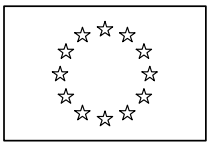

EUROPEAN COMMISSION
HEALTH AND CONSUMERS DIRECTORATE-GENERAL

Directorate C – Public Health and Risk Assessment

POSSIBLE REVISION OF THE TOBACCO PRODUCTS DIRECTIVE 2001/37/EC

PUBLIC CONSULTATION DOCUMENT

DG SANCO

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I. INTRODUCTION

The present Tobacco Products Directive[1] has the objectives of facilitating the functioning of the internal market in the tobacco products sector while ensuring a high level of protection to public health.
It mainly covers:

- the maximum content of tar (10 mg), nicotine (1 mg) and carbon monoxide (10 mg) per cigarette [2]
- the health warnings and other labelling requirements
- reporting on the tobacco ingredients by the industry to the authorities
- ban on misleading texts, names or signs in tobacco packages
- ban on oral tobacco.

The tar, nicotine and carbon monoxide yields per cigarette must be printed on one side of the cigarette packet in the official language or languages of the Member State where the product is placed on the market, so that at least 10 % of the corresponding surface is covered.[3]

All tobacco products should also bear compulsory text warnings on the harmful effects of the consumption of tobacco products on the packages. [4]

Text warnings may be combined with pictures. It is optional for Member States to make picture warnings compulsory in tobacco packages.[5] Currently, four Member States (Belgium, Romania, The United Kingdom and Latvia) have made picture warnings compulsory. Two Member States plan to do so as of 2011(Spain and France).

Manufacturers must communicate on a yearly basis to the Member States a list of all tobacco ingredients, together with available toxicological data. The Directive does not foresee any specific assessment of the information provided by manufacturers. The objective is to ensure that consumers have access to data on ingredients. [6]

Member States may ban the use of ingredients which have the effect of increasing the addictive properties of tobacco products.[7]

Oral tobacco ("snus") is prohibited in the EU, except in Sweden that obtained derogation in its Accession Treaty.[8] The derogation was granted on condition that Sweden shall take all measures necessary to ensure that oral tobacco is not placed on the market in the Member States for which the Tobacco Products Directive is applicable.

The Directive includes the so-called "free movement clause". Member States may not ban or restrict the imports on their markets of tobacco products that comply with the Directive.[9]

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[1] Directive 2001/37/EC of the European Parliament and of the Council of 5 June 2001 on the approximation of the laws, regulations and administrative provisions of the Member States concerning the manufacture, presentation and sale of tobacco products - Commission statement (OJ L 194, 18.7.2001, p. 26–35).
[2] Article 3
[3] Article 4
[4] Article 5
[5] Article 5(3); Commission Decision 2003/641/EC
[6] Article 6
[7] Article 13(3)
[8] Act of Accession of Austria, Finland and Sweden, Annex XV…
[9] Article 13(1)

However, Member States may apply more stringent rules in order to protect public health, insofar as such rules do not prejudice the rules laid down in the Directive.[10]

The Tobacco Products Directive dates from 2001. New international, scientific and market developments require reflecting whether the Directive still fully guarantees an appropriate functioning of the internal market while ensuring a high level of health protection.

This consultation is based on existing knowledge and aims at providing an early opportunity for all stakeholders to input on the possible need to revise the Directive and on the different policy options that such revision might involve.

At the present stage, the Union competence to adopt the different options, their implications on the functioning of the internal market and their proportionality have not yet been fully examined. These issues will be analysed at a later stage when the problems and the policy options are developed further.

[10] Article 13(2)

II AREAS OF POSSIBLE CHANGE

1. SCOPE OF THE DIRECTIVE

1.1. Problem definition

Since the adoption of the Directive in 2001, the tobacco products market has increasingly diversified.

The Directive does not cover electronic nicotine delivery systems (ENDS), such as electronic cigarettes. Yet they are generally marketed as alternatives to smoking.

Some Member States classify electronic cigarettes that contain nicotine as pharmaceutical products. This means they cannot be put on the market unless they have proven efficacy, safety and quality. However, in many Member States electronic cigarettes (with and without nicotine) are marketed as consumer products with no prior authorisation or safety checks. This results in a legal uncertainty.

In addition, nicotine drinks are in the market in some Member States, and are likely to enter other Member States' markets. There is also an emerging market of nicotine sweets world wide. However, by definition these products are covered by food legislation.[11]

Furthermore, the Directive does not cover cigarette-like products which do not contain tobacco, such as herbal cigarettes, that have similar harmful effects as regular cigarettes.

The legislation of Member States to classify or regulate these products varies. There are no uniform conditions for regulating ENDS and herbal cigarettes. This might imply both a distortion of the internal market and a failure to ensure a high level of health protection in the EU.

1.2. Possible options

Option 1 - No change

Tobacco and nicotine products that are not covered by the Tobacco Products Directive, or other EU legislation (food, pharmaceutical) would remain subject to different legislations in different Member States. The same would be true for products that are smoked, but do not fall under any of the above legislations (such as herbal cigarettes).

Option 2 - Extend of the scope of the Directive

An extension of the scope of the Directive could be envisaged to include novel forms of oral tobacco, herbal cigarettes, and electronic nicotine delivery systems, insofar as they are not already covered by other EU legislation (food, pharmaceutical). Specific safety and quality requirements would be developed for ENDS.

[11] Regulation 178/2002/EC and The Novel Foods Regulation (258/97)

For cigarette-like products (herbal cigarettes), appropriate indications of contents and health warnings would be required.

New tobacco products would bear harmonised information on harmful substances in the product and health warnings. Member States would require manufacturers and importers to inform competent authorities about all ingredients used in the manufacture of a product.

Novel forms of oral tobacco would be banned similarly to snus.

1.3 Questions

1) **Do you agree with the problem definition? If not, please provide explanations.**
2) **In your view, which option addresses the problem most effectively?**
3) **Do you recommend any additional option that would effectively address the problem?**

2. SMOKELESS TOBACCO PRODUCTS

2.1. Problem definition

The current regulatory framework bans some smokeless tobacco products ("snus") while others (e.g. chewing tobacco) are freely available in many Member States.

All smokeless tobacco products are addictive and can cause cancer. They also increase the risk of death after a myocardial infarction and may have additional cardiovascular effects as stated in the Opinion of the Scientific Committee on Emerging and Newly Identified Health Risks (SCENIHR) of February 2008[12].

For an individual, substitution of smoking by the use of smokeless tobacco products would probably decrease the incidence of some tobacco-related diseases. It has also been proposed that the use of these products could be a way to quit smoking, but at this moment there is not enough scientific evidence available on the efficacy of snus as quitting aid. On the contrary, as all tobacco products, snus causes dependence and according to the evidence from some countries, the use of smokeless tobacco products may lead to subsequent cigarette smoking.

2.2. Possible options

Option 1 - No change

The prohibition on the marketing of tobacco for oral use ("snus") remains unchanged. Other smokeless tobacco products that are perceived as marginal products can continue to be marketed in all Member States.

[12] The SCENIHR Opinion can be found here:
http://ec.europa.eu/health/archive/ph_risk/committees/04_scenihr/docs/scenihr_o_013.pdf

Option 2 - Lifting the ban on snus

All types of smokeless tobacco products would be freely marketed in the EU, subject to possible requirements for appropriate consumer information such as health warnings.

Option 3 - Ban on all types of smokeless tobacco products

The ban on "snus" would be extended to all types of smokeless tobacco products.

2.3 Questions

1) **Is the problem definition correct? If not, please provide your comments and supporting evidence.**
2) **In your view, which option addresses the problem most effectively?**
3) **Do you recommend any additional option that would effectively address the problem?**

3. CONSUMER INFORMATION

3.1 Problem definition

Currently the use of pictorial warnings by Member States is limited. It does not cover all tobacco products and their visibility is limited. Currently, combined warnings shall cover not less than 40 % of the back side of the package[13]. 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.

The current situation, whereby some Member States have made such warnings compulsory and others not, has lead to a disparity in labelling throughout the EU and has an impact on the functioning of the internal market as well as in consumers' awareness and consequently, the impact in their smoking behaviour.

Packaging as an advertising tool is not covered by the current Directive. Tobacco packaging and product features are increasingly used to attract consumers, to promote products and brand image.

According to a recent Eurobarometer, published in May 2010[14], light coloured packages are perceived to deliver lower amounts of tar, have a smoother taste and, in some cases, to be less risky for the health of consumers.

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[13] 2003/641/EC: Commission Decision of 5 September 2003 on the use of colour photographs or other illustrations as health warnings on tobacco packages
http://eur-lex.europa.eu/smartapi/cgi/sga_doc?smartapi!celexapi!prod!CELEXnumdoc&lg=EN&numdoc=32003D0641&model=guichett

[14] Results of the survey can be found here: http://ec.europa.eu/health/tobacco/docs/ebs332_en.pdf

Several other elements of the current package design e.g. graphic illustrations generating evocative images such as luxury, freedom and glamour, often distract consumers from the health warnings.

The current requirement of putting on the cigarette packages the measured levels on tar, nicotine and carbon monoxide yields has shown to be misleading for consumers because they might think that lower levels indicate that a product is less risky to their health. Some consumers might even decide to smoke or increase their consumption of cigarettes with lower levels of tar, nicotine and carbon monoxide in preference to quitting.

The Directive does not explicitly regulate labelling of water pipes. There is a widespread belief among consumers that use of water pipe is a relatively safe practice but recent studies have shown that it is not a safe alternative to cigarette smoking.

3.2. Possible options

Option 1 - No change

Pictorial warnings remain optional in the Member States. Different labelling patterns in the Member States will continue to exist. Water pipes remain without health warnings.

Option 2 - Improve consumer information

Option 2 a - **Picture warnings** would become mandatory in all Member States. They would be enlarged; required on both sides of the package and placed towards the top of the pack.

Option 2b - **Information on the levels of tar, nicotine and carbon monoxide (TNCO)** measured by machine in cigarette yields, would be replaced with general information on harmful substances in tobacco products and in particular in their burnt forms. Also, information on a telephone service to help quit smoking would be placed on the package.

Option 2c - **Information on harmful substances in tobacco products** that cannot be placed on the package would be placed inside the package. These inserts would also include more detailed information on health effects of tobacco consumption and provide information on how to quit smoking.

Option 2d - **Health warnings would be placed on water pipes**.

Option 3 - Introduce generic or plain packaging

Plain or generic packaging would standardise the appearance of tobacco packaging. Manufacturers would only be allowed to print brand and product names, the quantity of the product, health warnings and other mandatory information such as security markings. The package itself would be plain coloured (such as white, grey or plain cardboard). The size and shape of the package could also be regulated.

3.3 Questions

1) **Do you agree with the problem definition? If not, please provide explanations**
2) **In your view, which option addresses the problem most effectively?**
3) **Do you recommend any additional option that would effectively address the problem?**

4. REPORTING AND REGISTRATION OF INGREDIENTS

4.1. Problem definition

The formats and reporting mechanisms for submitting data on tobacco products ingredients vary between and even within Member States. Therefore, authorities find it difficult to compare and analyse the data. Also, manufacturers and importers may have difficulties to provide requested information using different reporting formats, implying an even heavier burden on smaller manufacturers.

Manufacturers have concerns about their trade secrets. The level of industry compliance with the data reporting requirements varies.

Collection and analysis on the reported data on ingredients requires substantial resources for national competent authorities. It has proven difficult to get financing for the development, validation and carrying out of the appropriate toxicological and addictiveness tests.

4. 2. Possible options

Option 1 - No change

Information on ingredients will be submitted by tobacco industry using different formats in different Member States.

Option 2 - Establish a common compulsory reporting format

Tobacco industry would be obliged to use one harmonised reporting format, ideally combined with the electronic submission of data. This could be based on the voluntary reporting format developed by the Commission in May 2007 on how industry could report to Member States.[15]

Option 3 - Introduce fees and sanctions

There would be 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.

Effective, proportionate and dissuasive penalties applicable in case of non-compliance with the delivery of data on tobacco products ingredients would be required.

[15]Practical guide can be found here:
http://ec.europa.eu/health/ph_determinants/life_style/Tobacco/Documents/practical_guidance_en.pdf

4.3 Questions

1) **Do you agree with the problem definition? If not, please provide explanations**

2) **In your view, which option addresses the problem while supporting the objectives of the directive most effectively?**

3) **Do you recommend any additional option that would effectively address the problem?**

5. REGULATION OF INGREDIENTS

5.1. Problem definition

Attractive substances are added into tobacco products such as liquorice to increase the smoothness of the smoke and menthol to enable deeper inhalation. During the process of burning majority of additives form substances that are carcinogenic, mutagenic and/or toxic for reproduction.
There are no common conditions for the internal market ensuring a uniform high level of health protection. Some Member States allow a number of listed ingredients (so-called positive list) while some others have banned certain ingredients (so-called negative list). Some other Member States have both negative and positive lists. The existence of different positive lists in some Member States and negative lists in others lead to the authorisation of different ingredients used in the manufacturing of tobacco products. As a result substances that can be used in one Member State may not be used in another.

5. 2. Possible options

Option 1 - No Change

Member States continue to be free in regulating tobacco products ingredients.[16] Industry has to comply with different national regulations on positive and/or negative lists of ingredients for the manufacturing of tobacco products.

Option 2 - Introducing the basic criteria on the EU level without a common list

The Directive would lay down the basic criteria to be used by the Member States for restricting or prohibiting the use of certain ingredients in the manufacturing of tobacco products. The criteria may be related to toxicity, the attractiveness and the addictiveness of a product when consumed (oral tobacco) or smoked (the combustion/inhalation effect).

Member States would retain the right to have national bans according to national circumstances in so far as this would be deemed necessary and proportionate to protect public health.

[16] Article 13(3) of the Tobacco Products Directive (2001/37/EC).

Option 3 - Establish a common list of tobacco ingredients

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).

Option 3a – Establish a positive common list of tobacco products ingredients

Only those ingredients that are on the list can be used for the manufacturing of tobacco products.

Option 3b - Establish a negative common list of tobacco ingredients

Listed ingredients cannot be used in the manufacturing of tobacco products (except subject to restrictions and conditions laid down).

5.3 Questions

1) **Do you agree with the problem definition? If not, please provide explanations**

2) **In your view, which option addresses the problem most effectively?**

3) **Do you recommend any additional option that would effectively address the problem?**

6. ACCESS TO TOBACCO PRODUCTS

6.1. Problem definition

The cross-border sale of tobacco products (via the **Internet**) potentially undermines national tobacco control efforts, in particular the enforcement of the minimum purchasing age as well as the collection of tax revenues. Products sold on the Internet do not always bear health warnings or text warnings are not in the official language(s) of the Member State of the citizen ordering via the Internet. In order to address this compliance issue with legal conditions (e.g. purchasing age, labelling, tax collection), some Member States have either banned or restricted distance sale of tobacco products.

Vending machines are banned in a large number of Member States.

The UK 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. In Finland it will be prohibited to display tobacco in points of sale as from the beginning of 2012. A similar ban has been announced by Ireland.

6.2. Possible changes

Option 1 - No change

Member States remain competent to have national measures on limiting the access to tobacco products.

Option 2 – Controlled supply and access

Option 2a - Age verification of buyers and other legal conditions (registration, licensing etc.) would be set for cross-border retail sales of tobacco products.

Option 2b - Access to vending machines would be restricted to adults.

Option 2c - Tobacco display and promotion at points of sales would be restricted (e.g. allowing visibility for one package per brand).

Option 3 – Ban

Option 3a - Cross-border retail sales of tobacco products would be banned over the Internet. This might also include ban for postal delivery of tobacco to consumers.

Option 3b - Vending machines would be banned in all Member States.

Option 3c - Promotions and displays in retail stores would be banned in all Member States.

6.3 Questions

1. **Do you agree with the problem definition? If not, please provide explanations**
2. **In your view, which option addresses the problem most effectively?**
3. **Do you recommend any additional option that would effectively address the problem?**