo, il plain packaging non aiuterebbe a ridurre il consumo di tabacco. Il packaging nei prodotti da fumo è diretto solo verso coloro che già si qualificano come consumatori di sigari e sigarette, che si sono, in altre parole, già determinati all'acquisto, a differenza della pubblicità che si rivolge ad una platea indifferenziata di individui per attrarre potenziali consumatori. Il packaging delle sigarette non serve, dunque, ad attirare nuovi consumatori, bensì ad aiutare il fumatore a distinguere un prodotto dall'altro per effettuare la scelta finale, che non è, però, quella tra fumare e non fumare, bensì quella di acquistare un brand e non un altro. Se la finalità della adozione del pacchetto generico è dunque quella di tutelare la salute, la misura non appare inidonea allo scopo. Inoltre, non è da escludere che le case produttrici dei prodotti del tabacco, non potendo più distinguersi e competere sotto il profilo del packaging, potrebbero competere tra loro solo sui prezzi, con il rischio di una probabile diminuzione generalizzata dei prezzi, con conseguente maggiore incentivazione al consumo del fumo, anche e soprattutto per i minori, ed una diminuzione della qualità del prodotto. I consumatori, infine, perderebbero anche la possibilità di ottenere informazioni facilmente deducibili dai packaging attuali, ovvero la qualità, la storia del marchio, l'esclusività di un certo prodotto. In ogni caso ci sembra di poter dire che tale misura risulterebbe comunque sproporzionata: non esistendo alcuna prova certa del fatto che il plain packaging riduca il consumo di fumo, dal momento che la vendita di prodotti da fumo è legittima, ai consumatori deve essere consentita la possibilità di scegliere cosa fumare, così come si può fare per qualsiasi altro prodotto. Inoltre, un bel packaging non ha un effetto ingannevole sui consumatori, né distrae dagli avvertimenti sulla salute posti sul pacchetto, determinando, piuttosto, l'effetto opposto: se il pacchetto è "bello", guardo il pacchetto e leggo tutto quello che vi si trova scritto sopra. Un ultimo rilievo circa il plain packaging è che tale misura potrebbe anche avere un effetto distorsivo della concorrenza tra paesi comunitari ed extra-comunitari. Il fumatore, abituato ad acquistare un determinato pacchetto di sigarette in virtù del suo legame con la storia della società produttrice e in quanto abituato a "quel pacchetto", potrebbe essere indotto ad acquistare proprio quel pacchetto, almeno inizialmente, in paesi limitrofi all'UE, ove il plain packaging non è adottato, come la Russia, e dove presumibilmente il pacchetto del suo brand preferito resterebbe uguale. Ciò costituirebbe, altresì, un incentivo per il contrabbando ed il commercio transfrontaliero di sigarette, vendute nei loro pacchetti, per così dire, originari ed "originali". Da ultimo, ma non certo meno importante, la standardizzazione dei pacchetti di sigarette faciliterebbe moltissimo la contraffazione dei medesimi, poiché sarebbe molto più facile imitare e produrre i nuovi pacchetti uniformi, con un conseguente proliferare incontrollato ed incontrollabile dei prodotti contraffatti, sempre più difficilmente distinguibili dagli originali, troppo semplici e privi di elementi davvero distintivi. Tutto ciò renderebbe i prodotti da fumo contraffatti sempre meno facilmente individuabili da parte delle forze dell'ordine che operano per contrastare il fenomeno della contraffazione (Dogane e Guardia di Finanza), con conseguenti danni alla salute pubblica.

---

## **NGO submission**

### **identification**

#### **affiliation**

NGO

#### **name**

American Chamber of Commerce in the Slovak Republic

#### **email**

Slovak Republic

### **additional comments**

No

### **questions consumer**

#### **problem definition**

The American Chamber of Commerce in the Slovak Republic (AmCham SK) welcomes the initiative of the European Commission to review the current Tobacco Products Directive 2001/37/EC, but cannot agree with proposed options for the packaging of tobacco products. Protection, enforcement and promotion of intellectual property rights are essential to the future of any innovation-based economy. Therefore, AmCham Slovakia is very concerned about the proposal to introduce plain or generic packaging. Plain packaging could mandate that branding information, including logos, and other distinctive elements which are protected under trademark law, would be banned from the packaging of tobacco products (with the exception of a single brand name in a standardised typeface, size and colour). As a result, trademarks could be negatively affected as it would notably limit product differentiation. Plain packaging legislation would essentially remove most means for companies to differentiate their products from those of their competitors through product packaging. This would mean that trademarks will not be able to function as an indication of origin - an essential function of trademarks - in the same way. Trademarks are not only brand names. Additionally, they can be words and logos, colors and other distinctive signs. Thus, even if arguably, plain packaging would allow for the limited use of single brand names in a standard typeface and color, it would deprive trademark owners of their intellectual property rights that would otherwise be available. For consumers plain or generic packaging means a significant limitation to make a conscious decision when purchasing tobacco products – trademarks are basic characteristics that allow consumers to differentiate products from various producers. It will also cause a significant difficulty to introduce a new brand of products, which will also limit the choice for consumers and ability of producers to enter the market. Tobacco manufacturers will have limited ability to differentiate their products from various competitors. Plain packaging will also most likely lead to unwanted consequences in a form of increased illicit trade. AmCham SK is concerned by the potential implications of such measures on the trademark system as a whole and that the proposed action may lead to the deprivation of other intellectual property rights.

### **explanations**

No change

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**NGO submission****identification****affiliation**

NGO

**name**

Associação de Grossistas de Tabaco do Sul

**email**

Portugal

**additional comments**

No

**questions consumer****problem definition**

- There is no evidence to confirm that generic packaging reduces the consumption of tobacco products, nor that it has a more positive effect on consumers' health. - The smoker has the right to be able to easily differentiate the brand of product they prefer to consume, and has the right to obtain information on the packaging on the product he/she chooses to consume. - With generic packaging, consumers are not able to identify and reject counterfeit tobacco products. - Generic packaging makes the processing of counterfeit and fake products much easier. One can predict the negative consequences for human health, inherent lack of hygienic and sanitary control of production processes of counterfeit tobacco products, with the likely unmeasurable increase of harmfulness to human health at the time of its consumption.

**explanations**

No change

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**NGO submission****identification****affiliation**

NGO

**name**

Centromarca-Associação Portuguesa de Empresas de Produtos de Marca

**email**

Portugal

**additional comments**

No

**questions consumer**

**problem definition**

Não existe evidência que a utilização das embalagens genéricas melhore o funcionamento do mercado interno ou que tenha benefícios para a saúde pública, será mais fácil a entrada e disseminação de cópias e terá como consequência a promoção do comércio de contrafacção

**explanations**

No change

**additional option**

Os direitos da propriedade industrial são um aspecto crucial da economia global. As marcas são o mecanismo mais eficaz para um comércio livre, competitivo e de concorrência leal. A obrigação de utilização de embalagens genéricas ou “plain packaging” retira às empresas um direito e activo adquirido ao longo do tempo, materializado –o direito - nas marcas e na sua capacidade de se diferenciarem e inovarem. Esta capacidade dá ao consumidor a possibilidade de fazer uma escolha informada e segura, aspectos fundamentais para um consumo responsável. Esta iniciativa, caso seja introduzida, representa um desrespeito pelos direitos das marcas, uma expropriação que a ter lugar não pode deixar de dar lugar a invocação de direitos patrimoniais. Não só viola os direitos da marca e da capacidade dos fabricantes para competir de forma legal, como também abriria portas para o comércio ilícito que é já uma ameaça neste sector podendo trazer graves problemas de saúde pública para os consumidores. A comparação entre um produto legal de marca e uma contrafacção é praticamente impossível com esta opção. Acreditamos, assim, existir a possibilidade de iniciativas alternativas que não ponham em causa tão importante valor do nosso sistema de mercado, já que as restrições impostas por este tipo de regulamentação constituem uma limitação desproporcionada para os fabricantes, face aos objectivos propostos pelo regulador. Ao defendermos uma publicidade e promoção responsável esta opção é uma restrição à liberdade de comunicação, base da possibilidade de uma escolha livre e informada. As potenciais implicações desta opção para os consumidores são: menos informação (escolha mais difícil e menos informada), menor qualidade de produtos, preços mais baixos (maior consumo), barreiras mais altas à entrada (menos concorrentes e mais contrafacção), prejuízo aos direitos da propriedade industrial e mais difícil enforcement da Lei. As marcas e os registos são direitos de propriedade reconhecidos e protegidos nos mais diversos sistemas legislativos e tratados, nacionais e internacionais, que a proposta de aplicação de embalagens genéricas contraria.

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**NGO submission****identification****affiliation**

NGO

**name**

TRGOVINSKA ZBORNICA SLOVENIJE - SLOVENIAN CHAMBER OF COMMERCE

**email**

SLOVENIJA

**additional comments**

No

**questions consumer****problem definition**

Nevtralna embalaža (plain packaging) bi olajšala ponarejanje in nezakonito trgovino. Zaradi relativno enostavne nabave materialov za tobačne proizvode in ponarejanja cigaret, je ravno embalaža ena od ključnih komponent v boju proti ponarejanju. Embalaža ima vidne in skrite elemente, ki otežujejo poskuse kopiranja embalaže, in omogočajo, da se lahko proizvod identificira kot ponaredek. Nevtralna embalaža bo imela tudi negativni vpliv na konkurenčnost. Menimo, da mora biti vsak ukrep jasno opredeljen tako z vidika namena in obsega, kot tudi utemeljen z dokazi. Nenazadnje mora biti vsak ukrep sorazmeren in mora upoštevati nenamenske posledice in pravice vseh interesnih skupin.

**explanations**

No change

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**NGO submission****identification****affiliation**

NGO

**name**

QUIT and European Network of Quitlines

**email**

UK

**additional comments**

No

**questions consumer****problem definition**

The problem definition could be improved. We agree with the Commission that the current situation, whereby some Member States have made graphic warnings compulsory and others not, has led to a disparity in labelling throughout the EU. Consequently, this has an impact on the functioning of the internal market, on consumers' awareness and as a result, on their smoking behaviour. We also agree that packaging as an advertising tool is not covered by the current Directive. Finally, we welcome the acknowledgement that tobacco packaging and product features are increasingly used to attract consumers, to promote products and brand image. In this context, it would have been judicious to highlight the fact that, in the Eurobarometer survey released in 2010, the policy that received the most positive response is that of putting health warnings on all packages of tobacco products (on average, 75% of EU citizens are in favour of mandatory pictorial warnings, and over 54% support plain packaging measures).

**explanations**

Improve consumer information; Introduce generic or plain packaging

### **which option**

Picture warnings to become mandatory; Tar, nicotine and carbon monoxide levels to be replaced with general information on harmful substances in tobacco products; Information on harmful substances in tobacco products that cannot be placed on the package would be placed inside the package; Health warnings to be put on water pipes

### **which improvement**

Crucial importance of Graphic health warnings: Evidence shows that text only warning messages are not as effective as graphic warnings. Pictures, especially fear inducing pictures, are proven to be effective in getting consumers more engaged with the warning message. Pictures are able to immediately provoke a reaction and prompt people to read the associated text message. The need for graphic health warnings on both sides of the pack: There is also evidence that pictures on both sides of the packaging have a greater impact. The need for LARGE pictorial health warnings (80%): Evidence clearly shows that increasing the size of warning messages (text only and combined text and picture) increases the effectiveness of the warning amongst both young and adult smokers / non smokers. Research carried out in Canada by Createc on behalf of Health Canada in 2007 showed that young and adult smokers/non smokers are sensitive to the size of health warning messages. Results showed that warning messages that cover 100% of the pack are significantly more effective across all measured effectiveness indicators compared with warning messages that cover only 50% of the pack. The importance of Rotation: Warning texts and pictures should be displayed on a rotating basis, so that each message is given equal display and can reach its target audience. The proved effectiveness of shocking health warnings & targeted messages: as specified in the Sambrook Research International report, fear inducing warnings (using strong “shocking” images related to health risks such as rotten teeth or throat cancer) and strong emotion inducing warnings (especially involving children and unborn babies) are the most effective way to educate consumers on the health risks of tobacco use and to achieve changes in attitudes and behaviour. These warnings’ effectiveness is enhanced if they are used in conjunction with a quit line. Generic or plain packaging: We strongly recommend the introduction of standardised/plain packaging. This should include not only the removal of all branding from the packaging but the size and shape of the packaging should also be standardised. Not only would this prevent the promotion of smoking through branding as occurs presently but it would reinforce the health warning messages. Tobacco packaging provides a direct link between consumers and manufacturers and is the main marketing channel, particularly in jurisdictions with tobacco advertising bans. Branding gives the misleading impression some cigarettes are safer than others. The tobacco industry claims that plain packaging would contravene intellectual property law. However, legal analysis concludes that this is incorrect and there are no international legal impediments to the implementation of generic packaging. Replace TNCO quantitative labelling with qualitative information on contents, emissions and quit-lines: The inclusion of machine-based tar, nicotine and carbon monoxide yields on cigarette packs promotes the mistaken belief that some cigarette brands are less harmful than others. We support the proposal to replace numerical measurements with descriptive information on the hazardous effects of tobacco constituents and emissions. We stress the importance of putting quit line numbers on the package. As underlined in the Sambrook research (p46), providing a telephone number on the pack is more effective than telling smokers to seek advice from a doctor or pharmacist. P46 Health warnings on water pipes: There is a growing body of evidence to show that water pipes are at least as hazardous, if not more so, than other forms of tobacco use. Warnings should also be included on the packaging of tobacco used in water pipes.

**additional option**

Under Article 5.3 of the TPD 2001, Member States have the option to adopt pictorial warnings. This situation emphasised the right of Member States to go further than the Directive to protect public health as set out in Article 30 of the Treaty of the Union (now article 36). Ten years after the entering into force of the TPD, four countries (the UK, Belgium, Romania and Malta) have adopted the option. More countries such as Spain and France are planning to adopt mandatory pictorial warnings. Such measures are in compliance with the current TPD and are welcomed by the tobacco control community. However, their adoption by some Member States necessarily creates growing discrepancies between Member States. As stated above, there is clear evidence that pictorial warnings are much more powerful than written health warnings. Extending the information and protection to all EU Member States would be in harmony with Article 168 of the TFEU and consistent with the objectives of the internal market stated in Article 114.3 of the TFEU and reiterated in Recital 19 of the Directive. A revision of the TPD should, therefore, aim at making pictorial health warnings of tobacco products subject to common rules. Note: Legislation on labelling, advertising and product regulation put forward by the Commission in the field of tobacco control, has been based on the internal market legislation (Articles 26 and 114 of the TFEU). Article 26 of the TFEU establishes the internal market. Article 114 gives EU institutions the competence to regulate and set rules for the functioning of the internal market. More specifically, article 114.3 also states that when establishing rules for the functioning of the internal market in the context of health, safety, environmental protection and consumer protection, the Commission “will take as a base a high level of protection, taking account in particular of any new development based on scientific facts.” The European Court of Justice (the “ECJ”) made an extensive analysis of Article 95 EC (now Article 114) throughout the years. In *Spain v. Council*, the Court observed that “recourse to Article 100a (now Article 114) as a legal basis is possible if the aim is to prevent the emergence of future obstacles to trade resulting from multifarious development of national laws.” The TPD was adopted on the basis of Article 114 TFEU (ex Article 95). As a result, Recital 19 of the TPD states that “[t]he presentation of warning labels and yields has continued to remain variable in the different Member States. As a consequence, consumers in one Member State may be better informed as to the risks of tobacco products than in another. Such differences are unacceptable and are liable to constitute a barrier to trade and to impede the operation of the internal market in tobacco products, and should therefore be eliminated.”

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**NGO submission****identification****affiliation**

NGO

**name**

Paolo Ceresa on behalf of American Chamber of Commerce in Italy

**email**

Italy

**additional comments**

No

**questions consumer****problem definition**

Plain packaging could mandate that branding information, including logos, and other distinctive elements which are protected under trademark law, would be banned from the packaging of tobacco products (with the exception of a single brand name in a standardized typeface, size and color). As a result, trademarks could be negatively affected as it would notably limit product differentiation. Plain packaging legislation would essentially remove most means for companies to differentiate their products from those of their competitors through product packaging. This would mean that trademarks will not be able to function as an indication of origin - an essential function of trademarks - in the same way.

**explanations**

No change

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**NGO submission****identification****affiliation**

NGO

**name**

CHAMBER OF COMMERCE AND INDUSTRY OF SLOVENIA

**email**

SLOVENIA

**additional comments**

No

**questions consumer****problem definition**

Glede obvezne uporabe generične embalaže ni nobenih dokazov, da bo njena uvedba zmanjšala porabo tobačnih izdelkov. Ravno nasprotno - njena uporaba bo znižala cene, zaradi česar se bo poraba kvečjemu povečala. Enobarvna embalaža brez vsakega vzorca bo okrepila črni trg ter zmanjšala prihodke vlad in trgovcev na drobno, zato se o uvedbi take embalaže ne bi smelo razmišljati. Svetovni podatki ne kažejo povezave med velikostjo zdravstvenih opozoril in razširjenostjo kajenja. Ni dokazov, da bi bilo zaradi večjih zdravstvenih opozoril, le to učinkovitejše. Prav tako ni dokazov, da bi bila opozorila, natisnjena na zgornjem delu embalaže, učinkovitejša.

**explanations**

No change

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**NGO submission****identification**



**affiliation**

NGO

**name**

Asian Quitline

**email**

UK

**additional comments**

Yes

**explanations**

Introduce generic or plain packaging

**which improvement**

Offer Quitlines ( WHO FCTC article 14 guidelines) on all cigarette packs.

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**NGO submission****identification****affiliation**

NGO

**name**

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**email**

Italy

**additional comments**

No

**questions consumer****problem definition**

It is necessary to improve the level of information of consumers under the 2001/37 Directive. We maintain that awareness is not increased by the use of pictorial warnings, which are not an efficient measure to drive down tobacco consumption. Therefore, we deem that use and compulsoriness of such warnings should be a prerogative of Member States. Moreover, the presence of too many information on the package could mislead consumers in choosing. It would be better if tar, nicotine and monoxide levels were replaced with general information on harmful substances in tobacco products. Besides, other information on harmful substances, which cannot be placed on the package, could be easily put inside it.

**explanations**

Improve consumer information

### **which option**

Tar, nicotine and carbon monoxide levels to be replaced with general information on harmful substances in tobacco products; Information on harmful substances in tobacco products that cannot be placed on the package would be placed inside the package

### **which improvement**

We deem that the new Directive should foresee that, besides data placed on and inside the packages, Tobacco producers can inform consumers about contents, ingredients and components of tobacco products, through special customer numbers or thanks to their official websites or dedicated website.

### **additional option**

We deem that plain packaging is an ineffective measure to improve Tobacco Products Directive 2001/37. First, plain packaging seems unfit to reduce tobacco consumption. Whereas advertisement seems focused even to non-smokers, packages appearance is mainly directed to smokers, in order to help them distinguishing one product from another. Smokers' choice is not only driven by the characteristics of the product itself, but mainly by the brand image; plain or rough packaging may even have the opposite effect to give cigarettes a "forbidden" image, becoming a "cool" sign of transgression for consumers. Plain packaging makes consumers smoke any cigarette available and not only cigarettes of their preferred brand, since all cigarette packages would look the same. In addition, white packaging makes counterfeits easier, there will be more fakes on the market, normally sold at lower prices than the original ones, that will probably cause an increase of tobacco consumption. Secondly, this possible revision seems unreasonable and disproportioned. As smoking is legal in the European Union, consumers must have the opportunity to select products. Distinguishing one brand from another because of the package is legitimate and in line with the current market supply of any other product, even potentially dangerous for health, such as alcohol. It seems wrong even to claim that attractive packaging distracts from health pictorial warnings placed on the same package, while the opposite is true. Beautiful packaging does not mean deceptive packaging detrimental to the consumer's choice, even considering all safety warnings put on the package. Complex packages are more difficult to imitate, on the contrary plain packaging will make counterfeiting much easier, with damages to public faith and public health, besides an increase of the black market. Thirdly, plain packaging can be a worrying precedent for the business community as whole, since it limits manufacturer's trademark rights without any evidence of public health benefit. This measure would mean an important restriction on building brands. Besides, producers will lose an important tool to communicate with consumers: plain packaging will violate the right of speech foreseen by art. 10 of the European Convention on Human Right and the principle of freedom on how to conduct business. Plain packaging would have even the paradoxical effect of restricting competition: it would make practically impossible for a new EU competitor to enter the market, due to the lack of any possibility to distinguish one product from another. We underline that freedom of competition stands as a general principles of European Law. Fourthly, it interferes with trademark's main function: limiting and prohibiting the use of words, figurative elements, colors and other distinguishing elements, will preclude the possibility of trademark to function as indicator of origin, quality and goodwill. Furthermore, it reduces manufacturer's incentives to invest in quality and new products. For brands that use colors to differentiate amongst several kind of cigarettes under the same common brand, differentiation will become difficult or even impossible: so consumer information will not be enhanced but rather reduced. Finally, but not less important, this measure means an indirect expropriation of intellectual property rights and is contrary to many constitutional principles, international treaties and applicable

laws. First of all plain packaging goes against Italian constitution: Art. 3 (equality of treatment, reasonableness), art. 21 (freedom of speech), Art. 41 (freedom of economic initiative). Then, it violates several international treaties such as: the EC Treaty (art. 17(2), art. 28, art 29), the Lisbon Treaty, TRIPS (art. 2, 8 (1), 15 (4), 17 and 20), the Paris Convention (art 6 quinquies, art. 7), ECHR (art. 1 of First Protocol) and CTM EC Regulation (art. 1(2) and 4).

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## **NGO submission**

### **identification**

#### **affiliation**

NGO

#### **name**

Goedert

#### **email**

luxembourg

### **additional comments**

No

### **questions consumer**

#### **problem definition**

La directive 2001/37/CE a requis l'impression sur les emballages des produits du tabac d'avertissements sanitaires dont la large typologie assure pleinement leur visibilité et leur lisibilité. La décision 2003/641/CE a autorisé l'utilisation de photographies en couleurs ou d'autres illustrations comme avertissements tout en reconnaissant (notamment dans le guide pratique) la nécessité d'adapter ces règles en fonction des différents types de produits et d'emballages. Néanmoins, des recherches et des études quant à l'efficacité de ce genre de mesures nous semblent nécessaires (les études existantes étant incomplètes) avant que ne soient généralisées ces méthodes d'avertissements à tous les Etats membres et pour tous les produits du tabac. De plus, la notion d'attractivité ne peut constituer un objectif législatif, celle-ci ne répondant à aucun critère établi.

#### **explanations**

No change

### **additional option**

Nous sommes opposés aux 'inserts' dans la mesure où les informations figurants actuellement sur les emballages des produits du tabac nous semblent suffisamment informer les consommateurs. De plus la mise en œuvre de ces 'inserts' s'avère techniquement difficile voir impossible pour certains types de produits du tabac compte tenu de la spécificité de leur emballage (tabac à chiquer, tabac à priser ou tabac à pipe). Dans certains Etats membres le débat est ouvert sur les emballages neutres/standardisés. L'emballage neutre/standardisé contribuera à semer la confusion dans l'esprit des consommateurs en mettant en danger la possibilité de différencier les produits des fabricants légaux et les alternatives de meilleur marché offertes par les canaux de distributions illicites. Cela engendrera donc une

augmentation de la diffusion et de la consommation de produits de contrefaçon et le commerce illégal, ces produits étant moins chers. A l'heure actuelle, l'emballage est un des éléments des produits du tabac les plus difficiles à imiter et offre par conséquent la meilleure garantie pour distinguer les produits légaux, pour lesquels des droits à l'importation et des accises sont payés, des produits mis illégalement sur le marché. Refuser aux fabricants la possibilité d'utiliser des logos, marques, couleurs et autres éléments graphiques constituant l'identité de la marque serait une enfreinte aux lois nationales, européennes et internationales sur la propriété intellectuelle. Enfin l'effet qu'aurait un emballage neutre sur la diminution de la consommation, sur la protection contre le tabagisme passif ou tout autre objectif de santé n'est pas prouvé et n'a fait l'étude d'aucune recherche scientifique. Il nous semble également crucial qu'une analyse sur les implications juridiques d'une telle mesure soit menée par la Commission européenne avant de poursuivre en ce sens.

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## **NGO submission**

### **identification**

#### **affiliation**

NGO

#### **name**

Goedert

#### **email**

Luxembourg

### **additional comments**

No

### **questions consumer**

#### **problem definition**

La directive 2001/37/CE a requis l'impression sur les emballages des produits du tabac d'avertissements sanitaires dont la large typologie assure pleinement leur visibilité et leur lisibilité. La décision 2003/641/CE a autorisé l'utilisation de photographies en couleurs ou d'autres illustrations comme avertissements tout en reconnaissant (notamment dans le guide pratique) la nécessité d'adapter ces règles en fonction des différents types de produits et d'emballages. Néanmoins, des recherches et des études quant à l'efficacité de ce genre de mesures nous semblent nécessaires (les études existantes étant incomplètes) avant que ne soient généralisées ces méthodes d'avertissements à tous les Etats membres et pour tous les produits du tabac. De plus, la notion d'attractivité ne peut constituer un objectif législatif, celle-ci ne répondant à aucun critère établi.

### **explanations**

No change

---

## **NGO submission**

### **identification**

**affiliation**

NGO

**name**

Ulrich Szalata

**email**

Germany

**country**

52

**age**

male

**additional comments**

No

**questions consumer****problem definition**

Es existiert bereits ein allgemeines Bewusstsein der Risiken des Rauchens. Ein Hinzufügen von Bildern auf den Warnhinweisen erhöht dieses Bewusstsein nicht – die Bilder wirken lediglich überwiegend abstoßend ohne eine zusätzliche Information zu bieten. Durch die Umsetzung von neutralen Verpackungen wird Produktfälschern die Arbeit erleichtert und das Problem des Schmuggels weiter verschärft. Dies bedroht die Existenz des rein national tätigen Groß- und Einzelhandels in Deutschland. Über die Einführung von neutralen Verpackungen konzentriert sich der Wettbewerb verstärkt auf das Preis-Marketing. Sinkende Preise wären die Konsequenz. Dies ist in jeder Hinsicht (Jugend- und Gesundheitsschutz, Steuereinnahmen..) kontraproduktiv. Es wird pauschal unterstellt, dass die Einführung von Bildwarnhinweise auf das Rauchverhalten der Verbraucher einwirkt. Dafür gibt es bisher keine Nachweise aus Ländern, in denen Bildwarnhinweise bereits verpflichtend eingeführt wurden.

**explanations**

No change

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**NGO submission****identification****affiliation**

NGO

**name**

VNPI

**email**

Netherlands

**additional comments**

No

**questions consumer****problem definition**

De richtlijn dient met betrekking tot dergelijke maatregelen niet verder te worden uitgebreid, er zijn namelijk geen wetenschappelijke studies die aantonen dat het inzetten van middelen als pictorials en vergrootte gezondheidswaarschuwingen het roken zouden verminderen

**explanations**

No change

**which improvement**

Er bestaat geen bewijs voor een relatie tussen de grootte van de grafische waarschuwingen en hun effectiviteit. Betere voorlichting over teer-, nicotine- en koolmonoxidegehalten is nodig, maar de door de EC voorgestelde vermelding van algemene kwalitatieve informatie over schadelijke stoffen is niet effectief ons inziens.

**additional option**

Wij zijn dan ook geen voorstander van de optie "improve consumer information" aangezien; 1. we uit eigen ervaring twijfelen aan de effectiviteit van plain packaging met als doel de tabaksverkopen te verminderen 2. Plain packaging namaak eenvoudiger maakt hetgeen mogelijk tot smokkel leidt 3. Smokkel en namaak leiden tot daling van de legale verkopen (en hebben derhalve gevolgen voor het verkoopkanaal in Nederland) 4. Plain packaging zal tevens een operationele uitdaging zijn, aangezien het personeel het gevraagde product niet eenvoudig kan herkennen en vinden. Kortom wij kunnen de optie "introduce generic or plain packaging" niet ondersteunen.

---

**NGO submission****identification****affiliation**

NGO

**name**

Daniel Emmerink

**email**

Germany

**additional comments**

No

**questions consumer****problem definition**

- jeder Bürger ist mittlerweile sehr gut über die Gesundheitsgefahren informiert

**explanations**

No change

**additional option**

- durch einheitliche Pakungen erhöht sich die Fälschungsgefahr (Schwarzmarkt wächst)

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**NGO submission**

**identification**

**affiliation**

NGO

**name**

SEDEA / AGMORC Association of Greek Market and Opinion Research Companies

**email**

GREECE

**additional comments**

No

**questions consumer**

**problem definition**

no comment

**explanations**

No change

**which improvement**

no comment

**additional option**

no comment

---

**NGO submission**

**identification**

**affiliation**

NGO

**name**

Lietuvos Komunikacijos agentūrų asociacija KOMAA

**email**

Lietuva

**additional comments**

No

**questions consumer  
problem definition**

Vienas iš svarstomų šios direktyvos pakeitimo dokumento punktų aptaria galimus suvaržymus, informuojant tabako gaminių vartotojus. Pagrindinis siūlymas yra standartizuotos pakuotės įvedimas, kuris, mūsų manymu, pažeistų intelektinės nuosavybės teisę ir tarptautinių sutarčių principus. Mūsų įsitikinimu, prekių ženklai neturėtų būti nepagrįstai ribojami teisėtai parduodamiems produktams. Prekių ženklai yra pripažįstami intelektinės nuosavybės teise ir saugomi pagal įvairius nacionalinius ir tarptautinius teisės aktus ir sutartis. Intelektinės nuosavybės teisė yra vienas pagrindų globalios ekonomikos aspektų ir prekių ženklas atlieka svarbų vaidmenį laisvai prekybai ir konkurencijai. Prekės ženklo naudojimas praktiškai visose prekių ir paslaugų rūšyse palengvina prekybą, skatina komercinės veiklos efektyvumą ir vaidina svarbų vaidmenį kuriant darbo vietas. Europos Komisijos siūlymas užkirsti kelią įmonėms naudoti prekių ženklus ant pakuotės sukurtų pavojingą precedentą visiems teisėtai parduodamiems produktams. Pagrindinis prekės ženklo tikslas yra identifikuoti produkto "šaltinį" ir jis suteikia vartotojui naudos, nes padeda pasirinkti produktą. Taigi, prekės ženklas skatina vidaus rinkos augimą ir padeda išvengti painiavos. Standartizuotos pakuotės įvedimas, taip pat, paskatintų tabako gaminių klastojimą ir kontrabandą, kurios mastai šiuo metu yra labai dideli ir nuolat augantys (apie 40 proc. rinkos sudaro kontrabanda). Standartizuotos pakuotės įvedimas tik sumažintų legalių produktų rinkos dalį, nes nelegalus produktas įgautų dar vieną pranašumą prieš teisėtą produkciją, kuri jau dabar pralaimi dėl kainos skirtumo. Taip pat nėra jokių įrodymų, jog toks suvaržymas sumažintų rūkančiųjų skaičių ir/ar tabako suvartojimą, kaip formuluojama peržiūros tikslu. Priešingai, būtų palikta vienintelė galimybė konkurencijai, tai - kaina. Taigi, mūsų manymu, egzistuoja realus pavojus, jog vartojimas gali net išaugti, kainai likus vieninteliu konkurenciniu elementu. T.y. šiuo žingsniu gali būti pasiektas priešingas efektas, negu tikimasi. Standartizuotas pakuotes būtų lengviau atkartoti nei firmines ir taip klastotės lengviau patektų į ES rinką ir būtų sunkiau aptinkamos. Galiausiai suklastotiems tabako gaminiams nebus atlikta kokybės kontrolė ir tai sukeltų papildomą pavojų vartotojų sveikatai. Tai pat manome, kad iškyla grėsmė, jog patys gamintojai bus paskatinti į rinką tiekti kuo pigesnius ir atitinkamai mažiau kokybiškus produktus.

**explanations**

No change

---

**NGO submission****identification****affiliation**

NGO

**name**

Klein Tabak und Wein Diez

**email**

Germany

**additional comments**



No

**questions consumer  
problem definition**

Keine änderung

**explanations**

No change

---

**NGO submission**

**identification**

**affiliation**

NGO

**name**

Frank Birker

**email**

Germany

**additional comments**

No

**questions consumer**

**problem definition**

Was soll die Bevormundung der EU-Bürger. Es müssten dann auch alle Lebensmittelpackungen in neutrale Packungen geändert werden, damit der Kunde nicht durch Farben und Kennzeichnungen "verführt wird" evtl. falsche und vielleicht gesundheitsschädliche Lebensmittel zu kaufen. Alles Bunte vom Waschmittel bis zum Haarspray und, und, und müsste in neutrale Verpackungen geändert werden, damit der Verbraucher bloss nichts falsch macht. Wie grau sollen die Regale aussehen? Wieviel Arbeitsplätze wollen Sie vernichten?

**explanations**

No change

---

**NGO submission**

**identification**

**affiliation**

NGO

**name**

The Association of Swedish Advertisers is the sole organization that promotes and maintains the advertisers' interests on the Swedish advertising market. Around 500 corporations are members of the Association of Swedish Advertisers. Large, medium-size and small

companies in practically all lines of business, government and local authorities, county councils, organizations - they are all marketers, and they all buy and use market communication.

**email**

Sweden

**country**

0

**age**

male

**additional comments**

No

**questions consumer**

**problem definition**

As we understand it, plain packaging would mean that the brand name would be written in a standard font, color and size, and all other trademarks, logos, color schemes and graphics would be prohibited, and the actual pack would be in a neutral color. This in turn means that all products would be identical, apart from the standardized brand names, and trademarks would be prohibited. Brands and trademarks play a vital role for free undistorted competition and consumer choice – they make it easier for consumers to quickly identify the source of a product from a company that they trust and know the quality of. Plain packaging is completely disproportionate as it is totally bans trademarks, and eliminates the main function of trademarks, to distinguish one product from another. It would make it more or less impossible for new market entrants or brands to enter a market as there would be no way of differentiating new products/brands from the already existing products on that market. Plain packaging would severely infringe on and undermine trademark owners' rights to their registered trademarks. Trademarks are not only brand names - it is also words, colors, symbols, shape, sounds and design, which indicates the commercial origin of the products, and distinguish them from the products of competitors. As trademarks and design elements would not be allowed if plain packaging would be introduced, it would lead to commoditization of products, and would undermine the ability of manufacturers to compete legally and to inform consumers. Competition would be driven by price only, rather than price as well as quality, and it would be a higher risk for consumers to unintentionally purchase counterfeit products or products of inferior quality. In addition, trademarks are protected by law, both nationally and internationally, through e.g. the Paris Convention for the Protection of Industrial Property, and the TRIPs Agreement. Plain packaging would be inconsistent with these international treaties, and could constitute a breach of the trademark and intellectual property rights protected by them. Banning trademarks and brands through plain packaging is a serious threat to the business community, and infringes of the fundamental point of trademarks – to promote one of product over another. Trademarks do not necessarily impact total consumption, and as regards tobacco smoking specifically, we are not aware of any studies demonstrating that plain packaging would result in fewer smokers. We also note that the consultation paper includes an option for mandatory and enlarged picture warnings. Excessively large health warnings which dominate the pack would undermine trademark and intellectual property rights. Unless sufficient space is left for trademark owners to use their brands on packs, the situation would be similar to plain packaging, i.e. the possibility to

distinguish one product from another would be severely reduced. In addition, there seems to be no evidence that very large health warnings are more effective to reduce tobacco use.

**explanations**

No change

**which improvement**

No comment.

**additional option**

No comment.

---

**NGO submission**

**identification**

**affiliation**

NGO

**name**

The Association of Swedish Advertisers is the sole organization that promotes and maintains the advertisers' interests on the Swedish advertising market. Around 500 corporations are members of the Association of Swedish Advertisers. Large, medium-size and small companies in practically all lines of business, government and local authorities, county councils, organizations - they are all marketers, and they all buy and use market communication.

**email**

Sweden

**country**

46

**age**

male

**additional comments**

No

**questions consumer**

**problem definition**

As we understand it, plain packaging would mean that the brand name would be written in a standard font, color and size, and all other trademarks, logos, color schemes and graphics would be prohibited, and the actual pack would be in a neutral color. This in turn means that all products would be identical, apart from the standardized brand names, and trademarks would be prohibited. Brands and trademarks play a vital role for free undistorted competition and consumer choice – they make it easier for consumers to quickly identify the source of a product from a company that they trust and know the quality of. Plain packaging is completely disproportionate as it is totally bans trademarks, and eliminates the main function

of trademarks, to distinguish one product from another. It would make it more or less impossible for new market entrants or brands to enter a market as there would be no way of differentiating new products/brands from the already existing products on that market. Plain packaging would severely infringe on and undermine trademark owners' rights to their registered trademarks. Trademarks are not only brand names - it is also words, colors, symbols, shape, sounds and design, which indicates the commercial origin of the products, and distinguish them from the products of competitors. As trademarks and design elements would not be allowed if plain packaging would be introduced, it would lead to commoditization of products, and would undermine the ability of manufacturers to compete legally and to inform consumers. Competition would be driven by price only, rather than price as well as quality, and it would be a higher risk for consumers to unintentionally purchase counterfeit products or products of inferior quality. In addition, trademarks are protected by law, both nationally and internationally, through e.g. the Paris Convention for the Protection of Industrial Property, and the TRIPs Agreement. Plain packaging would be inconsistent with these international treaties, and could constitute a breach of the trademark and intellectual property rights protected by them. Banning trademarks and brands through plain packaging is a serious threat to the business community, and infringes of the fundamental point of trademarks – to promote one of product over another. Trademarks do not necessarily impact total consumption, and as regards tobacco smoking specifically, we are not aware of any studies demonstrating that plain packaging would result in fewer smokers. We also note that the consultation paper includes an option for mandatory and enlarged picture warnings. Excessively large health warnings which dominate the pack would undermine trademark and intellectual property rights. Unless sufficient space is left for trademark owners to use their brands on packs, the situation would be similar to plain packaging, i.e. the possibility to distinguish one product from another would be severely reduced. In addition, there seems to be no evidence that very large health warnings are more effective to reduce tobacco use.

**explanations**

No change

**which improvement**

No comment.

**additional option**

No comment

---

**NGO submission**

**identification**

**affiliation**

NGO

**name**

annette szalata

**email**

germany

**country**

47

**age**

female

**additional comments**

No

**questions consumer**

**problem definition**

Es existiert bereits ein allgemeines Bewusstsein der Risiken des Rauchens. Ein Hinzufügen von Bildern auf den Warnhinweisen erhöht dieses Bewusstsein nicht. Die Bilder wirken lediglich überwiegend abstoßend ohne eine zusätzliche Information zu bieten. Durch die Umsetzung von neutralen Packungen wird Produktfälschern die Arbeit erleichtert und das Problem des Schmuggelns weiter verschärft. Dies bedroht die Existenz des rein national tätigen Groß- und Einzelhandels in Deutschland. Über die Einführung von neutralen Packungen konzentriert sich der Wettbewerb verstärkt auf das Preismarketing. Sinkende Preise wären die Konsequenz. Dies ist in jeder Hinsicht kontraproduktiv.

**explanations**

No change

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**NGO submission**

**identification**

**affiliation**

NGO

**name**

American-Hellenic Chamber of Commerce

**email**

Greece

**additional comments**

No

**questions consumer**

**problem definition**

The American-Hellenic Chamber of Commerce has consistently and strongly opposed any unjustified restrictions to intellectual property rights (IPR) within any sector, as it represents a potential precedent for other sectors, types of consumer goods or services. Protecting and enforcing intellectual property rights is key to the future of the innovation-based economy. Plain packaging could mandate that branding information, including logos, and other distinctive elements which are protected under trademark law, would be banned from the packaging of tobacco products (with the exception of a single brand name in a standardised typeface, size and colour). As a result, trademarks could be negatively affected as it would

notably limit product differentiation. Plain packaging legislation would essentially remove most means for companies to differentiate their products from those of their competitors through product packaging. This would mean that trademarks will not be able to function as an indication of origin - an essential function of trademarks - in the same way. Trademarks are not only brand names. Additionally, they can be words and logos, colours and other distinctive signs<sup>1</sup>. Thus, even if arguably, plain packaging allows for the limited use of single brand names in a standard typeface and colour, it would deprive trademark owners of their intellectual property rights that would otherwise be available. In addition to the IPR, such a measure will elevate circulation of illegally made tobacco's products which creates concerns on quality assurance issues and therefore on health care issues.

**explanations**

No change

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**NGO submission**

**identification**

**affiliation**

NGO

**name**

FOOX Groothandelsorganisatie

**email**

Nederland

**additional comments**

No

**questions consumer**

**problem definition**

There is no convincing scientific evidence that a warning is more effective, the bigger its size. There already exists a general awareness of the risks of smoking. Adding pictures to the warnings does not augment this awareness – the pictures only appear predominantly repulsive without offering additional information. Sound scientific evidence that tobacco packaging and product features of tobacco products influence/support the smoking behavior of consumers does not exist. Plain packaging would violate the essence of trademark law and thus also the interest of the consumers. Namely, the brand also serves as an indicator of origin and thus is an essential element to preserve the citizens` freedom of decision-taking and choice. In the scope of the Tobacco Products Directive, the Commission itself has limited the maximum contents of tar, nicotine and carbon monoxide.

**explanations**

No change

---

**NGO submission**

**identification**  
**affiliation**  
NGO

**name**  
AMERICAN CHAMBER OF COMMERCE IN SLOVENIA

**email**  
SLOVENIA

**additional comments**  
No

**questions consumer**  
**problem definition**

Plain packaging could mandate that branding information, including logos, and other distinctive elements which are protected under trademark law, would be banned from the packaging of tobacco products (with the exception of a single brand name in a standardised typeface, size and colour). As a result, trademarks could be negatively affected as it would notably limit product differentiation. Plain packaging legislation would essentially remove most means for companies to differentiate their products from those of their competitors through product packaging. This would mean that trademarks will not be able to function as an indication of origin - an essential function of trademarks - in the same way.

**explanations**  
No change

**additional option**

AmCham therefore respectfully calls upon the European Commission to give due consideration to intellectual property rights should it undertake any future analysis of the legal issues and the evidence base for the impact of plain packaging, including on the functioning of the internal market. \* \*

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**NGO submission**

**identification**  
**affiliation**  
NGO

**name**  
The Slovak Advertising Standards Council (SASC)

**email**  
Slovak Republic

**additional comments**  
No

**questions consumer  
problem definition**

Trademarks, brands and names belong to legal business with consumer goods for centuries. Ability to place a logo, and/or a trademark on a product is one of the fundamental rights of every legal entrepreneur. Proposals, as indicated in options 2 and 3 of the DG Sanco proposal are completely removing this right from the tobacco manufacturers. This is, in our view, unacceptable. Limiting the ability to brand, limits the ability to compete. Limiting the ability to compete is a restriction of trade. We believe, that the right to differentiate between products is not only a right of the manufacturer, but also a right of consumers. We also believe that brand differentiations exist to facilitate consumer choice, information and convenience. Plain packaging will vastly increase consumer confusion without even discouraging the use of the product itself. By accepting proposed removal of all trademarks from packaging, this right will be denied to every adult citizen of the EU. We also cannot accept the proposal for larger health warnings, as this will interfere with highly valuable trademarks and logos of cigarettes and other tobacco products. Introduction of larger health warnings and/or plain packaging should be not even considered as an option.

**explanations**

No change

---

**NGO submission**

**identification**

**affiliation**

NGO

**name**

Ροντούλης Γ. Αστέριος

**email**

Ελλάδα

**country**

44

**age**

male

**additional comments**

No

**questions consumer**

**problem definition**

KANENA ΣΧΟΛΙΟ

**explanations**

No change

---



## **NGO submission**

### **identification**

#### **affiliation**

NGO

#### **name**

Groothandel Bergsma / s. Van der Zee

#### **email**

Nederland

#### **country**

39

#### **age**

male

#### **additional comments**

No

#### **questions consumer**

#### **problem definition**

There is no convincing scientific evidence that a warning is more effective, the bigger its size. There already exists a general awareness of the risks of smoking. Adding pictures to the warnings does not augment this awareness – the pictures only appear predominantly repulsive without offering additional information. Sound scientific evidence that tobacco packaging and product features of tobacco products influence/support the smoking behavior of consumers does not exist. Plain packaging would violate the essence of trademark law and thus also the interest of the consumers. Namely, the brand also serves as an indicator of origin and thus is an essential element to preserve the citizens` freedom of decision-taking and choice. In the scope of the Tobacco Products Directive, the Commission itself has limited the maximum contents of tar, nicotine and carbon monoxide.

#### **explanations**

No change

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## **NGO submission**

### **identification**

#### **affiliation**

NGO

#### **name**

G.W. de Vries, director of Lekkerland Nederland BV, the largest wholesaler of tobacco products in Holland

**email**

Netherlands

**age**

male

**additional comments**

No

**questions consumer  
problem definition**

There is no convincing scientific evidence that a warning is more effective, the bigger its size. There already exists a general awareness of the risks of smoking. Adding pictures to the warnings does not augment this awareness – the pictures only appear predominantly repulsive without offering additional information. Sound scientific evidence that tobacco packaging and product features of tobacco products influence/support the smoking behavior of consumers does not exist. Plain packaging would violate the essence of trademark law and thus also the interest of the consumers. Namely, the brand also serves as an indicator of origin and thus is an essential element to preserve the citizens` freedom of decision-taking and choice. In the scope of the Tobacco Products Directive, the Commission itself has limited the maximum contents of tar, nicotine and carbon monoxide.

**explanations**

No change

---

**NGO submission****identification****affiliation**

NGO

**name**

Entrepreneurship Club

**email**

Greece

**additional comments**

No

**questions consumer  
problem definition**

No comment

**explanations**

No change

---

**NGO submission**

**identification**

**affiliation**

NGO

**name**

FEDERATION OF ATTICA AND PIRAEUS INDUSTRIES

**email**

Greece

**additional comments**

No

**questions consumer**

**problem definition**

no comments

**explanations**

No change

---

**NGO submission**

**identification**

**affiliation**

NGO

**name**

René van der Steeg

**email**

NL

**country**

44

**age**

male

**additional comments**

No

**questions consumer**

**problem definition**

There is no convincing scientific evidence that a warning is more effective, the bigger its size. There already exists a general awareness of the risks of smoking. Adding pictures to the

warnings does not augment this awareness – the pictures only appear predominantly repulsive without offering additional information. Sound scientific evidence that tobacco packaging and product features of tobacco products influence/support the smoking behavior of consumers does not exist. Plain packaging would violate the essence of trademark law and thus also the interest of the consumers. Namely, the brand also serves as an indicator of origin and thus is an essential element to preserve the citizens` freedom of decision-taking and choice. In the scope of the Tobacco Products Directive, the Commission itself has limited the maximum contents of tar, nicotine and carbon monoxide.

**explanations**

No change

---

**NGO submission**

**identification**

**affiliation**

NGO

**name**

René van der Steeg

**email**

NL

**country**

44

**age**

male

**additional comments**

No

**questions consumer**

**problem definition**

There is no convincing scientific evidence that a warning is more effective, the bigger its size. There already exists a general awareness of the risks of smoking. Adding pictures to the warnings does not augment this awareness – the pictures only appear predominantly repulsive without offering additional information. Sound scientific evidence that tobacco packaging and product features of tobacco products influence/support the smoking behavior of consumers does not exist. Plain packaging would violate the essence of trademark law and thus also the interest of the consumers. Namely, the brand also serves as an indicator of origin and thus is an essential element to preserve the citizens` freedom of decision-taking and choice. In the scope of the Tobacco Products Directive, the Commission itself has limited the maximum contents of tar, nicotine and carbon monoxide.

**explanations**

No change

---

**NGO submission****identification****affiliation**

NGO

**name**

Dorota Kreft

**email**

deutschland

**country**

32

**age**

female

**additional comments**

No

**questions consumer****problem definition**

Ich weiß nicht warum das alles eingeführt werden soll?! Als ob das etwas helfen würde, ganz im Gegenteil es wird wahrscheinlich noch schlimmer, es wird mehr Schmuggel Ware geben. Und mal ganz im Ernst, es ist doch jedem selbst überlassen was man mit seinem Leben anstellt, es kann doch nicht sein als Erwachsener Mensch sich vorschreiben lassen zu müssen von den SCHEIß POLITIKERN was richtig und falsch ist. Ich glaub langsam fangen alle an einbisschen zu Spinnen. Das die Jugendlichen unter beobachtung stehen ist vollkommen korrekt, aber das wir Erwachsene genauso behandelt werden wir kleine Kinder ist doch echt die höhe. Das sind alles nur die Politiker Schuld und ganz besonders die Merkel, nur weil die keine erziehung bekommen hat, will sie das an uns auslassen... Deutschland ist mittlerweile ein Scheiß Land. VERBIETET DOCH DAS WIR MENSCHEN KEINE STEUERN MEHR ZAHLEN MÜSSEN, DAS IST AUCH GESÜNDER FÜR UNS!!!! KOMISCH AUF SOLCHE IDEEN KOMMT KEINER...

**explanations**

No change

---

**NGO submission****identification****affiliation**

NGO

**name**

Eis, Elke

**email**  
Germany

**country**  
44

**age**  
female

**additional comments**  
No

**questions consumer  
problem definition**  
Es existiert bereits ein allgemeines Bewusstsein der Risiken des Rauchens. Ein Hinzufügen von Bildern auf den Warnhinweisen erhöht diesen Bewusstsein nicht- die Bilder wirken lediglich überwiegend abstossend ohne eine zusätzliche Information zu bieten und sind unnötig. Wenn eine Rauchen will, tut er es sowieso.

**explanations**  
No change

---

**NGO submission**

**identification  
affiliation**  
NGO

**name**  
Dietmar Franz

**email**  
Deutschland

**additional comments**  
No

**questions consumer  
problem definition**  
Ich möchte grundsätzlich selber entscheiden was ich kaufe.

**explanations**  
No change

---

**NGO submission**

**identification****affiliation**

NGO

**name**

Karin Erpenbach

**email**

Deutschland NRW

**country**

54

**additional comments**

No

**questions consumer****problem definition**

Es existiert bereits ein allgemeines Bewusstsein der Risiken des Rauchens.

**explanations**

No change

---

**NGO submission****identification****affiliation**

NGO

**name**

Vesna Kovič

**email**

Slovenia

**country**

46

**age**

female

**additional comments**

No

**questions consumer****problem definition**

the issue and especially the proposal for introducing the generic or plain packaging it is

contrary to Article 7 of Paris Convention

**explanations**

No change

**which improvement**

No.

**additional option**

No.

---

**NGO submission**

**identification**

**affiliation**

NGO

**name**

Chariskos Georgios

**email**

Germany

**country**

44

**age**

male

**additional comments**

No

**questions consumer**

**problem definition**

Durch die Umsetzung von neutralen verpackungen wird Produktfälschern die arbeit erleichtert und das problem des schmuggels weiter verschärft. Dies bedroht die existenz des rein national tätigen Groß- und Einzelhandels in deutschland. Es existiert bereits ein allgemeines Bewusstsein deer risiken des rauchens.

**explanations**

No change

---

**NGO submission**

**identification**

**affiliation**

NGO



**name**

Hans Jürgen Meinel

**email**

Deutschland

**country**

64

**age**

male

**additional comments**

No

**questions consumer****problem definition**

Durch die Umsetzung von neutralen Verpackungen wird Produktfälschern die Arbeit erleichtert und das Problem des Schmuggels weiter verschärft. Dies bedroht die Existenz der rein national tätigen Groß- und Einzelhandels in Deutschland.

**explanations**

No change

---

**NGO submission****identification****affiliation**

NGO

**name**

Ingo Klaue

**email**

Deutschland

**country**

49

**age**

male

**additional comments**

No

**questions consumer****problem definition**

Es existiert bereits ein Bewusstsein der Risiken des Rauchens. Durch die Umsetzung von neutralen Packungen wird Produktfälschern die Arbeit erleichtert. Desweiteren wird das Problem des Schmuggels verschärft. Daraus resultiert eine massive Existenzbedrohung des Groß- und Einzelhandels in Deutschland.

**explanations**

No change

**which improvement**

Ich wünsche keine Änderung der Verpackungsgestaltung.

---

**NGO submission**

**identification**

**affiliation**

NGO

**name**

Chris Christodoulou, President of AmCham Cyprus (Cyprus-American Business Association)

**email**

Cyprus

**additional comments**

No

**questions consumer**

**problem definition**

The measure of plain packaging would essentially undermine the ability of companies to differentiate their products from those of their competitors. The Commission should consider the implications of the measure on the whole trademark system.

**explanations**

No change

---

**NGO submission**

**identification**

**affiliation**

NGO

**name**

Chris Christodoulou, President of Cyprus-American Association (Cyprus AmCham)

**email**

Cyprus

**additional comments**

No

**questions consumer  
problem definition**

The measure of plain packaging would essentially undermine the ability of companies to differentiate their products from those of their competitors. The Commission should consider the implications of the measure on the whole trademark system.

**explanations**

No change

---

**NGO submission****identification  
affiliation**

NGO

**name**

Silke Rabe

**email**

Deutschland

**country**

36

---

**NGO submission****identification  
affiliation**

NGO

**name**

Pfeffermann Maritta

**email**

Germany

**country**

53

**age**

female

**additional comments**

No

**questions consumer****problem definition**

Neutrale Verpackungen erleichtern Produktfälschern die Arbeit und fördern den Schmuggel, was die Existenz der Groß- und Einzelhändler Deutschlands bedroht. Es gibt keinen Nachweis, dass Bildwarnhinweise sich auf das Rauchverhalten der Verbraucher auswirken.

**explanations**

No change

---

**NGO submission****identification****affiliation**

NGO

**name**

Per Kim Nielsen Danish Cancer Society

**email**

Denmark

**country**

54

**age**

male

**additional comments**

Yes

**explanations**

Introduce generic or plain packaging

**which improvement**

All rules must apply to all tobacco products and be simple and unambiguous.

**additional option**

We agree with the problem definition, but also see a problem that the packets are presented at the points of sale and thereby act as advertising for the tobacco products. Warning texts and pictures should be on all tobacco products as it is important to tell that tobacco products are health hazardous regardless of the design. We agree with Option 3, but applicable to all tobacco products

---

**NGO submission****identification**

**affiliation**

NGO

**name**

Kirsten Götz

**email**

Deutschland

**country**

45

**age**

female

**additional comments**

Yes

**explanations**

No change

---

**NGO submission****identification****affiliation**

NGO

**name**

Kirsten Götz

**email**

Deutschland

**country**

45

---

**NGO submission****identification****affiliation**

NGO

**name**

CYPRUS COMMUNICATION AGENCIES ASSOCIATION

**email**

CYPRUS

**additional comments**

Yes

**explanations**

No change

---

**NGO submission****identification****affiliation**

NGO

**name**

Bernd Burbes

**email**

Deutschland

**country**

57

**age**

male

**additional comments**

No

**questions consumer****problem definition**

Es existiert bereits ein allgemeines Bewusstsein der Risiken des Rauchens. Ein Hinzufügen von Bildern auf den Warnhinweisen erhöht dieses Bewusstsein nicht. Die Bilder wirken lediglich überwiegend abstoßend ohne eine zusätzliche Information zu bieten. Durch eine Umsetzung von neutralen Verpackungen wird Produktfälschern die Arbeit erleichtert und das Problem des Schmuggels weiter verschärft. Dies bedroht die Existenz des Groß- und Einzelhandels in Deutschland. Über die Einführung von neutralen Verpackungen konzentriert sich der Wettbewerb verstärkt auf das Preis-Marketing. Sinkende Preise öffnen Jugendlichen Tür und Tor.

**explanations**

No change

---

**NGO submission****identification****affiliation**

NGO

**name**

πανελλήνια ομοσπονδία εστιατορικών & συναφών επαγγελμάτων

**email**

hellas

**additional comments**

No

**questions consumer****problem definition**

κανένα σχόλιο

**explanations**

No change

---

**NGO submission****identification****affiliation**

NGO

**name**

Flunkert, Wolfgang

**email**

Deutschland

**country**

64

**age**

male

**additional comments**

No

**questions consumer****problem definition**

Es existiert bereits ein allgemeines Bewusstsein der Risiken des Rauchens. Ein Hinzufügen von Bildern auf den Warnhinweisen erhöht dieses Bewusstsein nicht

**explanations**

No change

---

**NGO submission**

**identification****affiliation**

NGO

**name**

Warcaba Michaela

**email**

Deutschland

**country**

43

**age**

female

**additional comments**

No

**questions consumer****problem definition**

Die Verbraucher sind eigentlich schon ausreichend über die Gesundheitsrisiken informiert worden und die Warnhinweise steigern nicht wirklich die Wahrnehmung und es wird dadurch niemand weniger rauchen.

**explanations**

No change

**additional option**

Bei Einheitsverpackungen wird dann nur noch über den Preis verkauft und die Markenstrukturen werden zerstört. Einheitsverpackungen lassen sich leichter fälschen.

---

**NGO submission****identification****affiliation**

NGO

**name**

Greek Association of Branded Products Manufacturers

**email**

Greece

**additional comments**

No



**questions consumer  
problem definition**

we do not analyse the problem for tobacco products per se. kindly see our comment below.

**explanations**

No change

**additional option**

The Greek Association of Branded Products Manufacturers considers that the tobacco products directive 200137/EC offers the possibility to generalize this directive in many other products. Which, in our point, undermines the essential European rules concerning the free competition? So we are opposed to the generalization of this directive and we are very skeptical regarding its necessity for the tobacco products.

---

**NGO submission**

**identification**

**affiliation**

NGO

**name**

BOVAG

**email**

Nederland

**country**

33

**age**

male

**additional comments**

Yes

**explanations**

No change

---

**NGO submission**

**identification**

**affiliation**

NGO

**name**

Cyprus Employers and Industrialists Federation (OEB)

**email**  
Cyprus

**additional comments**  
No

**questions consumer  
problem definition**

Η εφαρμογή του μέτρου του plain packaging καταστρατηγεί το σύνολο των διεθνών συμβάσεων που προστατεύει τα πνευματικά δικαιώματα. Παράλληλα, δεν τεκμηριώνεται επιστημονικά ότι το μέτρο προστατεύει τη δημόσια υγεία. Επίσης η εφαρμογή του plain packaging μπορεί να δημιουργήσει ένα νομικό προηγούμενο για τη λήψη παρόμοιων μέτρων και για άλλα καταναλωτικά αγαθά.

**explanations**  
No change

---

### **NGO submission**

**identification  
affiliation**  
NGO

**name**  
GEORG Klein

**email**  
Deutschland

**country**  
42

**age**  
male

**additional comments**  
No

**questions consumer  
problem definition**

Die jetzigen Regelungen Warnhinweise, keine Fernsehwerbung und Nichtrauchergetz schützen ausreichen Nichtraucher und warnen den Raucher. Jeder Bürger sollte selbst bestimmen in wie weit er sich auf Konsum von Zigaretten und Tabak einlässt. Wichtiger wäre die Kontrolle von Alkohol und Tabak an Minderjährige z.b. durch permanentes Ausweisen des Käufers gegenüber des Handels.

**explanations**  
No change

**which improvement**

Jeder Käufer muss ohne Aufforderung sein Alter durch vorzeigen eines Lichtbildausweises belegen.

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**NGO submission**

**identification**

**affiliation**

NGO

**name**

proedros INKA

**email**

GREECE

**country**

56

**age**

male

**additional comments**

No

**questions consumer**

**problem definition**

No comment

**explanations**

No change

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**NGO submission**

**identification**

**affiliation**

NGO

**name**

American Chamber of Commerce in Poland

**email**

Poland

**additional comments**

No

## **questions consumer problem definition**

Protection, enforcement and promotion of intellectual property rights are essential to the future of any knowledge-based economy. IPR protection is one of the key priorities for the Polish Presidency and AmCham PL fully supports it. Therefore, AmCham PL is very concerned about the proposal to introduce plain or generic packaging.

1. Under the rule of the Constitution of Poland plain or generic packaging would:
  - ♣ raise the allegation of defying the constitutional principle of business activity freedom - the possibility to introduce manufactured goods to the market is an element of constitutionally protected freedom to conduct business activity. In order to do this effectively, an entrepreneur needs to be able to differentiate his/her products from competition's. Trademarks are used to differentiate products. When there is no possibility to use a trademark, the right to conduct business activity freely is defied.
  - ♣ raise the allegation of defying the proportionality principle – i.e. how far a regulator may interfere and restrict the rights of entrepreneurs in order to achieve a particular objective. The purpose of the plain packaging concept according to its authors is to limit tobacco product consumption. This, however, has not been supported by any research that would confirm the effectiveness of this solution
  - ♣ raise the allegation of defying the constitutional principle to protect ownership and other property rights.
2. Plain or generic packaging is contrary to the binding provisions of the Industrial Ownership Act dated June 30th, 2000, which does not provide for:
  - ♣ excluding the ability to use accrued rights to protect already registered trademarks
  - ♣ the possibility to restrict registered trademarks with regard to any products, including tobacco products.
3. Plain or generic packaging is contrary to the Paris Convention on the protection of intellectual property which states, among others, that:
  - ♣ a product type cannot be an obstacle to register the trademark
  - ♣ a trademark registered in one country can be registered and protected in the same way it is protected in other countries (one can't be denied the right to register a trademark and a trademark's registration can't be cancelled).
4. Plain or generic packaging is contrary to the provisions of an agreement on trade-related aspects of intellectual property rights (TRIPS) which state, among others, that:
  - ♣ the ability to utilize a trademark commercially shouldn't be unreasonably impeded by specific requirements, such as (...), the necessity to utilize the trademark in a specific form or a harmful way that disallows one to differentiate goods or services provided by one entrepreneur from goods or services provided by another entrepreneur
  - ♣ again a product type cannot be an obstacle to register the trademark.
5. Plain or generic packaging is contrary to bilateral agreements on mutual support and protection of investment (e.g. the Treaty of 1990 on Trade and Economic Relationships between Poland and the United States) which refer to equal and fair treatment of investors in a country accepting an investment. The Plain packaging concept may be deemed as unfair treatment of tobacco investors due to the object of their business activity. In terms of competition in the market, plain or generic packaging means:
  - limiting the possibility to differentiate products from various competitors;
  - limiting the ability to introduce new players to the market/introduce new products.Plain or generic packaging implies additional, unwanted consequences such as risk that it will be much easier and cheaper to counterfeit standardized packages by organized crime groups. AmCham PL supports and understands the aim of the European Union to improve public health, but the proposed plain or generic packaging will have serious consequences of both legal and economic nature. Therefore, AmCham PL does not support introduction of plain or generic packaging.

## **explanations**

No change

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**NGO submission**

**identification**

**affiliation**

NGO

**name**

Armin Ptaszynski

**email**

Deutschland

**country**

46

**age**

male

**additional comments**

Yes

**explanations**

No change

**which improvement**

Eine Änderung würde Zigaretten und Tabakkonsum illegal machen, da der Kunde nicht mehr aussuchen kann welche Marke er gerne Rauchen möchte.

**additional option**

Es ist auch ein deutsches Problem, denn sollten die Tabakumsätze weiter zurück gehen bekommt der Staat weniger Steuereinnahmen. Dieses gefährdet die ganze Industrie.

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**NGO submission**

**identification**

**affiliation**

NGO

**name**

Fédération des Artisans du Grand Duché de Luxembourg

**email**

Luxembourg

**additional comments**

No

**questions consumer****problem definition**

There is enough consumer information on tobacco products right now. NO consumer ignores the dangers linked to tobacco consumption, still they do smoke. Moreover we think that the proposals exceed by far the regulatory powers of the commission and will inevitably pose a future trend concerning other products as well. The next step will then concern other products such as grease, sugar, sweets... which we cannot accept.

**explanations**

No change

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**NGO submission****identification****affiliation**

NGO

**name**

Wochner, Klaus

**email**

germany

**country**

50

**age**

male

**additional comments**

No

**questions consumer****problem definition**

Es existiert bereits ein allgemeines Bewusstsein der Risiken des Rauchens. Ein Hinzufügen von Bildern auf den Warnhinweisen erhöht dieses Bewusstsein nicht – die Bilder wirken lediglich überwiegend abstoßend ohne eine zusätzliche Information zu bieten. Durch die Umsetzung von neutralen Verpackungen wird Produktfälschern die Arbeit erleichtert und das Problem des Schmuggels weiter verschärft. Dies bedroht die Existenz des rein national tätigen Groß- und Einzelhandels in Deutschland. Über die Einführung von neutralen Verpackungen konzentriert sich der Wettbewerb verstärkt auf das Preis-Marketing. Sinkende Preise wären die Konsequenz. Dies ist in jeder Hinsicht (Jugend- und Gesundheitsschutz, Steuereinnahmen...) kontraproduktiv. Es wird pauschal unterstellt, dass die Einführung von Bildwarnhinweise auf das Rauchverhalten der Verbraucher einwirkt. Dafür gibt es bisher keine Nachweise aus Ländern, in denen Bildwarnhinweise bereits verpflichtend eingeführt wurden.

**explanations**

No change

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**NGO submission****identification****affiliation**

NGO

**name**

DAGBLADHANDEL DE VALK

**email**

Belgium

**additional comments**

No

**questions consumer****problem definition**

.

**explanations**

No change

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**NGO submission****identification****affiliation**

NGO

**name**

jawm van opdorp

**email**

nederlands

**country**

42

**age**

male

**additional comments**

No

**questions consumer**

**problem definition**

i do not agree

**explanations**

No change

---

**NGO submission****identification****affiliation**

NGO

**name**

American Chamber of Commerce Estonia MTÜ

**email**

Estonia

**additional comments**

No

**questions consumer****problem definition**

American Chamber of Commerce in Estonia would like to offer following comments to the European Commission public consultation on the possible revision of the Tobacco Products Directive 2001/37/EC. We understand and support the aim of the European Union to improve public health. We support, that various measures need to be assessed and considered to address public health concerns in this area. We oppose unjustified restrictions to intellectual property rights within any sector, as it represents a potential precedent for other sectors, types of consumer goods or services. Protecting and enforcing intellectual property rights is key to the future of the innovations based economy. We are concerned about potential implications of such measure on trademark system as a whole, not only concerning tobacco product trademarks. We urge the European Commission, to study the legal issues around plain packaging especially in respect of the following EU and international obligations, such as Paris Convention and TRIPs Agreement. We therefore recommend European Commission to give deep consideration to intellectual property rights when undertaking an analysis of the legal issues and evidence base for the impact of plain packaging.

**explanations**

No change

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**NGO submission****identification****affiliation**

NGO



**name**

Estonian Traders' Association

**email**

Estonia

**additional comments**

No

**questions consumer****problem definition**

Eesti Kaupmeeste Liit on alates 1996 aastast koondanud enda juurde Eestis tegutsevaid jae- ja hulgimüügiettevõtteid. Meie liikmeskonda kuuluvad ettevõtted opereerivad Eestis kokku 46 kaubandusüksusega. Kaupmeeste esindusorganisatsioonina jälgime me tähelepanelikult kauplemist ja levinumaid tooteid puudutavaid regulatsioone. Alates 2004. aastast puudutab see ka Euroopa Liidu tasandil toimuvaid protsesse. Tubakatoodete müügiga tegelevad kaupmehed teavad väga hästi, et tarbijate eelistused tubakatoodete vahel valides on üsna täpsed. Meie klientide soovid ja neile meelepärased tooted on iga kliendi puhul üsna täpselt defineeritud. Olukord, kus kõik sigaretipakid näeksid täpselt samasugused välja, tekitaks märkimisväärset segadust. Tarbijate jaoks muutuks palju keerulisemaks aru saada, milline toode on just see, mida ta osta soovib ja kohustus seda kliendile selgitada langeb paratamatult kaupmehele. Oleme oma liikmete seas aastaid juurutanud häid kauplemistavasid. Hea kauplemistava näeb muuhulgas ka ette, et Kaupmees ei eksita tarbijat ja jagab selgitusi müügil olevate kaupade kohta. Erinevaid tubakatooteid on kauplustes müügil 30-40 erinevat nimetust. Kui kõik need kaubad näeksid täpselt samamoodi välja, tekiks kaupmehel kohustus klienti nende omadustest ja eripäradest täpselt teavitada. Esiteks nõuab see kaupmeestelt täiendavate koolituste korraldamist, et müüjad ja kassapidajad oleksid võimelised kliente nende tootevalikus abistama. Teise ja peamise probleemina muudab ühevärviliste pakendite kasutuselevõtt teenindamise aga palju aeglasemaks. Kolmandaks võib antud meede suurendada salaturu osakaalu EL piiriirikes.

**explanations**

No change

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**NGO submission****identification****affiliation**

NGO

**name**

Secretary General Indicam Silvio Paschi

**email**

italy

**additional comments**

No

**questions consumer****problem definition**

"plain package" deprives consumer of the first information he is accustomed to use when choosing any consumption good, no matter what further information is added; "blank package" will therefore subtract and not add information making the choice for the consumer more difficult and confusing and thus favouring the diffusion of counterfeit products. and foremost information he uses to

**explanations**

No change

**additional option**

"plain package" furthermore hits companies forcing the expropriation of a property i.e. their fundamental rights in terms of IP, rights that are one of the basis of world economy and trade and are recognised and guaranteed by national laws and international treaties since XIX century

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**NGO submission****identification****affiliation**

NGO

**name**

Association of Lithuania trade enterprises

**email**

Lithuania

**additional comments**

No

**questions consumer****problem definition**

There are no statistic information how does this regulation affect self-determination of smokers, though statistics about illegal market in Lithuania is very clear – 40 percent. Labeling must functionate for internal market and should be left for producer contact with consumer. there is no correlation between size of warning on the packs of cigarettes and quitting to smoke. There are no evidence that the bigger size of the Picture warning the more effective it is. We think that the size of warning which have chosen UK is normal and shouldn't be expanding. Consumer is choosing at the store cigarettes according to producer. Label of producer helps for consumer to find desirable product quicker, therefore traders could serve the shop more effective and profitably. What is more illegal market of tobacco products increasing in Lithuania as well as in other states of EU just because of strict regulation. Association of Lithuanian trade enterprises is for equal rights for legal commerce subjects. We are against the illegal market of tobacco products. Current pack designs of different cigarette producers – intellectual property of commerce subjects. This right of producer – to

create and public their labels is economic and commercial freedom. Plain or generic packaging would standardize the appearance of tobacco packaging. So if the packs of cigarettes would be itself uncolored, it would be disqualification of commerce subjects rights and stops the consumer picking cigarettes easy and quiq at supermarkets. Also, plain packaging will make it much easier for criminals to copy packs and open the door wide to increased illicit trade.

**explanations**

No change

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**NGO submission**

**identification**

**affiliation**

NGO

**name**

herwig solar

**email**

austria

**country**

48

**age**

male

**additional comments**

No

**questions consumer**

**problem definition**

durch diese massnahmen würde nicht weniger geraucht werden, genauso wie beim jugendschutzgesetz bez. zigarettenautomaten, einfach lächerlich - haben sie als beamte inbrüssel keine anderen sorgen!

**explanations**

No change

---

**NGO submission**

**identification**

**affiliation**

NGO

**name**

ERMURI Einkaufsverband eG Am Brommerfeld 11 D-32758 Detmold

**email**

Germany

**additional comments**

No

**questions consumer**

**problem definition**

Wir hateln die jetzige Regelung für absolut ausreichend.

**explanations**

No change

**additional option**

Zu Option 2a: Abschreckendes Bildmaterial auf den Packungen fällt unseres Erachtens in die gleiche Kategorie, wie die Schockbilder von Benetton. Mit derartigen Bildern lassen sich Kinder erschrecken, keine erwachsenen Raucher. Zu Option 2c: Angaben zu schädlichen Stoffen in Tabakerzeugnissen in den Packungen platziert, wäre ein akzeptabler Ansatz. Zu Option 2d: Wasserpfeifentabake verfügen über die üblichen Warnhinweise, wie Zigaretten, Feinschnitt, Cigarren und Pfeifentabak. Wenn Wasserpfeifen selbst mit einem Warnhinweis versehen werden sollten, müsste Gleiches logischerweise für Tabakpfeifen und Zigarettenspitzen etc. gelten. Unseres Erachtens ist so etwas völlig unpraktisch. Der Warnhinweis auf dem Wasserpfeifentabak reicht völlig aus. Zu Option 3: Generische Verpackungen bzw. Plain Packaging verfehlen das gewünschte Ergebnis, da nur durch die Markenbezeichnung selbst eine Unterscheidung möglich wird. Durch die heutigen im Handel befindlichen Packungen, erfolgt die gleiche Unterscheidung. Die vermutete Wirkung, dass eine bunte Packung einen Nichtraucher zum Raucher macht, ist unsinnig.

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**NGO submission**

**identification**

**affiliation**

NGO

**name**

Latvian Traders Association

**email**

Latvia

**additional comments**

No

**questions consumer**

**problem definition**

LTA nav vienisprātis ar Komisijas doto problēmas raksturojumu attiecībā uz patērētājiem

sniedzamo informāciju. Veselības brīdinājumi uz tabakas iepakojuma virsmām šobrīd skaidri un saprotami komunicē informāciju par produkta lietošanas riskiem veselībai. Rietumeiropas attīstītajā sabiedrībā patērētājs ir zinošs par produkta kaitīgo ietekmi uz veselību.

Regulējumam ir jāatrod samērīgs balanss iepakojuma izmantošanā, lai vienlaikus komunicētu gan veselības riska brīdinājumu, gan sniegtu patērētājam informāciju par produkta īpašībām. Apstākļos, kad informācijas sniegšana patērētājiem par tabakas izstrādājumiem ir ierobežota, produkta iepakojums ir būtisks avots informācijas minimuma sniegšanai patērētājiem, kas nepieciešama pirkuma izvēles izdarīšanai, un pārdevējiem produkta identificēšanai un nav traktējams kā kārtējais reklāmas laukums, kas būtu aizliedzams. Līdzīgi arī norādes par darvas, oglekļa monoksīda un nikotīna saturu uz paciņas ir kalpo patērētājiem informācijai par produkta garšas īpašībām.

### **explanations**

No change

### **additional option**

LTA pauž bažas par vienkāršainā iepakojuma (plain packaging) rekomendēšanu kā risinājumu smēķēšanas mazināšanai. Valstīs, kur vienkāršainās iepakojums ir bijis apsvērts kā iespējamais risinājums sabiedrības veselības mērķu sasniegšanai, tas allaž ir ticis noraidīts, pirmkārt, nopietnu tiesisku apsvērumu dēļ (piemēram, šī gada sākumā Lietuvas parlaments noraidīja vienkāršaino iepakojumu kā anti-konstitucionālu), otrkārt, pierādījuma trūkumu dēļ par vienkāršainā iepakojuma spēju mazināt pieprasījumu. Vienkāršainā iepakojuma iespējamā pozitīvā ietekme uz smēķēšanas mazināšanu ir teorētisks pieņēmums, kas prasa nesamērīgus ierobežojumus attiecībā uz tabakas iepakojuma izmantošanu (t.i. cigarešu tirgošana baltās paciņās, aizliedzot parādīt preču zīmes, kas ir ar starptautiskām konvencijām un konstitūciju aizsargāts ražotāja intelektuālais īpašums). Turklāt cigarešu tirgošana baltās paciņās acīmredzami atvieglos dzīvi tabakas preču viltotājiem.

---

### **NGO submission**

#### **identification**

##### **affiliation**

NGO

##### **name**

ERMURI Händlervereinigung eV Am Brommerfeld 11 32758 Detmold

##### **email**

Germany

#### **additional comments**

No

#### **questions consumer**

##### **problem definition**

Wir halten die jetzige Regelung für absolut ausreichend.

#### **explanations**

No change

**additional option**

Zu Option 2a: Abschreckendes Bildmaterial auf den Packungen fällt unseres Erachtens in die gleiche Kategorie, wie die Schockbilder von Benetton. Mit derartigen Bildern lassen sich Kinder erschrecken, keine erwachsenen Raucher. Zu Option 2c: Angaben zu schädlichen Stoffen in Tabakerzeugnissen in den Packungen platziert, wäre ein akzeptabler Ansatz. Zu Option 2d: Wasserpfeifentabake verfügen über die üblichen Warnhinweise, wie Zigaretten, Feinschnitt, Cigarren und Pfeifentabak. Wenn Wasserpfeifen selbst mit einem Warnhinweis versehen werden sollten, müßte Gleiches logischerweise für Tabakpfeifen und Zigarettenspitzen etc. gelten. Unseres Erachtens ist so etwas völlig unpraktisch. Der Warnhinweis auf dem Wasserpfeifentabak reicht völlig aus. Zu Option 3: Generische Verpackungen bzw. Plain Packaging verfehlen das gewünschte Ergebnis, da nur durch die Markenbezeichnung selbst eine Unterscheidung möglich wird. Durch die heutigen im Handel befindlichen Packungen erfolgt die gleiche Unterscheidung. Die vermutete Wirkung, dass eine bunte Packung einen Nichtraucher zum Raucher macht, ist unsinnig.

---

**NGO submission**

**identification**

**affiliation**

NGO

**name**

ERMURI Händlervereinigung eV Am Brommerfeld 11 D - 32758 Detmold

**email**

Germany

**additional comments**

No

**questions consumer**

**problem definition**

Wir halten die jetzige Regelung für absolut ausreichend.

**explanations**

No change

**additional option**

Wasserpfeifentabake verfügen über die üblichen Warnhinweise, wie Zigaretten, Feinschnitt, Cigarren und Pfeifentabak. Wenn Wasserpfeifen selbst mit einem Warnhinweis versehen werden sollen, müßte Gleiches logischerweise für Tabakpfeifen und Zigarettenspitzen etc. gelten. Unseres Erachtens ist so etwas völlig unpraktisch. Der Warnhinweis auf dem Wasserpfeifentabak reicht völlig aus.

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**NGO submission**

**identification****affiliation**

NGO

**name**

QUIT and European Network of Quitlines

**email**

UK

**additional comments**

Yes

**explanations**

Establish a common compulsory reporting format

**additional options**

The current situation which allows different formats and reporting mechanisms is unsatisfactory, making it difficult for authorities to compare and analyse the data. All tobacco manufacturers and importers should be subject to the same reporting requirements. The SFP believes that tobacco products, which are highly harmful, should be subject to an effective reporting system that allows the gathering and analysis of relevant data, including comparison as appropriate, in order to ensure high levels of consumer safety and information. The format already exists (based on the voluntary reporting format developed by the Commission in May 2007) and it would therefore be very easy to adopt this measure and to implement it. We welcome the introduction of yearly registration fees in order to finance the data collection on ingredients by the national authorities and their analysis work on ingredients. The payment of penalties in case of non-compliance with the requirements of delivery of data on tobacco product ingredients also seems adequate and would contribute to fund the tests conducted on these products. It is crucial that the appropriate toxicological and addictiveness tests are properly conducted. Such tests would allow policy-makers to make more informed decisions in this field, as there would be more scientific evidence. It would enhance the scientific knowledge of the dangers of tobacco products and would contribute to a high protection of health, as stated in Article 95.3 TFEU. Besides, such measures would also have an indirect impact on illicit trade, since only registered products would be allowed on the market.

---

**NGO submission****identification****affiliation**

NGO

**name**

Goedert

**email**

Luxembourg

**additional comments**

No

**questions on reporting****problem definition**

Nous soutenons la généralisation de la mise en œuvre du système EMTOC à tous les Etats membres.

**explanations**

No change

**additional options**

La directive 2001/37/CE n'impose ni outil ni format afin de soumettre les données relatives aux ingrédients aux autorités nationales. En dépit des initiatives et des efforts mis en œuvre par toutes les parties -notamment l'industrie- depuis 2001, il n'existe à ce jour pas de modèle unique au sein de l'UE. L'exercice de divulgation des données sur les ingrédients est une obligation lourde et coûteuse pour les petites et moyennes entreprises et cet aspect devrait également être pris en compte par les différentes autorités lors de la mise en œuvre d'un système européen de soumission des données. Nous souhaitons de plus renouveler l'importance d'une protection adéquate des secrets de fabrication lors de la divulgation des données relatives aux ingrédients.

---

**NGO submission****identification****affiliation**

NGO

**name**

EPA - European Parents' Association

**email**

Europe

**additional comments**

No

**questions on reporting****problem definition**

As far as we know, member states can already impose sanctions at national level and require registration fees. We agree that a common and compulsory european format for submitting the list of ingredients is needed.

**explanations**

Establish a common compulsory reporting format

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## **NGO submission**

### **identification**

#### **affiliation**

NGO

#### **name**

Per Kim Nielsen Danish Cancer Society

#### **email**

Denmark

#### **country**

54

#### **age**

male

#### **additional comments**

Yes

#### **explanations**

Introduce fees and sanctions

#### **which option**

The reported data should be used for other purposes than approval of the products, and also lead to research of the products and the effects of the additives etc. We therefore recommend that taxes for administration of reporting additives are also spent on general research of the harmful effects of tobacco, addiction and which elements cause increased attraction to tobacco products, so that the EU may be at the forefront of research and so that knowledge about tobacco comes from independent research sources.

---

## **NGO submission**

### **identification**

#### **affiliation**

NGO

#### **name**

BOVAG

#### **email**

Nederland

#### **country**

33

**age**  
male

**additional comments**  
Yes

**explanations**  
No change

---

**NGO submission**

**identification**  
**affiliation**  
NGO

**name**  
Proedros INKA

**email**  
GREECE

**country**  
56

**age**  
male

**additional comments**  
No

**questions on reporting**  
**problem definition**  
No comment

**explanations**  
No change

---

**NGO submission**

**identification**  
**affiliation**  
NGO

**name**  
vbw Vereinigung der Bayerischen Wirtschaft e. V.

**email**

Germany

**additional comments**

No

**questions on reporting**

**problem definition**

Mitgliedstaaten können bereits zum jetzigen Zeitpunkt Strafmaßnahmen ergreifen. Die Durchsetzung der Richtlinie sollte auch weiterhin Sache der Mitgliedstaaten sein.

**explanations**

Establish a common compulsory reporting format

---

**NGO submission**

**identification**

**affiliation**

NGO

**name**

Jörg Bähr

**email**

Germany

**country**

42

**age**

male

**additional comments**

No

**questions on reporting**

**problem definition**

kein Kommentar

**explanations**

No change

**which option**

Kein Kommentar

**additional options**

No

---

## **NGO submission**

### **identification**

#### **affiliation**

NGO

#### **name**

ERMURI Einkaufsverband eG Am Brommerfeld 11 D - 32758 Detmold

#### **email**

Germany

### **additional comments**

Yes

### **explanations**

Establish a common compulsory reporting format

### **additional options**

Gebühren und Sanktionen einzuführen, erfordern einen erheblichen Verwaltungsaufwand, der letztendlich von den Herstellern etc. zu tragen ist. Kleine und mittlere Hersteller, werden mit diesen zusätzlichen Kosten Probleme bekommen, so dass zu befürchten ist, dass diese schließen müssen und damit Arbeitsplätze gefährden.

---

## **NGO submission**

### **identification**

#### **affiliation**

NGO

#### **name**

ASSOUTENTI Vicolo Orbetelli 10 00186, Roma

#### **email**

Italia

### **additional comments**

No

### **regulation of ingredients**

#### **problem definition**

La Direttiva non prevede attualmente quali siano gli ingredienti consentiti o, al contrario, proibiti per i prodotti del tabacco, lasciando impregiudicato il diritto dei singoli Stati membri di decidere tale rilevante aspetto. La Direttiva dovrebbe, invece, prevedere meccanismi di controllo atti ad escludere l'utilizzo di quegli ingredienti dei i quali sia scientificamente provata l'idoneità ad aumentarne la tossicità. Parimenti, dovrebbe altresì essere introdotto il divieto di usare quegli ingredienti che rendano il prodotto da fumo più appetibile nel gusto,

come il gusto caramella o il gusto chewing gum.

**explanations**

Establish a common list of tobacco ingredients

**which option**

Establish a negative common list of tobacco ingredients

---

**NGO submission**

**identification**

**affiliation**

NGO

**name**

KYRIAKIDES TASSOS

**email**

GREECE

**age**

male

**additional comments**

No

**regulation of ingredients**

**problem definition**

NO COMMENTS

**explanations**

No Change

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**NGO submission**

**identification**

**affiliation**

NGO

**name**

QUIT

**email**

UK

**additional comments**

Yes

**explanations**

Establish a common list of tobacco ingredients

**which option**

Establish a positive common list of tobacco ingredients

**additional option**

We support the adoption of a positive common list of tobacco ingredients. We believe that tobacco products are highly toxic and addictive, and that their content should therefore be closely regulated, in order to achieve high standards of health protection, as stated under article 114.3. There is a need for such a list at EU level since at the moment, consumers in the internal market are not subject to the same level of protection. Some citizens may be using substances that are banned in other Member States. Apart from creating unequal health protection across the EU, this may constitute an obstacle to free movement of goods within the internal market: some countries can refuse access to their markets of cigarettes from Member States that do not comply with the importing Member State's national requirements. Regulation of Flavours and Ingredients: Flavourings are an increasingly important part of tobacco industry marketing, particularly to young people. Flavourings enhance attractiveness, encourage youth initiation, and discourage cessation. The prohibition of ingredients that may be used to increase attractiveness, such as sugars and sweeteners, flavouring substances, and spices and herbs, in cigarettes and cigarette-like tobacco products should be introduced. The prohibition of ingredients that may create the impression of a health benefit (e.g. vitamins), ingredients associated with energy and vitality (e.g. caffeine), and ingredients with colouring properties (e.g. pink cigarette paper) should also be banned. Tobacco manufacturers and importers should report sales volume information by brand. This information is essential to help governments ensure that product regulation is effective. The above measures should be compliant with the Guidelines on Art. 9/10, adopted unanimously at the Fourth Conference of the Parties in Uruguay on the 20th November 2010.

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**NGO submission****identification****affiliation**

NGO

**name**

QUIT and European Network of Quitlines

**email**

UK

**additional comments**

Yes

**explanations**

Establish a common list of tobacco ingredients

**which option**

Establish a positive common list of tobacco ingredients

**additional option**

We support the adoption of a positive common list of tobacco ingredients. We believe that tobacco products are highly toxic and addictive, and that their content should therefore be closely regulated, in order to achieve high standards of health protection, as stated under article 114.3. There is a need for such a list at EU level since at the moment, consumers in the internal market are not subject to the same level of protection. Some citizens may be using substances that are banned in other Member States. Apart from creating unequal health protection across the EU, this may constitute an obstacle to free movement of goods within the internal market: some countries can refuse access to their markets of cigarettes from Member States that do not comply with the importing Member State's national requirements. Regulation of Flavours and Ingredients: Flavourings are an increasingly important part of tobacco industry marketing, particularly to young people. Flavourings enhance attractiveness, encourage youth initiation, and discourage cessation. The prohibition of ingredients that may be used to increase attractiveness, such as sugars and sweeteners, flavouring substances, and spices and herbs, in cigarettes and cigarette-like tobacco products should be introduced. The prohibition of ingredients that may create the impression of a health benefit (e.g. vitamins), ingredients associated with energy and vitality (e.g. caffeine), and ingredients with colouring properties (e.g. pink cigarette paper) should also be banned. Tobacco manufacturers and importers should report sales volume information by brand. This information is essential to help governments ensure that product regulation is effective. The above measures should be compliant with the Guidelines on Art. 9/10, adopted unanimously at the Fourth Conference of the Parties in Uruguay on the 20th November 2010.

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**NGO submission****identification****affiliation**

NGO

**name**

CHAMBER OF COMMERCE AND INDUSTRY OF SLOVENIA

**email**

SLOVENIA

**additional comments**

No

**regulation of ingredients****problem definition**

Evropska komisija mora v skladu s členom 12 direktive o tobačnih izdelkih pripraviti skupni seznam sestavin na podlagi objektivnih znanstvenih meril in toksikoloških informacij.

Prepoved sestavin ni opravičljiva bližnjica.

**explanations**

No Change

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**NGO submission****identification****affiliation**

NGO

**name**

Asian Quitline

**email**

UK

**additional comments**

Yes

**explanations**

Establish a common list of tobacco ingredients

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**NGO submission****identification****affiliation**

NGO

**name**

Goedert

**email**

Luxembourg

**additional comments**

No

**regulation of ingredients****problem definition**

Une méthode doit être développée et acceptée préalablement à l'établissement d'une liste commune qu'elle soit positive ou négative. Toute méthode envisagée devra examiner l'interaction entre les différents ingrédients et l'effet de la combustion. C'est pourquoi aucune option ne nous semble fournir de solution dans la mesure où il n'existe à ce jour ni méthode de recherche scientifique acceptée, ni critères acceptés sur le plan international.

**explanations**

No Change



**additional option**

Une politique équilibrée en matière d'ingrédients doit tenir compte d'éléments tels que : 1.La définition d'ingrédient, référence peut être faite à l'article 2 (5) de la Directive 2001/37/CE et qui précise « toute substance ou tout composant autre que les feuilles et autres parties naturelles ou non transformées de la plante de tabac, utilisés dans la fabrication ou la préparation d'un produit du tabac et encore présents dans le produit fini, même sous une forme modifiée, y compris le papier, le filtre, les encres et les colles » 2.Les principes scientifiques développés conjointement par l'OMS et l'Organisation des Nations Unies pour l'alimentation et l'agriculture (FAO) notamment en ce qui concerne le Codex Alimentarius Commission (CAC). Le concept du seuil de toxicité pour l'inhalation (Inhalation Threshold of toxicological concern) doit aussi être pris en compte. 3.Le lien entre ingrédient et problème de santé ne nous semble pas établi en l'absence de base scientifique pour analyser ce lien potentiel. 4.Il nous semble primordial que la directive révisée ne cible que les produits mis en consommation sur le marché intérieur de l'UE sans que la production au sein de l'UE de produits destinés à l'exportation ne soit soumise aux règles européennes. En matière d'ingrédients, domaine hautement complexe et technique, les entreprises du secteur du tabac sont prêtes à offrir leur expertise au législateur.

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**NGO submission****identification****affiliation**

NGO

**name**

Goedert

**email**

Luxembourg

**additional comments**

No

**regulation of ingredients****problem definition**

Une méthode doit être développée et acceptée préalablement à l'établissement d'une liste commune qu'elle soit positive ou négative. Toute méthode envisagée devra examiner l'interaction entre les différents ingrédients et l'effet de la combustion. C'est pourquoi aucune option ne nous semble fournir de solution dans la mesure où il n'existe à ce jour ni méthode de recherche scientifique acceptée, ni critères acceptés sur le plan international.

**explanations**

No Change

**additional option**

Une politique équilibrée en matière d'ingrédients doit tenir compte d'éléments tels que : 1.La définition d'ingrédient, référence peut être faite à l'article 2 (5) de la Directive 2001/37/CE et qui précise « toute substance ou tout composant autre que les feuilles et autres parties

naturelles ou non transformées de la plante de tabac, utilisés dans la fabrication ou la préparation d'un produit du tabac et encore présents dans le produit fini, même sous une forme modifiée, y compris le papier, le filtre, les encres et les colles »

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### **NGO submission**

#### **identification**

##### **affiliation**

NGO

##### **name**

SEDEA/AGMORC Association of Greek Market and Opinion Research Companies

##### **email**

GREECE

#### **additional comments**

No

#### **regulation of ingredients**

##### **problem definition**

no comments

#### **explanations**

No Change

#### **which one**

no comments

#### **additional option**

no comments

---

### **NGO submission**

#### **identification**

##### **affiliation**

NGO

##### **name**

Foos Groothandelsorganisatie

##### **email**

Nederland

#### **additional comments**

No

**regulation of ingredients****problem definition**

The definition of the problem is not a proper basis of discussion oriented on scientific testing strategies and standards as well as on the scale of proportionality. The term "attractive" is a subjective criterion for a prohibition or regulation of additives and lacks any scientific basis. The prevalence of smoking in countries such as Great Britain and Ireland, in which predominantly cigarettes without additives (products of the Virginia-type) are sold is not less than the prevalence in countries where they mainly sell cigarettes containing additives (American-blend products).

**explanations**

No Change

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**NGO submission****identification****affiliation**

NGO

**name**

G.W. de Vries, director of Lekkerland Nederland BV, the largest wholesaler of tobacco products in Holland

**email**

Netherlands

**age**

male

**additional comments**

No

**regulation of ingredients****problem definition**

The definition of the problem is not a proper basis of discussion oriented on scientific testing strategies and standards as well as on the scale of proportionality. The term "attractive" is a subjective criterion for a prohibition or regulation of additives and lacks any scientific basis. The prevalence of smoking in countries such as Great Britain and Ireland, in which predominantly cigarettes without additives (products of the Virginia-type) are sold is not less than the prevalence in countries where they mainly sell cigarettes containing additives (American-blend products).

**explanations**

No Change

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**NGO submission**

**identification**  
**affiliation**  
NGO

**name**  
FEDERATION OF ATTICA AND PIRAEUS INDUSTRIES

**email**  
Greece

**additional comments**  
No

**regulation of ingredients**  
**problem definition**  
no comments

**explanations**  
No Change

**which one**  
no comments

**additional option**  
no comments

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**NGO submission**

**identification**  
**affiliation**  
NGO

**name**  
Latvijas Darba devēju konfederācija (LDDK)

**email**  
Latvija

**country**  
47

**age**  
female

**additional comments**  
No

**regulation of ingredients**

**problem definition**

1. Pievilcība ir subjektīvs, patvaļīgs, nenoteikts kritērijs un nevar kalpot kā piemērots un leģitīms likumdošanas standarts nedz attiecībā uz tabakas izstrādājumiem, nedz citiem produktiem. Nedz vadlīnijas, nedz SCENIHR dokuments, kas apkopo pieejamo zinātnisko informāciju par šo tēmu, nespēj dot "pievilcības" jēdziena definīciju zinātniski pamatotās un izmērāmās kategorijās un atzīst, ka metodes pievilcības novērtēšanai ir nepietiekamas ("esošās metodes nav uzskatāmas par pietiekamām ticamai pievilcīguma mērīšanai", CSENIHR secinājumu 9.punkts) 2. Tā kā SCENIHR paustie zinātniskie secinājumi par piedevu lomu produkta pievilcības veidošanā ir nepārliciecināmi ("ir ļoti grūti noteikt katras piedevas lomu pievilcīguma vairošanā", SCENIHR secinājumu 10.punkts), kā arī trūkst datu par ietekmi uz patēriņu, pierādījumu bāze piedevu regulējumam pēc pievilcīguma kritērijiem ir nepietiekama. 3. Vienlaikus jāmin, ka vispārīgam piedevu aizliegumam varētu būt sagaidāmas vērienīgas sekas: tā kā plašs piedevu izmantošanas aizliegums ietekmētu visu Latvijā tirgto cigarešu garšas īpašības (piedevas tiek izmantotas visu American Blend cigarešu ražošanā, Latvijas tirgū tiek tirgotas tikai American Blend cigaretes), aizliegums būtu spēcīgs stimuls aizrobežu kontrabandas cigarešu tirdzniecībai un kārtējais trieciens valsts budžeta ieņēmumiem.

**explanations**

No Change

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**NGO submission****identification****affiliation**

NGO

**name**

René van der Steeg

**email**

NL

**country**

44

**age**

male

**additional comments**

No

**regulation of ingredients****problem definition**

The definition of the problem is not a proper basis of discussion oriented on scientific testing strategies and standards as well as on the scale of proportionality. The term "attractive" is a subjective criterion for a prohibition or regulation of additives and lacks any scientific basis. The prevalence of smoking in countries such as Great Britain and Ireland, in which

predominantly cigarettes without additives (products of the Virginia-type) are sold is not less than the prevalence in countries where they mainly sell cigarettes containing additives (American-blend products).

**explanations**

No Change

---

**NGO submission**

**identification**

**affiliation**

NGO

**name**

René van der Steeg

**email**

NL

**country**

44

**age**

male

**additional comments**

No

**regulation of ingredients**

**problem definition**

The definition of the problem is not a proper basis of discussion oriented on scientific testing strategies and standards as well as on the scale of proportionality. The term "attractive" is a subjective criterion for a prohibition or regulation of additives and lacks any scientific basis. The prevalence of smoking in countries such as Great Britain and Ireland, in which predominantly cigarettes without additives (products of the Virginia-type) are sold is not less than the prevalence in countries where they mainly sell cigarettes containing additives (American-blend products).

**explanations**

No Change

---

**NGO submission**

**identification**

**affiliation**

NGO

**name**

Mag. Christoph Bösch

**email**

Austria

**country**

47

**age**

male

**additional comments**

No

**regulation of ingredients****problem definition**

Ich sehe das Rauchen in Österreich nicht als ein Problem. Der Raucher gönnt sich diesen Genuss. Falls es versucht wird die Geschmackstoffe dem Tabak zu entziehen, werden sich die Raucher helfen müssen und werden Ihre eigenen Additives entwickeln, die Geschmackstoffe werden sicherlich von einer Nebenbranche erzeugt und angeboten werden.

**explanations**

No Change

**which one**

no

**additional option**

no

---

**NGO submission****identification****affiliation**

NGO

**name**

Per Kim Nielsen Danish Cancer Society

**email**

Denmark

**country**

54

**age**

male

**additional comments**

Yes

**explanations**

Establish a common list of tobacco ingredients

**which option**

Establish a negative common list of tobacco ingredients

**which one**

Option 3a. In case of a positive list it will require an approval of the ingredient in question. In case of a negative list it will cause problems monitoring the development of new ingredients. At present we see a development towards using more additives in smaller doses, but with the same effect. Approval of ingredients should be based on scientific documentation that the ingredient does not have a toxic, attractive and addictive effect. Documentation must be performed by impartial research institutions and be paid by the producers.

**additional option**

We agree to the problem definition, but the problem definition also includes all the additives that cause increased attractiveness and cause greater addiction to nicotine. A clear definition is also missing of what is included in the term ingredients.

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**NGO submission****identification****affiliation**

NGO

**name**

πανελληνία ομοσπονδία εστιατορικών & συναφών επαγγελματιών

**email**

hellas

**additional comments**

No

**regulation of ingredients****problem definition**

ανένα σχόλιο

**explanations**

No Change

---

**NGO submission**



**identification**  
**affiliation**  
NGO

**name**  
BOVAG

**email**  
Nederland

**country**  
33

**age**  
male

**additional comments**  
Yes

**explanations**  
No Change

---

**NGO submission**

**identification**  
**affiliation**  
NGO

**name**  
National Association of tobacco growers -2009(Bulgaria)

**email**  
Bulgaria

**additional comments**  
No

**regulation of ingredients**  
**problem definition**

The ingredients should be valuated based on evidence for increaced toxicity. All type of tobacco products are harmfull .Smokers preference do not depend on if tobacco products have or do not have ingredients.

**explanations**  
No Change

**which one**  
Any new regulation should be based on serious cintific studdies and resurch for long term

results.

**additional option**

If enredians are bannd this will have a negative impact on the life of 70 000 tobacco growers in Bulgaria.

---

**NGO submission**

**identification**

**affiliation**

NGO

**name**

Proedros INKA

**email**

GREECE

**country**

56

**age**

male

**additional comments**

No

**regulation of ingredients**

**problem definition**

no comment

**explanations**

No Change

---

**NGO submission**

**identification**

**affiliation**

NGO

**name**

Armin Ptaszynski

**email**

Deutschland

**country**

46

**age**  
male

**additional comments**  
Yes

**explanations**  
No Change

---

**NGO submission**

**identification**  
**affiliation**  
NGO

**name**  
Jörg Bähr

**email**  
Germany

**country**  
42

**age**  
male

**additional comments**  
No

**regulation of ingredients**  
**problem definition**  
Kein Kommentar

**explanations**  
No Change

**which one**  
Kein Kommentar

**additional option**  
Kein Kommentar

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**NGO submission**

**identification****affiliation**

NGO

**name**

Estonian Traders Association

**email**

Estonia

**additional comments**

No

**regulation of ingredients****problem definition**

Eesti Kaupmeeste Liit on alates 1996 aastast koondanud enda juurde Eestis tegutsevaid jae- ja hulgimüügiettevõtteid. Meie liikmeskonda kuuluvad ettevõtted opereerivad Eestis kokku 46 kaubandusüksusega. Kaupmeeste esindusorganisatsioonina jälgime me tähelepanelikult kauplemist ja levinumaid tooteid puudutavaid regulatsioone. Alates 2004. aastast puudutab see ka Euroopa Liidu tasandil toimuvaid protsesse. Komisjon ei selgita oma probleemipüstituses, kas erinevate lisaainete kasutamine, juurde lisamine või ära jätmise kuidagi toote vähkitekitaavust muudab. Olgu kehtestatav piirang lisaainetele siis positiivse või negatiivse nimekirja vormis, ei muuda see asjaolu, et tulemusena peaks sigaret või muu tubakatoode olema vähem vähkitekitaav või toksiline. Paraku ei tule Komisjoni probleemipüstituses välja, kas on olemas vastavat teaduslikku tõendusmaterjali. Oleme aastaid olnud mures tubakatoodete salaturu arengute pärast, mis on tänaseks viinud 25-30% Eestis müüdavatest sigarettidest väljapoole legaalselt tarneahelat. Ettepanekud, mis muudavad radikaalselt meie kaupmeeste poolt müüdavate sigarettide maitset, tõukavad veelgi enam tarbijaid salakauba juurde. Kui Komisjon kavatses reguleerida tubakatoodete koostisosi, tuleks kindlasti meeles pidada, et traditsioonilised sigaretid jäävad salaturul tarbijatele endiselt kättesaadavaks ja seetõttu väheneb veelgi kavandatava meetme positiivne mõju rahva tervisele. Seda eriti EL-i piiriregioonides, nagu seda on Eesti. Kui Komisjonil siiski õnnestub kehtestada piirangud, mille tulemusena saab tagada, et müügile jäävad vaid tervislikud sigaretid ja neid saaks sellistena ka tarbijatele pakkuda, siis Kaupmeeste Liit mõistagi tervitab sellist ettepanekut. Kui Komisjoni eesmärk on aga siiski suitsetamist ühiskonnas vähendada, siis ei näe Eesti Kaupmeeste Liit esitatud ettepaneku tõhusust selle eesmärgi saavutamisel ja palub nii probleemipüstituse kui ka pakutavad meetmed veelkord üle vaadata.

**explanations**

No Change

---

**NGO submission****identification****affiliation**

NGO

**name**

MOIGE - Movimento Italiano Genitori

**email**

Italy

**additional comments**

No

**regulation of ingredients**

**problem definition**

Le sigarette senza ingredienti non sono meno dannose di quelle con ingredienti.

**explanations**

No Change

---

**NGO submission**

**identification**

**affiliation**

NGO

**name**

ERMURI Einkaufsverband eG Am Brommerfeld 11 D - 32758 Detmold

**email**

Germany

**additional comments**

Yes

**explanations**

No Change

**additional option**

Keine weiteren Bemerkungen

---

**NGO submission**

**identification**

**affiliation**

NGO

**name**

Latvian Traders Association

**email**

Latvia

**additional comments**

No

**regulation of ingredients****problem definition**

LTA nevar pilnībā piekrist Komisijas dotajam problēmas raksturojumam attiecībā uz produktu sastāvdaļu regulējumu. Kaut arī LTA piekrīt Komisijas uzstādījumam, ka regulējumam jābūt vienotam visā ES teritorijā, lai likvidētu barjeras tirdzniecībā, pieņemami kritēriji regulējuma ieviešanai ir sastāvdaļu toksiskums un pieraduma veicināšana. Nav zinātniska pamata regulēt produktu pēc pievilcīguma kritērija, jo produkta pievilcīgums ir subjektīvs, plašs un mainīgs lielums (kā to labi ilustrē SCENIHR), kas nevar kalpot par pamatu standartiem un regulējumam.

**explanations**

No Change

**additional option**

Līdzīgi kā jautājumā par vienkāršāko iepakojumu, uzskats, ka piedevu aizliegšana uz pievilcīguma kritērijiem mazinās tabakas lietošanu, ir pieņemams, kas ir pretrunā ar datiem par bezpiedevu tabakas (Virginia cigarešu) pieprasījumu pasaulē. No Latvijas perspektīvas, kur tiek patērēts tikai American Blend cigarešu tips jeb cigaretes ar ražošanas procesā tabakai pievienotām piedevām (galvenokārt, aromātiem), vispārīgs piedevu aizliegums nostādītu valsti ekonomiski neizdevīgā situācijā, kad nespējot iegādāties savu iecienīto cigarešu kategoriju legālajā tirdzniecībā smēķētāji to meklēs aiz robežām ar nelegālo tirgotāju starpniecību, tādējādi stimulējot ēnu ekonomiku.

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**NGO submission****identification****affiliation**

NGO

**name**

NFRN Ireland

**email**

IRELAND

**additional comments**

No

**access to tobacco products****problem definition**

We do not agree with the problem definition. In the countries where a display of tobacco products ban has been introduced the legislation has simply not been effective. Since the introduction of the point of sale display ban in Ireland in 2009, there is much evidence to point to an increase in the illicit tobacco trade. There have been over a quarter of a billion

cigarettes seized in Ireland recovering €85 million of lost tax revenue.[1] The number of cigarettes seized in Ireland since the introduction of the Point of Sale Display ban in July 2009 is just less than the combined 305 million cigarettes seized for 2005, 2006, 2007 and 2008.[2] Furthermore, the UK government has recently acknowledged that a full tobacco display ban could harm small businesses and encourage black-market sales of cigarettes and as such the Department of Health in the UK has indicated that they will push for a compromise on the tobacco display regulations due to be introduced in 2011.[3]

### **explanations**

No change

### **which one2**

The Problem definition does not outline any problem in relation to a point of sale display ban. It is our view that evidence from the only EU country that has a complete ban of tobacco products in effect shows that such a ban does not reduce the impact of tobacco on children as the legislation intends. It is reported that crime gangs in the Republic of Ireland making €3 million a week from selling smuggled cigarettes are using children as young as 12 as “runners” to hold their cash for them at open-air markets where the cigarettes are openly for sale.[4]

### **additional option**

We would strongly urge the European Commission against introducing legislation that will prohibit the display of tobacco products. We believe that the introduction of a tobacco product display ban will not lead to a reduction in the prevalence of smoking but will rather put retailers in Ireland and across the EU under severe pressure in a time of difficult economic conditions. Evidence from Ireland shows that the ban has directly led to the increase in the illicit tobacco trade from which many criminal gangs and dissident terrorist groups are known to be profiting. Similarly, the UK has recently signalled it will push for a compromise on the tobacco display regulations it is due to introduce in 2011 after acknowledging that a full tobacco display ban could harm small businesses and encourage black-market sales of cigarettes.[5] Since the introduction of the Point of Sale Display Ban in Ireland in 2009, there have been over a quarter of a billion cigarettes seized recovering €85 million of lost tax revenue.[6] The number of cigarettes seized in Ireland since the introduction of the Point of Sale Display ban in July 2009 is just less than the combined 305 million cigarettes seized for 2005, 2006, 2007 and 2008.[7] In this time there is much evidence from retailers in Ireland to suggest that the increased involvement of criminal gangs and dissident republicans in the illicit cigarette trade is seriously affecting business. Retailers, and in particular small independent shopkeepers, rely heavily on the sale of tobacco products and can account for up to 30% of overall turnover[8]. Since the introduction of the Point of Sale Display Ban in 2009 Ireland's retailers collectively lost close to €700 million from tobacco being sold illegally on the black market.[9] In the same year legitimate sales have taken a 5% hit since the ban was implemented[10] with one store owner from the Dublin area reporting his turnover had plummeted from €30,000 a week to €17,000 in the past 12 months.[11] Moving tobacco products under the counter has undoubtedly made it easier for smugglers, counterfeiters and illegal street salesmen to enter the legitimate trade with counterfeit and contraband packets. The percentage of people smoking in Ireland who are over the age of 18, still stands at approximately 30 per cent yet shop sales were down as much as 25 per cent which means that people are still smoking but they have been buying them through illegitimate and illegal sources.[12] In addition to putting retailers in Ireland and the EU, already struggling in difficult economic times, under greater pressure, the introduction of this legislation will have

detrimental effects on public health, rather than reducing the rate of smoking as the legislation intends. Illicit and counterfeit cigarettes are known to contain 75% more tar, 28% more nicotine, and about 63% more carbon monoxide than regular cigarettes.[13] In light of this evidence we would suggest that Commission could pursue a more proportionate approach rather than the total ban on the display of tobacco products across the EU, which we believe will not achieve the desired affects but will rather lead to an increase in the illicit tobacco trade and greatly reduce the revenues of both the exchequer and retailers.

---

## **NGO submission**

### **identification**

#### **affiliation**

NGO

#### **name**

AHRESP - Associação da Hotelaria, Restauração e Similares de Portugal

#### **email**

Portugal

#### **additional comments**

No

### **access to tobacco products**

#### **problem definition**

We underline what has been mentioned in question 3. We are talking about a product whose is not illegal, therefore we do not understand why this product has to act in the "underground" and cannot be displayed at points of sale. That would surely make the inspection work more difficult, and on the other hand it will make life easier for counterfeiters and those who collude with them. People will buy the product no matter if he is displayed or not. It is not, of course, because the product can not be exposed and visible, that people will no longer purchase tobacco. There is no evidence that the ban on product display at point of sale, obtain any gain in terms of public health. In fact, the hiding makes tobacco more desirable, especially among young people. This question has nothing to do with the free trade. We do not understand the reason for mentioning the example of UK law to define the problem of access to tobacco products. Therefore, it should not result in the "blind" application to other countries where the realities and contexts vary. Today, the Portuguese law already allows to verify the age of the buyer, and the access to vending machines of tobacco is conditioned. The national legislation of each country should regulate these matters, according to their own reality and needs, establishing appropriate measures, fulfilling the wise principle of subsidiarity.

#### **explanations**

No change

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## **NGO submission**



**identification****affiliation**

NGO

**name**

Centromarca-Associação Portuguesa de Empresas de Produtos de Marca

**email**

Portuguesa

**additional comments**

No

**access to tobacco products****problem definition**

Estas medidas, tal como propostas e face aos objectivos expostos, não parecem ser efectivas no plano de saúde pública, levantando dúvidas no plano de melhor funcionamento do Mercado Interno. Sobre a proposta de proibição de “vending machines” e de exposição dos produtos Estas medidas reduzem de forma drástica a capacidade de comunicar com o consumidor. Os efeitos imediatos na qualidade e liberdade de escolha, seriam: - a inexistência de possibilidade de comparação, - a redução da conveniência, - a dependência do consumidor do retalhista, pela capacidade de impor ao consumidor a sua escolha; - a fragilização dos mecanismos leias de concorrência, ao facilitar a introdução de produtos contrafeitos. Estas medidas ao reduzirem significativamente a capacidade de concorrer, a liberdade de comunicar e a capacidade de realizar uma escolha de forma livre, informada e completa, importa que tenham subjacentes um estudo rigoroso e quantificado sobre o seu impacto, face aos objectivos que pretendem atingir: redução no consumo. Em suma estas medidas, tal como propostas e face aos objectivos expostos, não parecem justificar-se no plano de saúde pública, levantando dúvidas no plano de melhor funcionamento do Mercado Interno.

**explanations**

No change

**additional option**

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**NGO submission****identification****affiliation**

NGO

**name**

Nick Hayns - Institute of Economic Affairs

**email**

UK

**additional comments**

Yes

**explanations**

No change

**which one2**

The Commission has sought comments on a wide range of proposed tobacco control measures. This submission provides comment on three of the proposals: banning point-of-sale tobacco displays; requiring all tobacco products to be sold in plain packages; and the use of graphic health warnings on tobacco products. The submission is based on two factors. First, clear criteria of what constitutes acceptable tobacco control policy and, second, a careful examination of the empirical evidence for both of these tobacco control measures. With respect to the first, we believe that acceptable tobacco control policy is policy that results in 1) reductions in tobacco initiation, prevalence, and consumption and 2) increases in both quit attempts and successful quit attempts. Policies that cannot promise these results are not acceptable instances of tobacco control. With respect to the second we believe, as the evidence outlined below demonstrates, that there is no compelling scientific evidence that establishes that either tobacco display bans or plain packaging or graphic health warnings will result in substantial reductions in tobacco initiation, prevalence, and consumption, or increases in both quit attempts and successful quit attempts. In short, none of these regulatory measures can demonstrate an effect in preventing smoking uptake or reducing current levels of smoking. Consequently, none of these policies meets the crucial test of legitimate tobacco control policy.

**additional option**

A full pdf submission was sent, attached to an email from nhayns@iea.org.uk, at 13:57 GMT on 17.12.2010.

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**NGO submission****identification****affiliation**

NGO

**name**

ASSOUTENTI Vicolo Orbetelli 10 00186, Roma

**email**

Italia

**additional comments**

No

**explanations**

Controlled supply and access

**which option**

Age verification of buyers and other legal conditions to be set for cross-border retail sale;  
Access to vending machines to be restricted to adults

### **which one2**

Occorrerebbe prevedere altre misure atte a responsabilizzare i rivenditori di prodotti del tabacco, quali, ad esempio, controlli casuali e/o sanzioni nel caso di vendita a minori, quali la sospensione o, in caso di recidiva, revoca della licenza di vendita.

### **additional option**

Tra le alternative proposte, si ritiene utile una modifica diretta a controllare l'offerta di tali prodotti, soprattutto con riferimento alla verifica dell'età degli acquirenti. Una misura aggiuntiva molto importante potrebbe essere quella dell'unificazione dell'età minima per l'acquisto di prodotti da fumo in tutta l'Unione Europea. In alcuni paesi, infatti, l'età minima è di 16 anni (ad esempio in Italia), mentre in altri è di 18. In secondo luogo, appare corretto il mantenimento dei distributori di sigarette automatici all'interno dell'Unione Europea: il loro uso dovrebbe essere consentito, però, solo alle persone alle quali, per età, i prodotti da fumo possono essere venduti. Dal momento che i prodotti rientranti nell'ambito della direttiva sono considerati leciti, non si comprende quale sia la motivazione/giustificazione a renderne troppo difficile la vendita. L'assenza dei distributori automatici renderebbe, di fatto, impossibile l'acquisto durante l'orario notturno o durante i giorni festivi. Il fumatore sarebbe, dunque, spinto, almeno in quelle fasce orarie, all'acquisto dei prodotti tramite mercato nero. Tale misura sarebbe sproporzionata anche qualora fosse giustificata dal proposito di impedire l'acquisto dei prodotti del tabacco da parte dei minori d'età. E' palese che debba essere impedito con ogni strumento a disposizione il consumo da parte dei minorenni dei prodotti rientranti nell'ambito della Direttiva. Tale risultato, tuttavia, può essere raggiunto anche tramite altri strumenti. Ad esempio, si potrebbe predisporre, come già previsto in Italia, che i distributori automatici richiedano l'inserimento della tessera sanitaria o una carta di credito prima dell'acquisto, al fine di rilevare l'età del consumatore. Un'ulteriore considerazione merita la facoltà per i rivenditori di esibire al pubblico e promuovere all'interno del punto vendita i prodotti rientranti nell'ambito della Direttiva. A tal proposito valgano le medesime osservazioni svolte in relazione al mantenimento dei distributori automatici: poiché la vendita di questi prodotti è ritenuta lecita all'interno dell'Unione Europea, non si comprende perché debba essere impedita o limitata qualsiasi forma di comunicazione al pubblico, già fortemente regolamentata in molti Paesi UE dal generale divieto di pubblicità dei prodotti da fumo. Non solo: privare il consumatore di visualizzare in tabaccheria il prodotto che sta per acquistare, e così riconoscerlo, potrebbe portarlo ad acquistare il prodotto sbagliato, e, dunque, a compromettere la sua possibilità di scelta. Sappiamo infatti che di un stesso brand esistono diversi prodotti, contraddistinti da diversi colori e segni grafici. Non consentire al fumatore di individuare chiaramente tali elementi al momento dell'acquisto ne pregiudica la possibilità di effettuare un acquisto consapevole.

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### **NGO submission**

#### **identification**

#### **affiliation**

NGO

#### **name**

Johan Hjertqvist

**email**

Belgium

**additional comments**

No

**access to tobacco products**

**problem definition**

In almost all EU countries, cigarettes account for more than 98 % of the tobacco use. For this reason we find it rational to focus on the kind of tobacco use causing the very large majority of disease, deaths and need for healthcare interventions. It should be kept in mind that the cigarette is the only product of any kind, which is harmful already when used as intended, which is allowed for sale to the public! With conventional measures it is difficult to bring the smoking rate significantly below the level of 20 % smokers in the adult population of Europe. Still around 80 million Europeans regularly smoke tobacco. This is a ticking bomb as diseases caused by smoking, such as COPD, typically take decades before reaching a critical condition. The increasing pressure on healthcare resources in an ageing Europe, particularly COPD, lung cancer, diabetes and CVD caused by smoking, threaten the sustainable funding and delivery of healthcare services. Thus powerful smoking prevention should be part of the EU healthy ageing strategy. The measures discussed by this proposal are too marginal and insufficient. The Commission perspective seems to be that smoking is a matter of lack of information. But several surveys indicate that the health risks of smoking are known by almost all adult Europeans. Research tells us that smoking is a life-style habit, with much more subtle and irrational reasons than pure lack of knowledge. Few European smokers can today claim to be uninformed or ignorant of the risks from smoking. That is why the EU strategy needs to improve to really make a break-through to save many more lives. In the EU there are some champions in smoking prevention and cessation practice, with Sweden being the country having the lowest smoking prevalence by a large margin. It would be embarrassing to find that the European Commission would ignore success stories in smoking prevention. In every measurement Sweden stands out as having the lowest levels of smoking-related diseases in the EU. We guess the European Commission should be curious about the reasons? Swedish males show the lowest smoking prevalence in Europe at ~10 %. Swedish women are also low on smoking, but with less outstanding figures (14 – 15% level). The smoking participation among young people is comparatively low as well. Swedes are also among the most frequent users of Pharmaceutical Nicotine (“PN”) such as chewing gum and patches, which could be a contributing factor. However, even the high Swedish consumption of PN, is overshadowed by the use of snus. Even the high Swedish consumption of PN, approximately 28 million Defined Daily Doses per year (women use that more than men), can be compared to the use of snus, expressed as “DDD:s”, of 400 million DDD/year. The “snus factor”, which needs to be taken into account in not only Sweden but also Norway (apart from Sweden the only European country having a male smoking prevalence lower than that of women), ought to be of interest to assess in the context of tobacco harm prevention and cessation policy. There seem to exist Swedish tobacco habits which save lives. If the Swedish smoking behavior were to be transformed to the pan-European level we estimate that at least 250 000 less Europeans of both sexes would die every year. Population-level health outcomes depend on many factors why care should be taken when estimating real-life transfer opportunities. It should be difficult to ignore the Swedish example. Different conclusions can be drawn, but the impressive Swedish health outcomes ought to raise questions about the

pragmatic “Swedish mix” of (still occurring) smoking, snus, PN products and prevention policy.

### **explanations**

Controlled supply and access; Ban

### **which option**

Age verification of buyers and other legal conditions to be set for cross-border retail sale; Access to vending machines to be restricted to adults; Tobacco display and promotion at points of sales to be restricted

### **which supply and access**

Cross-border retail sales of tobacco to be banned over the Internet; Vending machines to be banned; Promotion and displays in retail stores to be banned

### **which one2**

Given the horrible negative health imprint from cigarettes, a rational measure would of course be an outright ban on retail sales of cigarettes. This is what HCP would suggest – but we understand at the same time the difficulties to implement such radical policy. But again Sweden could serve as an exceptional role model: Sweden is today the single EU member state where a retail ban would have a chance to be accepted. With close to 90 % of the population refraining from smoking, and an established above explained ”mix” of tobacco use and prevention, Sweden could become a test bed for radical policy: A self-imposed Swedish sales ban on cigarettes during a certain period (5 years?) would provide valuable experience and health performance data. Member States remain competent to have national measures on limiting the access to tobacco products, why a ban in Sweden would be within the national competence. HCP will be discussing this idea of a “real-life assessment” with the Swedish government. There most likely are a number of legal and practical objections to bring into the equation. An EU-Sweden co-operation to make this approach a pilot for experience and health impact evaluation would be recommendable.

### **additional option**

As said, we cannot see that the measures ventilated by the Commission will be enough to address the alarming smoking problem. They are, in context, of course better than nothing, why we support them. But again, the severity of the health threat caused mainly by cigarettes requires more drastic action!

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## **NGO submission**

### **identification**

#### **affiliation**

NGO

#### **name**

Mr Stephen Alfred Hoffman. I work as the parliamentary liaison for the Freedom Association. We are committed to freedom of the individual, free markets and national sovereignty.

#### **email**

United Kingdom

**age**

male

**additional comments**

No

**access to tobacco products**

**problem definition**

No. The problem with the definition is that it only concentrates on the negatives of cross-border tobacco sales through the Internet and only looks at the problem of tobacco control from the eyes of health officials. It ignores the fact that these sales of tobacco bring significant amounts of money into the economy. It also ignores the fact that if the government tries to enact more regulations on the sale of cross-border tobacco or even bans it; it will lead to a rise in illegal smugglers and cross-border sales going into the hands of some very dangerous illegal groups. In fact, this has already happened with such sales from Ireland to other countries. This is because, since the tobacco display ban has been in place in Ireland, there has been a rise in tobacco smuggling activity from groups like the IRA that have been enjoying the profits. Thus the definition seems to miss the point completely when it says there are insufficient health warnings on tobacco sold cross border or over the Internet and compliance issues. The problem definition should be changed to: "Across the EU there have been moves to legislate against tobacco being sold across the border and since this has happened there has been a rise in contraband tobacco sales. To combat this we are looking at reducing regulation sensibly so that the illegal market in tobacco is undermined." The problem definition also only mentions plans in member states like the UK to introduce tobacco display bans. It doesn't give examples of where tobacco display bans have been introduced and the effect of them. If there is going to be a constructive debate about how the problem is going to be solved, the consequences of the Tobacco Display Ban in Canada and Ireland need to be looked at.

**explanations**

No change

**which one2**

The EU should encourage member states to be less draconian when it comes to tobacco display. There is the belief across Europe that government knows best. However, as the success of privatisation across the world has highlighted, often they do not. When it comes to suggestions in the EU Tobacco Products Directive, it is all about the government controlling the marketing of tobacco, what goes into a cigarette and whether a so-called free individual can see a cigarette packet. The directive needs to change its focus away from this. In the UK a tobacco display ban will be introduced in 2011 and the compliance costs could be at least £33 million and a government impact assessment that is probably underestimating figures says to implement the ban would cost the average retailer £1000 (<http://www.velvetgloveironfist.com/pdfs/thedarkmarket.pdf>). It was also calculated, by Patrick Basham, if a similar situation took place as happened in Canada, 2,600 independent retailers in the UK could close (<http://www.iea.org.uk/files/upld-book517pdf?.pdf>). Multiply that cost by 27 member states and that is a significant loss of money and diversity of shops that member states could do without. At a time when many EU member states are facing an economic downturn choosing option 3c in the consultation document would only make a bad

economic situation disastrous. Display bans have not led to a lower prevalence in smoking. For example, 6 months after the display ban in Ireland, a survey of 4033 people found that 33% of the population had taken up or continued to smoke. This is the highest smoking rate recorded in the past 11 years in Ireland according to “EU’S HELP FOR A LIFE WITHOUT TOBACCO” campaign. <http://www.independent.ie/national-news/smoking-rate-soars-up-to-one-third-despite-ban-1923543.html>. Thus all the evidence against tobacco display bans highlights it is an ineffective policy that does not improve public health and has the unintended consequence of damaging small retailers. We also need to listen to a wider range of people. At present the only voices we hear are from public health bodies like ASH (Action on Smoking and Health) who are often funded by the government and have an interest in pushing for harsher laws when it comes to the availability, display and sale of tobacco. For example in the UK the taxpayer spent £142,000 in 2009 and £191,000 to ASH (<http://conservativehome.blogs.com/platform/2010/10/simon-clark.html>). This figure does not include salaries and campaigns of, the various Smoke Free quangos; stop smoking advisors, to nicotine replacement therapies such as patches and gum. The EU should look into introducing legislation in the Tobacco Products Directive to put in restrictions on the amount that tobacco control bodies can receive from the government. Those who do not take the line of groups like ASH are told that they are in the pay of the tobacco lobby. Speaking for the Freedom Association, I can honestly say there is not a scintilla of truth to it. To tackle this problem the EU should set guidelines in the EU Tobacco Products directive urging governments to include stakeholders from businesses and members of the general public in discussions, rather than just groups in favour of tobacco control. The debate would then become more balanced and legislation better thought out. At the moment free speech is damaged by the fact that often only voices in favour of tobacco control are heard. If the directive does not look into these additional options, responsible shop owners who have the interests of their customers at heart will be restricted from selling tobacco. Therefore increasingly tobacco consumers especially teenagers will go to alternative less controlled suppliers who do not have the interests of the customers at heart. These alternative suppliers will have no qualms about mixing tobacco with other more dangerous products and will use their proceeds for crime.

### **additional option**

In the report section called “Access” it only looks into access to tobacco products as a public health matter. It ignores that tobacco sales contribute a lot to the economy. Furthermore it ignores that it is widely accepted that 33% of retailers’ profit, in particular corner shops, comes from tobacco sales (<http://www.bigbrotherwatch.org.uk/home/2010/11/smoking-and-the-nanny-state.html>). This does not include profits made from other products bought by the person buying tobacco. Often consumers will buy other products like confectionery. If tobacco was not made readily available in these shops, either through a complete display ban or reduced marketing, then the flow of traffic to retail shops is likely to decrease. Larger supermarkets can get round it due to economies of scale and the vast array of products they sell. Thus independent retailers would face unfair competition from supermarkets. Additionally there would be a strong regulatory burden if access to tobacco products changed. If marketing were reduced, time and money would be needed to change the marketing of the product and in building cabinets to hide the tobacco in as well as training staff to use it. Small newsagents are already losing revenue due to the worldwide recession. In 2009, a report revealed that more than one newsagent a day was closing in the UK (<http://www.philip-davies.org.uk/newsshow.aspx?id=12&ref=1300>). A change in tobacco display laws will make this worse. The evidence is shown from Canada where, since the tobacco display ban has been in place, 15% of all small retailers have gone out of business (<http://www.iea.org.uk/files/upld-book517pdf?.pdf>). There is also the question of individual

freedom. It should be up to a shop owner to decide on the appearance of his shop and how he wants to market tobacco. A cherished value that shouldn't be undermined is that an owner has the right to use or permit a legal product on private property. It is not the role of the state, as they do not control the shop. Consequently Phillip Davies, MP for Shipley is correct to say, "This smacks of the Nanny State all over again. These proposals are simply not evidence-based, will increase counterfeit products and confuse consumers." Independent retailers have little confidence in legislation aimed at restricting the sale of tobacco. A study in Scotland by the Tobacco Retailers Alliance highlighted that 56% of shopkeepers believed a display ban would increase contraband sales (<http://www.bbc.co.uk/news/uk-scotland-11076046>). Therefore the proposed legislation is a threat to individual freedom and bureaucratic. Also shopkeepers have little confidence with regards to enforcement. Considering this, perhaps the Tobacco Products Directive should stop trying to reduce marketing on tobacco. If greater restrictions and bans are put on cigarettes, people will seek cheaper alternative routes, which tend to be illegal. Unlike Canada, the EU cannot pretend that they had little evidence on what would be the effects of introducing such legislation. The EU has plenty of evidence from Canada that there has been a significantly negative impact on independent retailers, a rise in contraband sales and a negligent effect on health.

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## **NGO submission**

### **identification**

#### **affiliation**

NGO

#### **name**

Associação de Grossistas de Tabaco do Sul

#### **email**

Portugal

### **additional comments**

No

### **access to tobacco products**

#### **problem definition**

-The only sales that are executed through vending machines are controlled by "Human Subjects", therefore the problem lies in human decisions of buying and selling the tobacco product and not the mechanical act of sale itself. - The purchase of tobacco by minors should be penalized, by punishing and holding accountable the parents and guardians of underage children who allow them to purchase tobacco products. - The assignment of tobacco products to minors by adults (friends) should be penalized. -Tobacco use (tobacco smoking) by minors should also be prohibited and penalized. - The vending machines are really part of the solution and not part of the problem because they constitute an important tool in combating the sale of counterfeit tobacco products since the offender risks a lot more to be discovered by authorities when selling counterfeit tobacco in their vending machine. - There is no evidence that the inhibition of exposure of products in commercial spaces diminishes the consumption of tobacco. Furthermore the ban on display of products is an inhibitor of "freedom of choice" by consumers and promotes confusion between the legal product and the illegal product.



**explanations**

No change

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**NGO submission****identification****affiliation**

NGO

**name**

Hans Kant on behalf of Koninklijke Horeca Nederlands (the Royal Dutch Horeca Association)

**email**

The Netherlands

**country**

42

**age**

male

**additional comments**

No

**explanations**

No change

**additional option**

Koninklijke Horeca Nederland, with 20.000 members in hotels, restaurants, cafés etc. representing the hospitality sector in The Netherlands, would like to reply to section 6 “Access to tobacco products” of the consultation on the possible revision of the Tobacco Products Directive. Koninklijke Horeca Nederland supports activities to promote health and to prevent smoking-related diseases. However, when cross-border sales of tobacco is not involved, Koninklijke Horeca Nederland is of the opinion that rules regarding “access to tobacco products” (e.g. automatic vending machines and display in retail outlets) should be decided at national level in accordance with the subsidiarity principle. As rules concerning access to “vending machines” and “display in retail outlets” do not have any impact on the functioning of the EU internal market, Member States should remain competent to adopt national measures. Furthermore, provisions set at national level can better take into account local conditions and needs rather than measures decided at EU level with a one-size-fits-all approach. In addition, Koninklijke Horeca Nederland notes that an EU ban on tobacco vending machines would have a negative impact on the hospitality sector in The Netherlands and in those Member States where these devices are still available in hospitality venues. For these reasons Koninklijke Horeca Nederland supports policy “Option 1 - No change”: “Member States remain competent to have national measures on limiting the access to tobacco Products”. This option would be the most effective, leaving each Member State to

decide the appropriate policy to deal with the issue in proper consultation with relevant stakeholders at national level.

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### **NGO submission**

#### **identification**

##### **affiliation**

NGO

##### **name**

TRGOVINSKA ZBORNICA SLOVENIJE - SLOVENIAN CHAMBER OF COMMERCE

##### **email**

SLOVENIJA

#### **additional comments**

No

#### **access to tobacco products**

##### **problem definition**

Pomembno je podariti, da prepoved razstavljanja tobačnih proizvodov na prodajnem mestu lahko še dodatno spodbudi nezakonito trgovino in ponarejene tobačne proizvode. S tem predpisom bi bila prizadeta zmožnost potrošnikov, da razlikujejo med zakonitimi in nezakonitimi proizvodi, s čemer bi bila olajšana distribucija in prodaja pretihotapljenih in ponarejenih tobačnih proizvodov. Če bo postala izdelava, distribucija in prodaja pretihotapljenih in ponarejenih tobačnih proizvodov enostavnejša, bo to izničilo ves dosednji napredek organov pregona pri zatiranju trgovanja z nezakonitimi proizvodi in ukrepanje v primeru razkritja kriminalnih združb. Po našem mnenju bi moral biti vsak nov ukrep kot eden od elementov obširne politike nadzora nad tobakom učinkovit, sorazmeren, praktičen, ob upoštevanju vrednot in kulture v posameznih okoljih in družbah. Po našem mnenju je predlagan ukrep prepovedi razstavljanja tobačnih proizvodov na prodajnem mestu neskladen in neustrezen z vsemi naštetimi principi.

#### **explanations**

No change

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### **NGO submission**

#### **identification**

##### **affiliation**

NGO

##### **name**

QUIT and European Network of Quitlines

##### **email**

UK

**additional comments**

Yes

**explanations**

Ban

**which supply and access**

Cross-border retail sales of tobacco to be banned over the Internet; Vending machines to be banned; Promotion and displays in retail stores to be banned

**which one2**

We urge the Commission to call for a ban on the promotion of tobacco products at point of sale and a ban on vending machines as described in the Art 13 Guidelines of the FCTC.

**additional option**

Internet. The principle of preventing cross-border promotion of tobacco products in order to protect public health was enshrined in the Tobacco Advertising directive (2001/0119). It is logical, therefore, to extend that principle to the sale of tobacco products between member states via the Internet. We support the prohibition of tobacco sales via the Internet. Vending machines. The majority of member states (22 out of 27) already prohibit the sale of tobacco products from vending machines in order to deter young people accessing cigarettes from this source. We support this measure. Point of Sale. Evidence shows that a coordinated cross border marketing strategy on the part of the tobacco companies is reflected at point of sale (i.e. point of sale marketing is similar in most EU countries (i.e.: a brand is advertised at point of sale in the same way in Germany and Belgium). There is a growing body of evidence to show that putting tobacco products out of sight in retail outlets can reduce youth smoking. To date, this measure has been adopted by Ireland and Finland (as well as Iceland and Norway). This measure is also official government policy in Scotland, Wales and Northern Ireland and a decision is awaited in England. We strongly support an EU-wide adoption of a ban on the display of tobacco products at the point of sale.

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**NGO submission****identification****affiliation**

NGO

**name**

CHAMBER OF COMMERCE AND INDUSTRY OF SLOVENIA

**email**

SLOVENIA

**additional comments**

No

**access to tobacco products**

**problem definition**

Prepoved prikazovanja je ovira za trgovino in je v nasprotju z načeli notranjega trga EU. EU nima pristojnosti za urejanje načinov prodaje.

**explanations**

No change

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**NGO submission****identification****affiliation**

NGO

**name**

Asain Quitline

**email**

UK

**additional comments**

Yes

**explanations**

Ban

**which supply and access**

Cross-border retail sales of tobacco to be banned over the Internet; Vending machines to be banned; Promotion and displays in retail stores to be banned

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**NGO submission****identification****affiliation**

NGO

**name**

Aéroport de Montpellier Méditerranée

**email**

France

**additional comments**

No

**access to tobacco products****problem definition**

En n'évoquant que les difficultés posées par les ventes de tabac sur internet et les différentes

mesures nationales d'interdiction d'étalage, la définition ne prend pas en compte les spécificités des ventes hors taxes transfrontières ayant lieu dans les aéroports. Les problématiques liées à la limite d'âge d'achat et à la perception de ressources fiscales ne sont pas transposables dans les aéroports dont les commerces peuvent être hors-taxes et les consommateurs majoritairement adultes et systématiquement dotés de documents d'identité. La définition fait référence au fait que le Royaume-Uni a annoncé l'interdiction de l'étalage des produits du tabac dans les grands magasins à partir d'octobre 2011 et dans tous les autres lieux en octobre 2013 en Angleterre, au Pays de Galles et en Irlande du Nord. Mais le Royaume-Uni a reconnu la nature unique des commerces hors taxes tels qu'ils existent dans les aéroports en les distinguant des détaillants du marché domestique et en les définissant comme étant des « fournisseurs de tabac en lot » (« bulk tobacconists »). La Pologne a récemment exempté les boutiques hors-taxes des aéroports des restrictions sur le tabac en libre service. Cette définition déclare également qu'une interdiction similaire a été annoncée en Irlande. En fait, l'Irlande applique un système différent plus pénalisant. Les boutiques hors-taxes irlandaises ne sont autorisées qu'à une représentation picturale du tabac très limitée. Depuis l'introduction de ce système, les ventes de tabac hors-taxes ont chuté de 35%.

### **explanations**

No change

### **which one2**

Ne procéder à aucun changement permet aux Etats membres de maintenir leur compétence pour répondre aux problèmes de vente de produits du tabac sans introduire une interdiction sur l'étalage de tabac. L'absence d'étalage augmenterait inévitablement le temps nécessaire aux passagers pour localiser leur achat et effectuer la transaction. Ceux-ci seraient aussi potentiellement pénalisés par la langue utilisée pour indiquer où se trouvent les produits s'ils ne parlent pas la langue du pays dans lequel se trouve l'aéroport. Dès lors, les passagers ne feraient que retarder leur achat pour l'effectuer dans l'avion ou à leur aéroport d'arrivée et les revenus afférents aux produits du tabac seraient perdus pour l'aéroport. Toute mesure tendant à pénaliser le passager aérien conduirait celui-ci à s'approvisionner du mieux possible dans des pays facilitateurs de prix. Aujourd'hui, de nombreuses contraintes nouvelles (réglementation, taxes...) pèsent sur le transport aérien et les pertes de revenus engendrées par l'interdiction d'exposition des produits du tabac aggraveraient cette situation. Il convient donc de prendre en compte la spécificité des aéroports et leurs commerces hors-taxe en tant qu'espace de distribution unique et contrôlé. Une application stricte de l'interdiction générale d'étalage aurait un impact important sur les revenus et le développement des aéroports européens.

### **additional option**

L'interdiction générale de l'exposition de tabac sur les étals des commerces aurait des conséquences disproportionnées sur le commerce hors-taxe des aéroports. Les aéroports dont les boutiques hors-taxes proposent des produits du tabac constituent, de par leur nature et leur situation, un environnement unique de vente. Les zones sous douane des aéroports n'ont pas vocation à être des espaces de consommation courante pour les citoyens des Etats membres. Cette spécificité a notamment déjà pu être consacrée dans le cadre de la notion d'Espace Voyageur. Les produits du tabac qui y sont vendus ont des formats spécifiques et sont exclusivement destinés aux passagers aériens pour l'exportation. Il n'est d'ailleurs pas commercialisé de paquets de cigarettes individuels de sorte qu'aucune consommation instantanée des produits achetés n'est possible. De plus, il est maintenant interdit de fumer dans les aéroports en France et de manière générale en Europe. Dans la plupart des Etats dans

lesquels une interdiction de l'étalage des produits du tabac a été introduite, il a été accepté certaines formes de dérogations pour les aéroports. Les revenus des aéroports seraient lourdement affectés par une telle interdiction à l'échelle européenne. La vente des produits du tabac donnent lieu à un prélèvement conséquent par l'aéroport. En effet, les ventes de produits du tabac représentent près d'un tiers des redevances perçues sur les commerces hors-taxes par les aéroports. Ces revenus commerciaux revêtent donc une importance particulière pour les aéroports. Par ailleurs, une diminution des ventes de produits du tabac impliquerait également une baisse corrélative des ventes des autres produits des boutiques hors-taxes. Ces ressources favorisent les voyages en avion en limitant l'augmentation des redevances aéronautiques réglementées (redevances passagers et atterrissage notamment) du fait de l'organisation comptable des aéroports et de l'application de la « caisse unique ». La perte de revenus liée à une interdiction générale de l'exposition de tabac sur les étals des commerces affaiblirait la compétitivité des gestionnaires d'aéroports face aux autres aéroports internationaux des Etats tiers.

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## **NGO submission**

### **identification**

#### **affiliation**

NGO

#### **name**

Rebecca Broadbelt

#### **email**

United Kingdom

#### **age**

female

### **additional comments**

Yes

### **explanations**

Controlled supply and access

### **which option**

Age verification of buyers and other legal conditions to be set for cross-border retail sale; Access to vending machines to be restricted to adults; Tobacco display and promotion at points of sales to be restricted

### **which one2**

There needs to be checks introduced similar to those for buying alcohol that checks on age limits for children attempting to buy tobacco products.

### **additional option**

I do not think that a ban is appropriate as I think that adults have the right to choose, I believe

the focus of education should be on preventing schoolchildren taking up smoking in the first place and education on the costs of smoking (financial and costs for health) long term.

---

### **NGO submission**

**identification**

**affiliation**

NGO

**name**

Goedert

**email**

Luxembourg

**additional comments**

No

**access to tobacco products**

**problem definition**

En ce qui concerne la vente par internet : cet aspect est déjà couvert et réglementé par la section 3 de la directive 2008/118/CE relative au régime général d'accise.

**explanations**

No change

**additional option**

Quant à une possible interdiction d'étalage des produits du tabac, nous souhaitons rappeler que le principe de subsidiarité devrait ici jouer et qu'une telle mesure est du ressort des Etats membres. Fumer est un choix fait par des adultes informés, les fabricants de tabac ne sont donc pas opposés à ce que les Etats membres prennent des mesures afin de garantir que les mineurs d'âge ne puissent avoir accès aux produits du tabac. De nombreux Etats membres ont déjà adoptés des législations en ce sens.

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### **NGO submission**

**identification**

**affiliation**

NGO

**name**

Annette Szalata

**email**

Germany

**country**

**age**  
female

**additional comments**  
No

**access to tobacco products**

**problem definition**

Tabakwaren sind ein legales Genussmittel, dessen Konsum – genauso wie Alkohol und Süßigkeiten – mit gesundheitlichen Risiken verbunden ist. Dennoch handelt es sich um ein legales Produkt. Mit den hier vorgeschlagenen Maßnahmen werden Grundrechte eingeschränkt. Dies steht nicht im Verhältnis zu den tatsächlichen Risiken. Die Untersagung der Auslage bzw. Sichtbarkeit von Zigaretten in Verkaufsstellen weisen keinen grenzüberschreitenden Bezug auf. Die hier vorgeschlagenen Maßnahmen betreffen nicht das Funktionieren des europäischen Binnenmarktes, sondern sie sind alleine gesundheitspolitisch motiviert. Die Gesundheitspolitik fällt aber nicht in den Kompetenzbereich der EU, sondern ist nach dem Subsidiaritätsprinzip allein auf nationaler Ebene zu regeln. Tatsächlich existieren ja in allen Ländern auch bereits regulierende Maßnahmen. Organisierte Kriminalität und Schmuggel werden die Lücke füllen, die entsteht, wenn legale Verkaufs- bzw. Bezugsstellen verschwinden.

**explanations**  
No change

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**NGO submission**

**identification**

**affiliation**  
NGO

**name**  
VNPI

**email**  
Netherlands

**additional comments**  
No

**access to tobacco products**

**problem definition**

VNPI is voorstander van toezicht op leeftijd met betrekking tot tabaksverkoop echter wij zijn geen voorstander van maatregelen zoals displayban, plain packaging en het voorstel tav pictorials

**explanations**



No change

**which one2**

1. Uit eigen ervaring twijfelen we aan de effectiviteit van een uitstalverbod met als doel de tabaksverkopen te verminderen 2. Een uitstalverbod leidt tot hoge kosten voor onze industrie (investeringen dienen gepleegd te worden per locatie voor naleving van dit verbod) 3. Uitstalverbod belemmert nieuwe toetredingen en belemmert daardoor de concurrentie (markttoegang of produktintroducties praktisch onmogelijk)

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**NGO submission**

**identification**

**affiliation**

NGO

**name**

SEDEA/AGMORC Association of Greek Market and Opinion Research Companies

**email**

GREECE

**additional comments**

No

**access to tobacco products**

**problem definition**

no comments

**explanations**

No change

**which one2**

no comments

**additional option**

no comments

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**NGO submission**

**identification**

**affiliation**

NGO

**name**

Rodrigo Cordoba García

**email**

Spain

**country**

56

**age**

male

**additional comments**

Yes

**explanations**

Controlled supply and access; Ban

**which option**

Access to vending machines to be restricted to adults

**which supply and access**

Cross-border retail sales of tobacco to be banned over the Internet; Vending machines to be banned; Promotion and displays in retail stores to be banned

**which one2**

Age verification don't works in the daily practice

**additional option**

Point of sales without tobacco promotion. Effective ban sales to youth.

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**NGO submission**

**identification**

**affiliation**

NGO

**name**

EPA - European Parents' Association

**email**

Europe

**additional comments**

No

**access to tobacco products**

**problem definition**

We strongly support measures based on scientific evidence. The display ban on tobacco products has not been proven as an effective tool to prevent children from smoking in countries such Norway and Iceland. On the other hand, we believe that EU should enhance enforcement of access restriction for minors. The real issue is that minors should have no

access to tobacco products. In addition in some countries it is still possible for minors aged 16-18 to buy cigarettes. The directive should mandate an increase of the minimum law to prohibit sales to youth under 18 for all countries.

**explanations**

No change

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**NGO submission**

**identification**

**affiliation**

NGO

**name**

Frank Birker

**email**

Germany

**additional comments**

No

**explanations**

No change

---

**NGO submission**

**identification**

**affiliation**

NGO

**name**

Frank Birker

**email**

Germany

**additional comments**

No

**explanations**

No change

---

**NGO submission**

**identification**  
**affiliation**  
NGO

**name**

The Association of Swedish Advertisers is the sole organization that promotes and maintains the advertisers' interests on the Swedish advertising market. Around 500 corporations are members of the Association of Swedish Advertisers. Large, medium-size and small companies in practically all lines of business, government and local authorities, county councils, organizations - they are all marketers, and they all buy and use market communication.

**email**  
Sweden

**country**  
0

**age**  
male

**additional comments**  
No

**access to tobacco products**

**problem definition**

The introduction of a display ban in stores would have significant impact on free competition, as manufacturers would not be able to compete on equal grounds. It would freeze the existing market, the market leader would keep their dominant position, and it would constitute a major barrier for new entrants. Furthermore, statistics and information from countries that have implemented a display ban, such as Canada, shows no support of the effectiveness of a display on smoking incidence, amongst adults as well as among young people.

**explanations**  
No change

**which one2**  
No comment.

**additional option**  
No comment.

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**NGO submission**

**identification**  
**affiliation**  
NGO

**name**

American-Hellenic Chamber of Commerce

**email**

Greece

**additional comments**

No

**explanations**

No change

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**NGO submission****identification****affiliation**

NGO

**name**

FOOX Groothandelsorganisatie

**email**

Nederland

**additional comments**

No

**access to tobacco products****problem definition**

The description that in many Member States the sale of tobacco products via vending machines is prohibited is not a problem description. Even if from country to country, different requirements for the composition of the machines impede the cross-border trade with the machine for reasons of youth protection, a ban on the operation of machines would withdraw the basis of the Community-wide trade of products via vending machines, thus affects it and does not make it easier. We believe that both the display ban as well as the ban on vending machines will meet with the most concern in view to all three levels of Article 5, Lisbon Treaty (the principle of conferral, subsidiarity and proportionality principle).

**explanations**

No change

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**NGO submission****identification****affiliation**

NGO

**name**

The Slovak Advertising Standards Council (SASC)

**email**

Slovak republic

**additional comments**

No

**access to tobacco products****problem definition**

We appreciate the effort for an effective regulation of the tobacco products since it is a matter of products which demonstratively have harmful health effects. From our point of view, we mainly encourage giving of true and veracious information on the smoking-related risks. However, we have to say that some of the proposals submitted by the DG Sanco, in our opinion, go beyond the scope of this. The Slovak Advertising Standards Council (SASC), as an advertisement self-regulation body, is ensuring the relevant marketing communication in Slovakia in a highly effective way. During the past years, the advertisement industry has build up an effective system by means of which it can regulate itself and is continuously improving its communication system. The RPR is sent to international meetings taking place in other countries on a regular basis by the EASA (The European Advertising Standards Alliance) as an example of a well working organisation. The RPR would like to accentuate that it is convinced about the active and effective self-regulation by the industry itself also in this case. The proposal includes in options 2 a restriction and option 3 a total ban of display of the tobacco products at points of sale. Without initiating discussion about whether the displaying of the products on the shop counters is or is not an advertisement we believe that such measure would illegally interfere in the rights of not only the producers, but also the tradesmen. Displaying of products is one of the most important tools of how to inform the customers about the range of products offered from the viewpoints of both the producers and the tradesmen.

**explanations**

No change

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**NGO submission****identification****affiliation**

NGO

**name**

Groothandel Bergsma / S. Van der Zee

**email**

nederland

**country**

39

**age**  
male

**additional comments**

No

**access to tobacco products**

**problem definition**

The description that in many Member States the sale of tobacco products via vending machines is prohibited is not a problem description. Even if from country to country, different requirements for the composition of the machines impede the cross-border trade with the machine for reasons of youth protection, a ban on the operation of machines would withdraw the basis of the Community-wide trade of products via vending machines, thus affects it and does not make it easier. We believe that both the display ban as well as the ban on vending machines will meet with the most concern in view to all three levels of Article 5, Lisbon Treaty (the principle of conferral, subsidiarity and proportionality principle).

**explanations**

No change

---

**NGO submission**

**identification**

**affiliation**

NGO

**name**

Frank Birker

**email**

Germany

**additional comments**

No

**access to tobacco products**

**problem definition**

Es existiert bereits ein allgemeines Bewusstsein der Risiken des Rauchens. Durch die Umsetzung von neutralen Verpackungen wird Produktfäschern die Arbeit erleichtert. Es fördert die organisierte Kriminalität. Es bedroht die Existenz vieler Groß- und Einzelhändler und kostet hunderttausende Arbeitsplätze.

**explanations**

No change

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**NGO submission**

**identification****affiliation**

NGO

**name**

German Airport Association ADV

**email**

Germany

**additional comments**

No

**explanations**

No change

**additional option**

Impact of a tobacco display ban: - Would impede international competitiveness of EU airports and significantly decrease their profits - Would decrease footfall sales and thus impact the overall duty free business - There is virtually no impulse buying of tobacco products at duty free, most purchases are made by smokers who already planned ahead to buy - Passengers are overwhelmingly adult and eligibility is easily verified, thus the protection of minors is not a strong point. Duty-free and travel retail - a unique, controlled sales channel: Airport duty free shops compete internationally with airlines and shops at other airports, not with the High Street. Tobacco bought in duty free shops is a considered and deliberate purchase, rather than an impulse buy. Cigarette cartons are sealed, are for export and cannot be opened until final destination. Duty free shops do not sell individual packets of cigarettes. The vast majority of airports are smoke-free areas, and passengers are not allowed to return 'landside', once they have cleared security. Those products cannot be used until many hours after purchase. Youth access - age profiles at airports: Young people and children are a small minority of those passing through international airports. To take the UK as an example, a BAA survey in 2008 showed that 14 to 17 year olds constitute less than 1% of total passengers at BAA airports. Children and young people are not overly exposed to tobacco within airport duty free stores as these are not stores that they would visit on a regular basis or without adult supervision. Children under 12, and in most cases under 16, are only allowed to travel alone with airline staff supervision and the overwhelming majority of underage teenagers travel with their parents. A complete ban on display of tobacco products in airport duty free and travel retail shops in order to protect younger passengers from tobacco displays when under-18s make up only one in twenty passengers, where a very small minority of these will be flying to a non-EU destination, and where it is impossible for them to buy tobacco, constitutes in our view a disproportionate response which will harm the financial wellbeing of Europe's airports. International competitiveness: Although duty free and travel retail shops do not compete with the domestic market, they are nevertheless in very real and direct competition with retail outlets at other international airports and with airline onboard sales. This fact was recognized by the European Commission competition investigation into the purchase of World Duty Free by Autogrill. If passengers do not buy at the departure airport, they will simply delay the purchase to onboard the airline, to their transfer airport, or in many cases to their arrival airport (a large number of airports now have duty free and travel retail on arrival). The sale and subsequent revenue is simply lost to another airport or airline. Passengers are frequently



under time pressure to catch flights and thus require quick transactions. Experience has shown that customers will walk away from even small queues of two or three people. As noted, sales in Irish airports are down 35% since the introduction of their display ban in July 2009. Also the nature of airport buildings is such that there is insufficient space to stock tobacco products off the shop floor. Conclusion: An airport duty free shop is an environment where product display is the only practical way to address unique airport specific problems of customer knowledge, language barriers, stock-holding and limitations of time. Duty free shop operators have always been recognised as responsible retailers. We suggests that the EU consider an adaptation to any future legislation with regard to airport duty free which will ensure policy objectives are met whilst protecting a much needed revenue stream for Europe's aviation industry.

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### **NGO submission**

#### **identification**

##### **affiliation**

NGO

##### **name**

G.W. de Vries, director of Lekkerland Nederland BV, the largest wholesaler of tobacco products in Holland

##### **email**

Netherlands

##### **age**

male

##### **additional comments**

No

#### **access to tobacco products**

##### **problem definition**

The description that in many Member States the sale of tobacco products via vending machines is prohibited is not a problem description. Even if from country to country, different requirements for the composition of the machines impede the cross-border trade with the machine for reasons of youth protection, a ban on the operation of machines would withdraw the basis of the Community-wide trade of products via vending machines, thus affects it and does not make it easier. We believe that both the display ban as well as the ban on vending machines will meet with the most concern in view to all three levels of Article 5, Lisbon Treaty (the principle of conferral, subsidiarity and proportionality principle).

##### **explanations**

No change

---

### **NGO submission**

**identification**  
**affiliation**  
NGO

**name**  
Hellenic Travel Trade Confederation - Dimitris A. Iliadis

**email**  
Hellenic Republic

**additional comments**  
No

**access to tobacco products**

**problem definition**

No, for the following reasons: As regard to the partial acceptance, as in Ireland, the reduction of sales of the tobacco products has reached to 35%. The same situation will be also come up in the UK following the interim period up to 2013. As the argument for the protection of the younger persons is completely weak and without substance, take into consideration that the young are the minority and usual are accompanied with their parents. The matter that the view of the tobacco products will push the passengers to buy is without substance and will not influence the intention of the buyers. The argument of the competition against the internal market is not applicable and practically doesn't exist and the commission has accepted this idea. on the contrary it will minimize the competition between airports. Finally when the Display Ban will be applied, will influence the hole market of airport sales and following this approach, in the coming time it will shape a trend to avoid sales in the airport. In spite of all the above the new situation when it will come up in the market will negatively influence the economic benefits of the airports will consequence the deterioration and the arising difficulties in the operation of the airports.

**explanations**  
No change

**additional option**

If the tobacco Display Ban is adopted, first and or most would impede the competitiveness of the EU airports and significantly would reduce their profitability, while also decreasing the sales and thus the overall impact of the duty free business. Secondly if is not necessary to ban the display because there is no impulse buying tobacco in the duty free since tobacco products are mostly pre-planned by the passengers. As regard the protection of the minors is not a strong reason in order to prohibit the display of the tobacco products. Thirdly duty free and travel retail is a unique control sales channels and airport shops actually compete internationally with the airlines and that shops and other airports – not with internal market Finally, further restricting display will negatively impact in total commercial revenue as tobacco products is one of the key drivers of sales in airports duty free and travel retails.

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**NGO submission**

**identification**

**affiliation**

NGO

**name**

Hellenic Travel Trade Confederation - Dimitris A. Iliadis

**email**

Hellenic Republic

**additional comments**

No

**access to tobacco products****problem definition**

No, for the following reasons: As regard to the partial acceptance, as in Ireland, the reduction of sales of the tobacco products has reached to 35%. The same situation will be also come up in the UK following the interim period up to 2013. As the argument for the protection of the younger persons is completely weak and without substance, take into consideration that the young are the minority and usual are accompanied with their parents. The matter that the view of the tobacco products will push the passengers to buy is without substance and will not influence the intention of the buyers. The argument of the competition against the internal market is not applicable and practically doesn't exist and the commission has accepted this idea. on the contrary it will minimize the competition between airports. Finally when the Display Ban will be applied, will influence the hole market of airport sales and following this approach, in the coming time it will shape a trend to avoid sales in the airport. In spite of all the above the new situation when it will come up in the market will negatively influence the economic benefits of the airports will consequence the deterioration and the arising difficulties in the operation of the airports.

**explanations**

No change

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**NGO submission****identification****affiliation**

NGO

**name**

Schmidt Oliver

**email**

Germany

**additional comments**

No

**access to tobacco products**

**problem definition**

Die hier vorgeschlagenen Maßnahmen betreffen nicht das Funktionieren des europäischen Binnenmarktes, sondern sie sind alleine gesundheitspolitisch motiviert. Die Gesundheitspolitik fällt aber nicht in den Kompetenzbereich der EU und ist allein auf nationaler Ebene zu regeln. Es gibt in allen Ländern bereits regulierende Maßnahmen. Die einzelnen auf nationaler Ebene bereits bestehenden Restriktionen haben sich bewährt.

**explanations**

No change

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**NGO submission****identification****affiliation**

NGO

**name**

Angela Dorbert

**email**

Germany

**additional comments**

No

**access to tobacco products****problem definition**

-Bewusstsein ist schon verschärft und ändert nichts, wenn die Packungen versteckt im Laden liegen -Existenzen stehen im ganz großen Rahmen bedroht!! -Schmuggler werden mehr - Diskriminierung -Dorfläden gehen kaputt -Einheitssortiment wie zu DDR Zeiten --lächerlich!

**explanations**

No change

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**NGO submission****identification****affiliation**

NGO

**name**

Stefan Lundin, Swedish Hotel and Restaurant Association (SHR)

**email**

Sweden

**additional comments**

No

**explanations**

No change

**additional option**

SHR representing the hospitality sector and about 5 600 businesses in Sweden would like to reply to section 6 “Access to tobacco products” of the consultation on the possible revision of the Tobacco Products Directive. SHR supports activities to promote health and to prevent smoking-related diseases. However, when cross-border sales of tobacco is not involved, SHR is of the opinion that rules regarding “access to tobacco products” (e.g. automatic vending machines and display in retail outlets) should be decided at national level in accordance with the subsidiarity principle. As rules concerning access to “vending machines” and “display in retail outlets” do not have any impact on the functioning of the EU internal market, Member States should remain competent to adopt national measures. Furthermore, provisions set at national level can better take into account local conditions and needs rather than measures decided at EU level with a one-size-fits-all approach. In addition, SHR notes that an EU ban on tobacco vending machines would have a negative impact on the hospitality sector in Sweden and in those Member States where these devices are still available in hospitality venues. For these reasons SHR supports policy “Option 1 - No change”: “Member States remain competent to have national measures on limiting the access to tobacco Products”. This option would be the most effective, leaving each Member State to decide the appropriate policy to deal with the issue in proper consultation with relevant stakeholders at national level.

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**NGO submission**

**identification**

**affiliation**

NGO

**name**

ATRI Italian Travel retail Association

**email**

ITALY

**country**

48

**age**

male

**additional comments**

No

**access to tobacco products**

**problem definition**

The definition claims states that the UK has announced that will prohibit the display of tobacco products in large shops from October 2011 and from all other places from October 2013 in England, Wales and Northern Ireland. This is not entirely accurate. The UK has recognised the unique nature of the Duty free Industry and has distinguished the duty free industry from domestic retailers. by classifying them as "bulk tobacconist" The definition also states that a similar ban has been announced by Ireland . In fact the ban is not similar to that of the United Kingdom as it does not distinguish the duty free industry from domestic retailers . As a result the sales of duty free tobacco in Ireland have dropped by 35% this is compared to the domestic market where tobacco sales has remain relatively static.

**explanations**

No change

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**NGO submission**

**identification**

**affiliation**

NGO

**name**

Entrepreneurship Club

**email**

Greece

**additional comments**

No

**access to tobacco products**

**problem definition**

No comment

**explanations**

No change

---

**NGO submission**

**identification**

**affiliation**

NGO

**name**

FEDERATION OF ATTICA AND PIRAEUS INDUSTRIES

**email**

Greece

**additional comments**

No

**access to tobacco products****problem definition**

no comments

**explanations**

No change

**which one2**

no change

**additional option**

no change

---

**NGO submission****identification****affiliation**

NGO

**name**

René van der Steeg

**email**

lbt@eppa.nl

**country**

44

**age**

male

**additional comments**

No

**access to tobacco products****problem definition**

The description that in many Member States the sale of tobacco products via vending machines is prohibited is not a problem description. Even if from country to country, different requirements for the composition of the machines impede the cross-border trade with the machine for reasons of youth protection, a ban on the operation of machines would withdraw the basis of the Community-wide trade of products via vending machines, thus affects it and does not make it easier. We believe that both the display ban as well as the ban on vending machines will meet with the most concern in view to all three levels of Article 5, Lisbon Treaty (the principle of conferral, subsidiarity and proportionality principle).

**explanations**

No change

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**NGO submission****identification****affiliation**

NGO

**name**

René van der Steeg

**email**

NL

**country**

44

**age**

male

**additional comments**

No

**access to tobacco products****problem definition**

The description that in many Member States the sale of tobacco products via vending machines is prohibited is not a problem description. Even if from country to country, different requirements for the composition of the machines impede the cross-border trade with the machine for reasons of youth protection, a ban on the operation of machines would withdraw the basis of the Community-wide trade of products via vending machines, thus affects it and does not make it easier. We believe that both the display ban as well as the ban on vending machines will meet with the most concern in view to all three levels of Article 5, Lisbon Treaty (the principle of conferral, subsidiarity and proportionality principle).

**explanations**

No change

---

**NGO submission****identification****affiliation**

NGO

**name**

German Airports Association (ADV)



**email**

Germany

**additional comments**

No

**explanations**

No change

---

**NGO submission****identification****affiliation**

NGO

**name**

Dietmar Franz

**email**

Deutschland

**additional comments**

No

**access to tobacco products****problem definition**

Ich habe für die geplanten Änderungen der Tabakprodukttrichtlinie keinerlei Verständnis

**explanations**

No change

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**NGO submission****identification****affiliation**

NGO

**name**

Karin Erpenbach

**email**

Deutschland

**country**

54

**additional comments**

No

**access to tobacco products**

**problem definition**

Es geht hierbei um die Sicherung der Arbeitsplätze aller Mitarbeiter im Bereich Tabak Groß- und Einzelhandel

**explanations**

No change

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**NGO submission**

**identification**

**affiliation**

NGO

**name**

Chariskos Georgios

**email**

Germany

**country**

44

**age**

male

**additional comments**

No

**access to tobacco products**

**problem definition**

Tabakwaren sind ein legales genussmittel, dessen konsum - genau wie alkohol und süsigkeiten- mit gesundheitlichen risiken verbunden ist. dennoch handelt es sich um ein legales produkt. Mit den hier vorgeschlagenen maßnahmen werden grundrechte eingeschränkt. Dies steht nicht im verhältnis zu den tatsächlichen risiken.

**explanations**

No change

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**NGO submission**

**identification**

**affiliation**

NGO

**name**

Scandlines Catering GmbH

**email**

Germany

**additional comments**

Yes

**explanations**

No change

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**NGO submission****identification****affiliation**

NGO

**name**

Hans Jürgen Meinel

**email**

Deutschland

**additional comments**

No

**access to tobacco products****problem definition**

Die einzelnen auf nationaler Ebene bereits bestehenden Restriktionen haben sich bewährt. Wenn man weitere Verbesserungen einzelner Restriktionen auf nationaler Ebene verfolgt, so führt dies zu einer erhöhten Akzeptanz der Regelungen bei den Bürgern. Die EU sollte sich nicht als Superbürokratie aufspielen, die die kleinsten Lebensgewohnheiten aller Menschen vereinheitlichend vorschreibt. Dadurch wird die EU Frust geschaffen! Wen wundert, dass Europas Bürger nichts mehr mit der EU anfangen können.

**explanations**

No change

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**NGO submission****identification****affiliation**

NGO

**name**

Chris Christodoulou, President of AmCham Cyprus (Cyprus-American Business Association)

**email**  
Cyprus

**additional comments**  
No

**access to tobacco products**  
**problem definition**

We have not seen enough evidence that proves that the ban on the display of tobacco products reduces smoking prevalence. However, we have seen that the measure as applied in Ireland and Iceland has created a number of problems to retailers.

**explanations**  
No change

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**NGO submission**

**identification**  
**affiliation**  
NGO

**name**  
Perkim Nielsen Danish Cancer Society

**email**  
Denmark

**country**  
54

**age**  
male

**additional comments**  
Yes

**explanations**  
Ban

**which supply and access**  
Cross-border retail sales of tobacco to be banned over the Internet; Vending machines to be banned; Promotion and displays in retail stores to be banned

**which one2**  
Absolutely option 3, with the addition all digital media, e.g. mobile phones.

**additional option**

We agree to the problem definition, but it should be remembered that sales and advertising may take place in many kinds of digital media, like e.g. mobile phones.

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**NGO submission**

**identification**

**affiliation**

NGO

**name**

Kirsten Götz

**email**

Deutschland

**country**

45

**additional comments**

Yes

**explanations**

No change

---

**NGO submission**

**identification**

**affiliation**

NGO

**name**

CYPRUS COMMUNICATION AGENCIES ASSOCIATION

**email**

CYPRUS

**additional comments**

Yes

**explanations**

No change

---

**NGO submission**

**identification**

**affiliation**

NGO

**name**

πανελλήνια ομοσπονδία εστιατορικών & συναφών επαγγελματιών

**email**

hellas

**additional comments**

No

**access to tobacco products****problem definition**

κανένα σχόλιο

**explanations**

No change

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**NGO submission****identification****affiliation**

NGO

**name**

Michaela Warcaba

**email**

Deutschland

**country**

43

**age**

male

**additional comments**

No

**access to tobacco products****problem definition**

Es gibt keine Probleme mit der Produktpräsentation. Es handelt sich nur um legale Produkte.

**explanations**

No change

**additional option**

Der Verbraucher findet schlecht seine bevorzugte Marke. Der illegale Handel wird vereinfacht. Finanzielle Folgen für Wirtschaft und Staat.

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**NGO submission**

**identification**

**affiliation**

NGO

**name**

BOVAG

**email**

Nederland

**country**

33

**age**

male

**additional comments**

Yes

**explanations**

Ban

**which supply and access**

Cross-border retail sales of tobacco to be banned over the Internet

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**NGO submission**

**identification**

**affiliation**

NGO

**name**

Aleksandra Kreft

**email**

Poland

**country**

25

**age**

female

**additional comments**

No

**access to tobacco products****problem definition**

Tabakwaren sind ein legales Genußmittel, dessen Konsum genauso wie ALKOHOL, SÜßIGKEITEN, FASTFOOD UND VIELES MEHR mit gesundheitlichen Risiken verbunden ist... Dennoch handelt es sich um legale Produkte. Pläne der Europäischen Kommission zur Abschaffung der Automaten schränken die Bezugsmöglichkeiten ein aber es dient dem Jugendschutz nicht. Schon alleine die Abschaffung der Automaten ist schwachsinn da diese eigentlich einer der sichersten Beschaffungsmaßnahmen sind durch die geregelten Zugangskontrollen. Wo steht das die Existenz der Automaten den Einfluss auf das Rauchverhalten der Jugendlichen beeinflusst. Die Kriminalität wird dadurch nur noch erhöht wenn legale Verkaufsstellen verschwinden.

**explanations**

No change

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**NGO submission****identification****affiliation**

NGO

**name**

Wachtler Rudolf

**email**

Österreich 8940 Liezen Hauptplatz 8

**additional comments**

Yes

**explanations**

No change

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**NGO submission****identification****affiliation**

NGO

**name**

Cyprus Employers and Industrialists Federation (OEB)

**email**



Cyprus

**additional comments**

No

**access to tobacco products**

**problem definition**

Το μέτρο της απαγόρευσης έκθεσης προϊόντων καπνού στα σημεία πώλησης θα προκαλέσει σοβαρά προβλήματα στο λιανεμπόριο. Γνωρίζουμε ότι το μέτρο αυτό έχει εφαρμοστεί στην Ιρλανδία και την Ισλανδία. Ωστόσο, βάσει των στοιχείων που έχουμε υπόψη μας, το μέτρο αυτό δεν έχει ωφελήσει τη δημόσια υγεία. Αντίθετα έχει προκαλέσει προβλήματα στη λειτουργία της νόμιμης αγοράς.

**explanations**

No change

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**NGO submission**

**identification**

**affiliation**

NGO

**name**

Cyprus Employers and Industrialists Federation (OEB)

**email**

Cyprus

**additional comments**

Yes

**explanations**

No change

**which one2**

Πιστεύουμε ότι η διεύρυνση του πεδίου εφαρμογής της Οδηγίας προκειμένου να συμπεριλαμβάνει και προϊόντα όπως είναι τα 'φυτικά' (herbal) τσιγάρα είναι εύλογη δεδομένου ότι ομοειδή προϊόντα πρέπει να ρυθμίζονται κατά τον ίδιο τρόπο έτσι ώστε να μην δημιουργούνται συνθήκες αθέμιτου ανταγωνισμού. Ωστόσο, η απαγόρευση κάποιων προϊόντων καπνού χωρίς καμία επιστημονική τεκμηρίωση είναι λανθασμένη. Κατά συνέπεια τασσόμαστε εναντίον της διεύρυνσης του πεδίου εφαρμογής της Οδηγίας.

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**NGO submission**

**identification**

**affiliation**

NGO

**name**

Asociación Española de Travel Retail (AETRE)

**email**

España

**additional comments**

No

**access to tobacco products****problem definition**

The definition claims states that the United Kingdom has announced that it will prohibit the display of tobacco products in large shops from October 2011 and from all other places from October 2013 in England, Wales and Northern Ireland. This is not entirely accurate. The UK has recognised the unique nature of the duty free industry and has distinguished duty free retailers from domestic retailers by classifying them as 'bulk tobacconists'. • The definition also states that a similar ban has been announced by Ireland. In fact, the ban is not similar to that of the United Kingdom as it does not distinguish the duty-free industry from domestic retailers. As a result the sales of duty-free tobacco in Ireland have dropped by 35%, this is compared to the domestic market where tobacco sales have remained relatively static

**explanations**

No change

**which one2**

Due to the unique market they serve, airport duty free and travel retail shops would be disproportionately affected by a tobacco product display ban. • In most jurisdictions where a tobacco display ban has been introduced, the government has accepted some sort of derogation for airports. • Displays inform the consumer of the products available, their prices, the pack sizes available and their characteristics. • Because of the international nature of airport retailing, a large number of brands are sold, many of which are not available in the domestic market. • Language barriers are a major factor for international travellers who may not speak the language of the airport he or she is passing through. • Maintaining the display of tobacco products at the point of sale is essential for efficient retailing given the high turnover and value of the product. • A display ban will negatively impact total commercial revenue as tobacco is one of the key drivers of sales in duty free and travel retail shops

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**NGO submission****identification****affiliation**

NGO

**name**

Proedros INKA

**email**

GREECE

**country**

56

**age**

male

**additional comments**

No

**access to tobacco products**

**problem definition**

No comment

**explanations**

No change

---

**NGO submission**

**identification**

**affiliation**

NGO

**name**

Armin Ptaszynski

**email**

Deutschland

**country**

46

**age**

male

**additional comments**

Yes

**explanations**

No change

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**NGO submission**

**identification**

**affiliation**

NGO

**name**

vbw Vereinigung der Bayerischen Wirtschaft e. V., München

**email**

Germany

**additional comments**

No

**access to tobacco products****problem definition**

Die Problemdefinition ist in Bezug auf Zigarettenautomaten und Produktpräsentation am Verkaufsort unklar. Bisher gibt es keine wissenschaftlichen Nachweise, dass diese Maßnahmen zu der erhofften Reduzierung des Konsums führen. Zu berücksichtigen ist die Existenzbedrohung vieler Automatenaufsteller und Tabakwareneinzelhändler. In Deutschland existieren technische Lösungen, um den Verkauf von Tabakwaren an Jugendliche zu unterbinden.

**explanations**

No change

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**NGO submission****identification****affiliation**

NGO

**name**

Jörg Bähr

**email**

Germany

**country**

42

**age**

male

**additional comments**

No

**access to tobacco products****problem definition**

Kein Kommentar

**explanations**

No change

**which one2**

Kein Kommentar

**additional option**

Kein Kommentar

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**NGO submission**

**identification**

**affiliation**

NGO

**name**

dagbladhandel DE VALK

**email**

Belgium

**additional comments**

No

**access to tobacco products**

**problem definition**

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**explanations**

No change

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**NGO submission**

**identification**

**affiliation**

NGO

**name**

Estonian Traders' Association

**email**

Estonia

**additional comments**

No

**access to tobacco products**

**problem definition**

Eesti Kaupmeeste Liit on alates 1996 aastast koondanud enda juurde Eestis tegutsevaid jae- ja hulgimüügiettevõtteid. Meie liikmeskonda kuuluvad ettevõtted opereerivad Eestis kokku 46 kaubandusüksusega. Kaupmeeste esindusorganisatsioonina jälgime me tähelepanelikult kauplemist ja levinumaid tooteid puudutavaid regulatsioone. Alates 2004. aastast puudutab see ka Euroopa Liidu tasandil toimuvaid protsesse. Euroopa Komisjon on välja pakkunud võimaluse piirata või keelustada tubakatoodete väljapanek müügikohas. Välja pakutud alternatiivi „3C“ puhul oleks igasugune tubakatoodete väljapanek müügikohtades keelatud. Selline lähenemine tooks kaupmeestele kaasa väga suure investeeringukohustuse, kuna olemasolevate tubakatoodete avatud riulite asemele oleksid kaupmehed sunnitud paigaldama uued, kinnised riulid. Kui tuleks muuta ka riulite asukohta (ja tõenäoliselt saaks see nii ka olema), tähendaks see kaupmeestele vajadust ka kaupluse ruumipaigutus ümber teha. Lähtudes Iirimaa kolleegide kogemusest ja ka praegu kasutuses olevate riulite maksumusest, võib oletada, et väiksemate kaupluste puhul ulatuks vajaminev investeering 1 500 – 3 000 euroni, mida on ilmselgelt liiga palju. Väiksemad kauplused, mis asuvad vaesemates ja kaugemates piirkondades ja mille müügikäibed on seetõttu väga väikesed, ei ole suutelised selliseid investeeringuid tegema ja peaksid reeglitega vastuolluminekku vältimiseks ukseid sulgema Ettepanek seadusloomeks, mis toob kaupmeestele seesugust märkimisväärset kahju, peaks olema varustatud piisava hulga toetavate argumentidega, mis näitaksid ettepanekust tulenevat potentsiaalset kasu. Antud juhul peaks kasu tulema rahvastiku paremast tervisekäitumisest ja suitsetamise vähenemisest. Praeguse seisuga ei ole me näinud piisavat tõenditepagasit, mis sellise positiivse mõju olemasolu ja võimalikku suurust kinnitaksid. Samuti ei ole Komisjon oma probleempüstituses sellele, kaupmehi väga valusalt puudutavale küsimusele, laiemat tähelepanu pööranud. Enne kui saaksime teha täiendavaid kommentaare, sooviksime Komisjonilt saada rohkemat infot meetme positiivsete mõjude kohta. Hetkel olemasolev puudutab vaid asjaolu, et Ühendkuningriik, Iirimaa ja Soome kavatsevad nimetatud meedet rakendada. Neist faktidest üksi ei piisa, et sõnastada eksisteeriv ja valus probleem ning kaugeltki ei piisa sellisest probleempüstitusest selleks, et kehtestada juba ainuüksi meie väikeses riigis miljonitesse eurodesse ulatuvaid investeeringuid nõudev, väga kitsendav ja põhjendamatu piirang. Jääme lootma, et arutelud keskenduvad meetmetele, millel on ka tegelik positiivne mõju rahva tervisele ja mis ei too kaasa kaupmeestele katastroofilisi tagajärgi.

#### **explanations**

No change

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#### **NGO submission**

##### **identification**

##### **affiliation**

NGO

##### **name**

Jan Burkhardt

##### **email**

deutschland

##### **additional comments**

Yes

**explanations**

No change

---

**NGO submission**

**identification**

**affiliation**

NGO

**name**

Association of Lithuanian trade enterprises

**email**

Lithuania

**additional comments**

No

**access to tobacco products**

**problem definition**

Definition of problem is not clear, because retail sales has no impact for functioning internal market. Legislation of banning displays will cause additional costs for retailers and will hinder the trade. National states is the best for regulating retail market according to local conditions. Displays should'nt be regulated by EU level of legislation.

**explanations**

No change

**additional option**

Consumer should be informed about products which they could purchase and after all – choose them by themselves. There is no evidence that a ban on product display would reduce smoking prevalence or restrict youth access to tobacco products, but creates additional burden for bussines especially for small and medium sized enterprises. What is more, this regulation is likely to increase illegal market of cigarettes, which in Lithuania is already 40 percent.

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**NGO submission**

**identification**

**affiliation**

NGO

**name**

ERMURI Einkaufsverband eG Am Brommerfeld 11 D - 32758 Detmold

**email**

Germany

**additional comments**

No

**explanations**

No change

**which one2**

Option 2 b ist empfehlenswert. Grundsätzlich müssen jedoch legale Produkte über jeden Vertriebsweg erhältlich sein, sofern nicht tabaksteuerrechtliche Gründe dieses ausschließen.

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**NGO submission**

**identification**

**affiliation**

NGO

**name**

Latvian Traders Association

**email**

Latvia

**additional comments**

No

**access to tobacco products**

**problem definition**

LTA nav vienisprātis ar Komisijas doto problēmas raksturojumu attiecībā uz tabakas produktu pieejamību. Attiecībā uz produktu izvietošānu tirdzniecības vietā problēmas definējums nav skaidrs – vai runa ir par barjerām tirdzniecībā starp ES dalībvalstīm vai kādu citu šī jautājuma aspektu.

**explanations**

No change

**additional option**

LTA vēlas norādīt, ka aizliegums izvietot tabakas izstrādājumus tirdzniecības vietās rada apgrūtinājumus ES iekšējā tirgus funkcionēšanai, kavējot jaunu dalībnieku ienākšanu tirgū un patērētāju iepazīstināšanu ar jauniem produktiem, kuru starpā agrāk vai vēlāk var parādīties arī tādi ar samazinātu risku veselībai. Šodien pircējs identificē un izvēlas tabakas izstrādājumu, vadoties pēc informācijas uz tā iepakojuma. Ja prece nav izstādīta redzami, ir praktiski neiespējami nokomunicēt pircējam informāciju par līdz šim nepazīstama produkta parādīšanos. Aizliegums izvietot tabakas izstrādājumus tirdzniecības vietās būtu nopietns apgrūtinājums mazumtirgotājiem, gan no izmaksu viedokļa (tirdzniecības aprīkojuma nomaiņa), gan no pircēju apkalpošanas perspektīvas, kas kļūtu ievērojami laikietilpīgāka, prasītu lielāku darbaspēka kvalifikāciju un tāpēc sadārdzinātu veikala izmaksas. Būtisks



jautājums, par ko Komisija konsultāciju dokumenta ietvaros nemin ne vārda, ir šī risinājuma ietekme uz smēķēšanas mazināšanu. Dati no valstīm, kur spēkā ir šāds aizliegums, neļauj izdarīt pārlicecinošus secinājumus par tā pozitīvu ietekmi uz smēķētāju skaita mazināšanu. Vienlaikus LTA pauž bažas, ka šāds risinājums varētu ietekmēt situāciju ar tabakas izstrādājumu nelegālu tirdzniecību – neredzot legālo produktu veikala plauktos pēc laika patērētājs nebūs spējīgs atšķirt īstu preci un būs viegls mērķis kontrabandas darboņiem.

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## **NGO submission**

### **identification**

#### **affiliation**

NGO

#### **name**

the Norwegian Cancer Society

#### **email**

Marianne.van.der.wel@kreftforeningen.no

#### **country**

Norway

### **additional comments**

EU legislation often affects Norwegian legislation. As an NGO in a non-member country, our interests are in the possible effects and consequences changes in the Tobacco Product Directive may have on Norwegian legislation. All tobacco products entail health risks. We endorse that new tobacco products and novel forms of oral tobacco would be banned similar to snus.

### **additional comments**

We strongly encourage that the prohibition on the marketing on tobacco for oral use (snus) remains. Experiences from Norway show that the use of oral tobacco in many cases encourages combined usage (both cigarettes and oral tobacco). snus is increasingly popular among young people and has over the last years contributed to an increase in recruitment of new tobacco users among secondary and high school students.

### **additional comments**

We endorse the introduction of mandatory pictorial health warnings on all tobacco products including snus, in combination with standardized packaging (e.g. the prohibition of the use of logos, colours, brand images or promotional information on the packaging of tobacco products). The Norwegian Cancer Society advocates a re-introduction of cancer-warnings on snus. Snus is carcinogenic, and increases the risk of developing pancreas cancer and cancer in oesophagus. Information on telephone services to help quit smoking should be placed on the package of all tobacco products.

### **additional comments**

We endorse the establishment of a common list of ingredients in tobacco products. Furthermore, we support a regulation of adding flavorings to tobacco products, which

enhance their attractiveness, especially to younger people.

**additional comments**

We would strongly encourage banning vending machines and a ban of tobacco displays. Norway implemented a ban on tobacco displays in stores 1.1.2010. The desired effects were a decrease in recruitment among young people and an increase in the quit-rate among smokers. The decision was made in March 2009 and during the following 8 months the involved stakeholders prepared the implementation. In 2009 over 60% supported the ban.

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