Assessing the Impacts of Revising the Tobacco Products Directive

Study to support a DG SANCO Impact Assessment

Final report

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TR- 823-EC

September 2010

Prepared for the European Commission
Directorate-General for Health and Consumer Protection

EUROPE

Preface

The European Commission Health and Consumer Directorate-General (DG SANCO) commissioned RAND Europe to provide support in assessing the impacts of revising the Tobacco Products Directive 2001/37/EC.

The research conducted by RAND Europe examines the evidence available for the key health, social and economic impacts that could be expected from the implementation of five policy options currently considered by DG SANCO for the revision of the Tobacco Products Directive 2001/37/EC. This research used a variety of qualitative and quantitative methods to assess the economic and health effects of future regulation, including rapid evidence reviews and econometric and health-economic modelling techniques.

This report will serve as an input to DG SANCO's own regulatory impact assessment exercise, which is a mandatory part of the legislative process in the European Union (EU), but the report also provides an up-to-date overview of the evidence and basis for current tobacco product regulation that may be of interest to a wider audience interested in tobacco control policies.

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List of acronyms and abbreviations

BAT	British American Tobacco
CMR	additive that is carcinogenic, mutagenic or toxic for reproduction
COPD	chronic obstructive pulmonary disease
DALY	Disability-adjusted life year
DG SANCO	European Commission Directorate-General for Health and Consumers
DG TAXUD	Directorate-General for Taxation and Customs Union
directive	Directive 2001/37/EC of the European Parliament and 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
EAHC	European Executive Agency for Health and Consumers
EC	European Commission
EMTOC	Electronic Model Tobacco Control
ENDS	Electronic Nicotine Delivery Systems, electronic cigarettes
EU	European Union
EU-10	Member States that joined in the 2004 enlargement of the European Union: Cyprus, Czech Republic, Estonia, Hungary, Latvia, Lithuania, Malta, Poland, Slovakia and Slovenia
EU-12	Member States that joined in the 2004 and 2006 enlargement rounds of the European Union, including EU-10 countries plus Bulgaria and Romania
EU-15	Member States of the European Union prior to 2004: Austria, Belgium, Denmark, Finland, France, Germany, Greece, Ireland, Italy, Luxembourg, The Netherlands, Portugal, Spain, Sweden and United Kingdom
EU-25	All current members of the European Union, excluding 2006 enlargement (Bulgaria and Romania)
EU-27	All current members of the European Union

FAO	Food and Agriculture Organization
FAO STAT	Food and Agriculture Organization Statistical Database
FCTC	Framework Convention on Tobacco Control
GYTS	Global Youth Tobacco Survey
HBSC	Health Behaviour in School-aged Children
HFA-DB	WHO's European Health for All Database
IARC	International Agency for Research on Cancer
ISSO	Inter Service Steering Group
ITC	International Tobacco Control
ITG	International Tobacco Group
JTI	Japan Tobacco International
MPPC	most popular price category
MRHA	Medicines and Healthcare Products
NACE	Nomenclature statistique des activités économiques dans la Communauté européenne (Statistical Classification of Economic Activities in the European Community)
NCP	nicotine-containing product
NRT	Nicotine Replacement Therapy
OECD	Organisation for Economic Cooperation and Development
OLAF	European Anti-Fraud Office
PMI	Philip Morris International
PoS	point of sale
RYO	roll-your-own cigarettes, often also called hand-rolled cigarettes
SACTob	Advisory Committee on Tobacco Product Regulation
SBS	Eurostat 'Structural Business Statistics'
SFE	smoke-free environment

SIRUS	Norwegian Institute for Alcohol and Drug Research
SKU	Stock Keeping Unit
SMSA	Swedish Match South Africa (Proprietary) Limited
ST	Skandinavisk Tobakskompagni
STP	smokeless tobacco product
TNCO	tar, nicotine and carbon monoxide, the commonly measured yields from tobacco smoke
WHO	World Health Organization

Summary

Smoking and other forms of tobacco use remain one of the largest avoidable causes of morbidity and premature death in the EU

With more than 650,000 deaths a year – representing more than 15 percent of all deaths in the EU – attributable to smoking, tobacco use is one of the largest avoidable causes of morbidity and premature death in the EU. For more than a decade smoking prevalence in the EU has, however, been declining, reflecting a wider trend of reduction in smoking prevalence that may be observed since the 1980s. Over the past 30 years, smoking has remained more prevalent among men than women in the EU-27, with some of the new Member States reporting the widest gaps between male and female smokers. For young smokers (13 to 15 years old) this situation is somewhat reversed, with slightly more girls than boys smoking.

The negative health impacts of tobacco use are well established and smoking has been linked to several forms of cancer, respiratory diseases, vascular diseases, negative reproductive effects and a wide range of other negative health impacts such as increased risks of cataracts and adverse surgical outcomes related to poor wound healing.

Tobacco-related diseases incur considerable direct and indirect costs for society, including direct healthcare costs and indirect costs such as productivity losses (absenteeism, lost skills, unemployment), welfare provision costs (sickness and unemployment benefits) and fire and other accidents (property losses, wild fires), as well as intangible costs such as pain and suffering that result from loss of life or illnesses brought on by tobacco use. These costs have been estimated to be up to €363 billion in 2000, corresponding to 3.9 percent of EU-27 GDP.

Tobacco manufacturing is dominated by a few large companies, while retail structures are more diverse across Europe

The tobacco industry sector may be roughly categorised into the following activities: tobacco growing, tobacco manufacturing, tobacco wholesale and tobacco retail activities.

Tobacco manufacturing, and in particular the production of manufactured cigarettes, is dominated by a few very large companies in the EU, displaying the characteristics of an oligopolistic market. These companies are Philip Morris International (PMI), British American Tobacco (BAT), Imperial Tobacco and Japan Tobacco International (JTI). Total employment in tobacco manufacturing in Europe was estimated to be 47,000 in 2006, according to Eurostat data. However, overall cigarette manufacturing is a capital-intensive business. According to Eurostat data, gross turnover was in the region of €48 billion in 2006, and tobacco manufacturing is highly profitable.

There are different models of tobacco retailing across the EU, with some Member States having monopoly systems and specific retail outlets while others allow tobacco sales in a wide range of retail outlets. Eurostat reports a total number of 64,000 retail outlets with some 150,000 employees across Europe.

Tobacco product regulation incurs administrative burdens for tobacco manufacturers in the form of labelling and reporting requirements. Based on self-reported data from the tobacco industry, which are likely to be overestimated, the current administrative burden amounts to between €33.2 and €55.4 million per annum.

Tobacco use generates substantial tax revenues for the Member States but illicit trade undermines national tobacco taxation and other tobacco control measures

The taxation of tobacco products through excise duties and VAT leads to substantial tax revenues for the Member States in the EU. In 2007 revenues from tobacco consumption accrued to just below €67 billion. Losses due to smuggling have been estimated to amount to €230 million a year in 2007.

The Tobacco Products Directive is a key instrument of European tobacco control policy

European tobacco control policies encompass a wide range of policy measures, including restrictions on cross-border advertising, harmonisation of tobacco excise duties, initiatives to reduce exposure to second-hand smoke, recommendations for comprehensive tobacco control policies across Member States and tobacco product regulation.

One of the key instruments is the Tobacco Products Directive (2001/37/EC), which establishes maximum tar, nicotine and carbon monoxide (TNCO) yields for cigarettes, specifies the labelling provisions, bans the use of misleading descriptors – such as 'mild', 'light' and so on, and bans the marketing of oral tobacco in the EU (except in Sweden). The implementation of the Tobacco Products Directive has been assessed in two reports on its application. These identified emerging issues and areas for further action which DG SANCO is now seeking to address in an upcoming revision of the directive.

DG SANCO considers changes in five areas of the regulation

DG SANCO is thus currently considering revising the directive in five areas of tobacco product regulation:

1. Adjusting the scope of the directive by including further tobacco products and paraphernalia.
2. Changes to the labelling requirements for producers.
3. Introducing reporting and registration requirements and market control fees.
4. Defining the ingredients of tobacco products.
5. Revising the sales arrangements for tobacco products.

For each of these areas of change, DG SANCO is presently considering a number of measures to strengthen current regulation, and has clustered these into five policy options. These options may be described as follows:

Option 1: No change.

Option 2: No binding measures.

Option 3: Minimum revision of the directive, bringing it in line with scientific and international developments.

Option 4: Revision of the directive, bringing it in line with scientific and international developments and strengthening the protection of vulnerable groups.

Option 5: Revision of the directive with the objective of strengthening product regulation and full implementation of the polluter pays principle.

This study will inform a full impact assessment by DG SANCO

Against this background, DG SANCO commissioned RAND Europe to provide support for assessing the impacts of these five policy options. This report serves as an input to DG SANCO's own impact assessment exercise. By taking into account the possible health, economic and social impacts of these policy options, RAND Europe weighs their costs and benefits and supports the identification of a preferred policy option to meet DG SANCO's objectives of achieving a high level of health protection and ensuring good functioning of the internal market. This report does follow the impact assessment guidelines of the European Commission (EC) as far as feasible; it, however, does not constitute a full impact assessment.

A variety of methods to assess possible impacts of European action has been used in this study

This study uses a variety of research methods and techniques of analysis to arrive at an assessment of the different social and economic impacts of the options currently being considered by DG SANCO. It is primarily based on analysis of existing literature and data sources, but additional primary data have also been gathered to inform the assessment of the administrative burden and compliance costs for industry. The key methods used are as follows:

1. Targeted literature reviews of both the health and economic impact of different measures of tobacco product regulation, including labelling and health warnings, changes in sales arrangement, more stringent regulation of ingredients and additives and reporting requirements.
2. The analysis of statistical data available based on official data sources, including data from the World Health Organization (WHO), Organisation for Economic Cooperation and Development (OECD), Eurostat and Eurobarometer.
3. Primary data gathering, using key informant interviews and questionnaires with tobacco manufactures and retailer associations, on the administrative burden and compliance cost of tobacco product regulation. These data were analysed using a methodology inspired by the standard cost model.
4. Two quantitative models were developed and used to forecast future mortality and morbidity rates, and healthcare costs, and to model the macroeconomic impacts of reductions in smoking prevalence.
5. A cost consequence framework and scoring mechanism to compare the different options and to identify their different impacts was also used.

With the strengths and limitations of these options in mind and taking into account the timeframe and scope of this research project, RAND Europe assessed the potential impacts of the options considered.

Stakeholder consultation

As part of the development of this research, key stakeholders were consulted in an informal consultation exercise, preceding the formal consultation to be conducted by DG SANCO as the legislative proposal is developed. The key objective of the stakeholder consultation was to provide input for this research project at an early stage and to ensure that the project team could obtain the best available information. The engagement with stakeholders had two key components:

1. Discussion of an interim report, with stakeholders having the opportunity to provide comments and feedback during a series of workshops, and to provide written comments for the research team.
2. An administrative burden measurement exercise with tobacco manufacturers and retailers, consisting of key informant interviews and the distribution of a cost questionnaire to a number of businesses and their umbrella organisations.

This study reviewed evidence and assessed measures in five areas of change

To assess the options suggested by DG SANCO, RAND Europe reviewed evidence in five areas of change to arrive at a balanced and reasoned assessment of the potential impacts of the different measures considered by DG SANCO.

Scope of the Tobacco Products Directive

Recent years have seen a diversification of tobacco products in use, such as roll-your-own cigarettes (RYO) and water pipes, and the emergence of new forms of product such as electronic cigarettes. Evidence shows that consumers do not have good knowledge about the harmfulness of these products and underestimate the health risks of their use. In the case of electronic cigarettes, very little is currently known about health impacts, and in many Member States they are not adequately regulated. Extending tobacco regulation to these products – as well as to paraphernalia such as rolling paper, water pipes, pipes, and so on – may help to increase consumer awareness and have positive health effects, but there is very little evidence available on the health impacts of regulating such products. Extending the scope of the Tobacco Products Directive would affect the producers of paraphernalia and electronic cigarettes, but given the limited information available on these business sectors, measuring this impact is fraught with difficulty.

Labelling and packaging

There is a large and clear body of evidence showing that health warnings on tobacco products increase consumers' knowledge about the health consequences of tobacco use, and contribute to changing attitudes towards tobacco and consumers' smoking behaviour. In general pictorial warnings are more effective than textual warnings; and the larger the warnings, the more effective they tend to be. There are, however, difficulties in observing this individual-level effect at the population level using prevalence rates. Generic or plain packaging has been shown to reduce the attractiveness of cigarette packages and to direct the attention of the consumer to the more prominent health warnings on the pack, and is thus likely to strengthen further the positive impact of health warnings. There is strong

evidence that quantitative TNCO measurement and labelling does not accurately represent the yields smokers are exposed to and that smokers wrongly interpret cigarettes with lower yields as less damaging for their health. Very limited information is available on the effect of additional inserts for tobacco packages.

Labelling and packaging are likely to result in administrative burden for tobacco manufacturers; these are, however, to a large extent one-off costs for adapting the label and can be further reduced by synchronising labelling changes due to regulation with labelling changes that would have occurred anyway (e.g. changes in text and pictorial warning contents). Thus the longer the transition period of introducing labelling changes, the lower the costs. Changes in the packaging regime may impact on brand values, but there is little evidence of such an effect.

Registration and market control fees

Improving the current unsatisfactory situation of ingredient reporting by having mandatory reporting formats may lead to better data about the composition of tobacco products becoming available, and subsequently to better consumer information and potentially better regulation. Using market control fees or a general liability principle to transfer healthcare costs to tobacco manufacturers has not been previously attempted, but it would be likely to have the same effect as a substantial rise in tobacco duty, leading to large positive health effects and savings in healthcare costs but also to reduced revenues and employment in the tobacco industry.

Ingredients

A substantial body of literature assesses the harmfulness, and in particular the carcinogenic nature, of specific tobacco ingredients, but little is known about the health effects a regulation or ban of these ingredients would have on tobacco consumers. Tightening the yield limits for manufactured cigarettes will not necessarily lead to better health outcomes as studies have shown that smokers compensate for lower (nicotine) yields by smoking more intensely or more.

Sales arrangements

Restricting or banning the promotion of tobacco products in retail outlets, and restricting or banning the display of tobacco products at the point of sale (PoS), have been shown to remove smoking cues and reduce triggers for unplanned tobacco purchases in stores. This effect is thought to be particularly strong among adolescents and young people, who are thought to be more susceptible to such displays and promotions. However, the literature does not provide any estimates of the effect of removing such displays and promotions on smoking prevalence. Vending machines are often considered an easily accessible source of tobacco products for adolescents. The literature shows that (technical) solutions to restrict access to vending machines do not necessarily succeed in effectively restricting youth access, and therefore that banning vending machines altogether might be more effective to curb youth consumption of tobacco. However, adolescents often use a wide range of sources in order to access tobacco products – such as older-looking or older friends and acquaintances – and therefore although banning vending machines may have some impacts on youth tobacco purchasing, it would not prevent them from accessing tobacco products altogether.

The effect of package size is very mixed in nature, with both positive and negative effects observed. Small packages lower the barrier for purchasing tobacco, making it more feasible for people on tight budgets, including children and adolescents, to purchase tobacco. Therefore enlarging packages raises the barriers for purchase. At the same time, it has been observed that smokers regulate their intake by packs rather than by individual cigarettes and therefore bigger packs may incite smokers to increase their cigarette consumption.

Little is known about the total extent of cross-border (internet) sales of tobacco products, but it has been shown elsewhere that cross-border trade may undermine national tobacco control policies, in particular different excise duty rates but also underage sales regulation.

Some of the suggested changes to sales regulation – such as banning the promotion and display of tobacco products – would have substantial economic impacts, mostly on tobacco retailers. They would need to make changes to their stores and sale processes as well as losing advertising revenues from tobacco manufacturers. These costs might have a knock-on effect on price and thus consumption of tobacco products. Packaging changes would involve compliance cost for manufacturers, but could also lead to long-term savings if they lead to a reduction in product lines.

Baseline scenario and the no-change option

To assess the impacts of changes to the Tobacco Products Directive and to assess the impacts of the 'no-change' policy option, RAND Europe developed a baseline scenario. The baseline scenario assumes that past trends in prevalence and health impacts will continue into the future. There are two main elements in the baseline scenario: a forecast of future prevalence, and a forecast of future mortality and morbidity. Derived from these two forecasts are impacts on healthcare costs and tax revenues on the tobacco industry.

Even in the absence of stricter tobacco product regulation, we forecast prevalence will fall across EU over the next decades. This result is based on a strong trend in prevalence reduction over the last decade or so, which has seen a considerable extent of tobacco control policy being implemented in the EU, and the scenario may thus overestimate the reduction in prevalence if regulatory activity in fields such as taxation and smoke-free environments is not maintained at the current level.

Based on falling prevalence, the baseline scenario forecasts a continuing fall in employment in the tobacco manufacturing and tobacco retail sectors. In all but one of the different forecasts available, tax revenues are likely to increase despite changes in prevalence, assuming the relationship between consumption and tax revenues remains the same as in previous years.

For assessing future health impacts we assumed an average time lag of health impacts of 17 years. Thus the baseline scenario will be dominated by past changes in prevalence and the effects of current policy will only be felt well into the 2020s. Male mortality and morbidity rates will therefore decline across the EU until 2027, while female rates will increase until 2027. Overall, we estimate a total of 342,000 tobacco-related deaths in 2027, direct healthcare costs of €36 billion and indirect costs of €43 billion.

RAND Europe assessed economic and health impacts of five different policy options

RAND Europe assessed the economic and health impacts of five different policy options. While smoking tobacco also has environmental effects, these were not considered central to this assessment.

Option 1

The baseline scenario describes the no-change option. In this case, even in the absence of tighter tobacco product regulation, smoking prevalence and tobacco-related morbidity, mortality and healthcare costs are likely to fall until 2027, accompanied by reduced employment and economic activity in the tobacco industry sector. This option would, however, not address the obvious shortcomings of the current directive. These include difficulties in dealing with new and emerging products, and unsatisfactory ingredient reporting and information and consumer awareness of the harmfulness of tobacco products other than manufactured cigarettes. The administrative burden arising from continuing reporting requirements would continue to be incurred by the tobacco industry, and is estimated to be at around €1 million to €10 million for cigarette manufacturers, and between €0.3 million and €1.7 million for cigar manufacturers.

Option 2

The impact assessment guidelines encourage EC services also to explore non-binding measures as an alternative to binding legislation. In the case of tobacco product regulation, where a range of binding legislation is already in place, such an approach is likely to encounter difficulties as the current legislative framework could not be amended or changed. In terms of effectiveness, experience with previous non-binding measures – such as harmonised reporting formats and laboratory cooperation – have not proved very successful. Against this background, no detailed list of non-binding measures has been developed by DG SANCO to be assessed in this study; nevertheless we should like to explore potential health and economic impacts briefly.

In terms of achieving positive health impacts, some impacts could be achieved by Member States implementing stricter measures on their own, as is already the case for the introduction of pictorial warnings, displays bans and restrictions or bans on vending machines. Other measures such as introducing large pictorial warnings or plain packaging would only be possible after a change in regulations. This might lead to more diverse tobacco product regulation in the areas where the current Tobacco Products Directive allows further measures by Member States, and to no change in the areas where a revision of the directive would be required. Thus, overall health impacts would be likely to be lower than in scenarios where a revision of the current directive is implemented.

More diverse national tobacco control regulations would, however, certainly have a negative impact on tobacco manufacturers across Europe. More diverse regulation increases the cost of compliance as more national particularities have to be taken into account. This includes, for example, a search for relevant information on regulation and adapting products to meet national requirements, and has the potential to undermine the functioning of the single European market.

Option 3

Option 3 is the first 'legislative option', combining measures in all areas of change. It has been designed as a minimum revision to the directive, bringing it into line with scientific and international developments. Our assessment starts with the health impact.

Health impact

Analysing this option, the strongest health impact may be expected from the introduction of mandatory pictorial warnings, which according to a UK impact assessment could reduce prevalence by at least 0.5 percent, saving 900 lives and preventing 9,300 cases of lung cancer, aerodigestive cancer and chronic obstructive pulmonary disease (COPD) annually from 2027, with related savings in healthcare costs.

Especially targeted at adolescent smokers are the measures relating to underage sales, vending machines and the promotion of tobacco products in retail stores. For all these measures positive health impacts, albeit not quantifiable, may be expected as these measures have been shown to influence purchasing decisions. The overall scope of the impacts will, however, remain limited as many Member States have implemented similar measures already and the changes would mean a further institutionalisation of common practice in the Member States. For example, all but two Member States have already instituted a minimum purchasing age of 18 years.

Introducing a minimum package size is also a measure designed to protect adolescent smokers. The reasoning here is that larger packets are more expensive, and would be less likely to be bought by cash-strapped youths. Evidence of the impact of this measure is, however, very mixed because bigger pack sizes have been shown to increase tobacco consumption. Therefore we do not expect positive, population-wide health effects from this measure.

Changes in the labelling of tobacco yields will without a doubt benefit consumers as it has been shown that quantitative yield information confuses consumers about the relative harmfulness of different tobacco products. This has to be set against the evidence that lower yield cigarettes are as harmful as high-yield cigarettes, given that smokers compensate for lower yield cigarettes by either smoking more intensely or smoking more cigarettes in order to obtain the dose of nicotine they require. We do not expect additional measurement methods and a further reduction of yields to have substantial health impacts. This is somewhat different for the ban on carcinogenic ingredients, which could reduce the presence of high-risk additives and ingredients currently used in tobacco products. However, there is not sufficient knowledge about this, and there is no common list of these ingredients that could be used to determine the most harmful ingredients and thus those whose reducation would be most likely to produce a positive impact on the health of consumers.

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. There are, however, difficulties regarding how far the current regulations could meaningfully be applied to the other product categories.

This leads us to a set of measures contained in Option 3, concerning the reporting and registration of tobacco products. While these measures do not have direct health impacts, they are set out to develop the (scientific) infrastructure to improve both scientific and regulatory knowledge about tobacco products, as well as to increase the information available to consumers and thus bring about clear long-term benefit.

Economic impact

For all options changes in prevalence, either directly induced by policies such as labelling or a result of increasing costs to industry, have the most wide-ranging economic impacts. For Option 3 we expect a decline in prevalence of 0.5 percent through labelling measures. Prevalence changes are likely to have an impact on industry revenue and profits (€200m and €35m) and on employment (–0.5 for manufacturers, retailers (–2.9 percent to –1.3 percent) and wholesalers (–1.5 percent to 0.1 percent).

Tax revenues may fluctuate in the range of –€350 million reduction or an increase of €1.1 billion if current trends of increased revenues continue. Prevalence changes resulting from new labelling requirements will save direct healthcare costs in the region of €91 million, and indirect costs of mortality and morbidity of €108 million.

For industry the economic impact of Options 3 to 5 arises out of the administrative burden for manufacturers and compliance costs for retailers. A number of measures in Option 3 are likely to result in administrative burden as they require changes to the packaging and labelling of tobacco products. These occur primarily as one-off costs for the change of a label; ongoing costs seem to be low. It is important to note that these costs are not simple to calculate. The maximum cost incurred by industry will be that of the most comprehensive labelling change.

In this option the costs would range between one-off costs of €101.8 million and €198.8 million, and only marginally increased ongoing costs. Indeed, introducing qualitative TNCO labelling may increase annual running costs by between €4.8 million and €9.8 million a year only. Adjustments to the reporting and registration requirements will cause additional administrative burden, but are overall relatively low. The introduction of standardised electronic reporting may even reduce the burden for tobacco manufacturers.

Owing to the large number of businesses, retailers face the most substantial economic cost in adapting to measures proposed in this option. The one-off costs for retailers have been estimated to be between €44.1 million and €394.2 million and ongoing compliance costs to be up to €70.8 million a year. Another cost for retailers will be that of the introduction of age restrictions for vending machines. However, these will be relatively low (up to €48m) as many Member States already have such measures in place.

Costs that could not be quantified, owing to uncertainty in the required action as well as a lack of data, include the costs for reformulating products because of changed ingredient regulation and the introduction of minimum package sizes.

Option 4

Option 4 is the second option that involves changes to the legislative framework. The suggested measures have been in particular designed to bring the directive into line with scientific and international development and strengthen the protection of vulnerable

groups, particularly adolescents. Again we started by looking at the health impact of this option.

Health impact

In this option even stronger labelling requirements are suggested, with the mandatory introduction of pictorial warnings covering 75 percent of the pack in combination with generic or plain packaging. These two measures are likely to have an even stronger impact on prevalence rate, so the conservatively estimated 0.5 percent reduction in prevalence – leading to reduced mortality of 900 lives and 9,300 fewer cases of lung cancer, aerodigestive cancer and COPD annually from 2027 with related savings in healthcare costs – will be the lower boundary of the expected effect.

Measures targeted at protecting adolescents from smoking are further strengthened in this option, with a complete ban on vending machines for adolescents – which would solve the enforcement problems related to age restrictions on vending machines and could lead to small reductions in youth smoking. It has, however, to be stated that this effect will be far less effective in reducing the current percentage of youths using vending machines as they are likely to compensate at least partially by using other sources of supply such as older-looking – or older – friends and acquaintances.

A ban on cross-border internet sales of tobacco products may help Member States to enforce their wider tobacco control policies, in particular taxes and age restrictions. Overall, internet purchases of tobacco products constitute only a very small proportion of tobacco purchases; therefore we do not expect this to have a measurable health effect.

Widening the definition of ingredients to cover the tobacco leaf, as well as introducing higher market control fees to cover the costs of ingredient work, would contribute to a better understanding of the harmfulness of specific ingredients, including the tobacco leaf, but health impacts would be achieved in the long term only if further action is taken on the basis of this information.

Finally, this option contains a measure to decrease continuously the yield limits of tobacco products. As discussed earlier, given the evidence that smokers compensate for lower yield cigarettes by smoking more intensely or more, there is little evidence that such measures would produce positive health impacts on consumers.

The economic impacts of Option 4 are only slightly higher than those for Option 3, with slightly increased costs for manufacturers and retailers, and with the same effect on smoking prevalence.

Economic impact

The economic impacts of Option 4 are only slightly higher than those for Option 3, primarily in the form of increased costs for manufacturers and retailers, and the same effect on smoking prevalence is expected.

For Option 4 we thus expect a decline in prevalence of 0.5 percent through labelling measures. Prevalence changes are likely to have an impact on industry revenue and profits (€200m and €35m) and on employment (–0.5 for manufacturers, –2.9 percent to –1.3 percent for retailers and –1.5 percent to 0.1 percent for wholesalers).

Tax revenues may fluctuate in the range of €350 million reduction or an increase in €1.1 billion if current trends of increased revenues continue. Prevalence changes resulting from new labelling requirements will save direct healthcare costs in the region of €91 million, and indirect costs of mortality and morbidity of €108 million.

Labelling costs for industry may be expected to stay the same between options as they already include the costs incurred for a substantial redesign of labels. However, the cost for retailers of implementing restriction on the display of tobacco products is potentially substantial.

In this option there are, however, important cost impacts that could not be quantified. The first are the costs of introducing a comprehensive ban of vending machines across Europe, which is very likely to be substantial in terms of sunk costs but which could be reduced by a long transition period. The second important cost that could not be quantified concerns tobacco manufacturers' brand equity, which would be substantially reduced if plain packaging is introduced and if other possibilities for maintaining brands, such as in-store advertising, are banned as well.

Option 5

In Option 5 a further strengthening of the directive is foreseen, with the objective of strengthening product regulation and fully implementing the polluter pays principle.

Health impact

Option 5 is again characterised by a further tightening of the labelling requirements, with pictorial health warnings covering most of the package surface of a plain tobacco pack. Compared to the other options, this is likely to have the largest health impact and is likely to exceed the conservative estimate we used in the quantitative estimation. For this option pictorial warnings are very large and there is no possibility of branding and other distracting designs. The success of producing inserts is less certain. There is only sparse evidence of the effectiveness of this measure and information, if provided in a text-heavy format, may be less effective in reaching less literate smokers.

The largest health effects of all options may, however, be expected through the two different approaches to internalising the external costs of smoking through fees or through making cigarette manufacturers liable for the external costs engendered by tobacco consumption. If the currently approximate €100 billion in indirect costs is passed on to tobacco manufacturers, this will have a substantial impact on the price of tobacco products and thus on the prevalence of tobacco use. Our calculation estimated a 25 percent reduction in prevalence, which would result in a reduction of around 45,000 in smoking-related deaths and 46,000 fewer cases of lung cancer, aerodigestive cancer and COPD per annum by 2027.

The complete ban of tobacco promotion and displays in store is likely to have a positive impact on adolescent smoking and to a lesser extent also on adult smokers – in particular on those attempting to quit or stay quit – as all smoking cues would be removed from stores. As the implementation of this measure is connected to considerable costs, this would have an additional impact on the price of tobacco products, which could lead to further reductions in prevalence, estimated at 0.12 percent, and result in 200 fewer deaths and 2,200 fewer cases of lung cancer, aerodigestive cancer and COPD annually by 2027.

From the introduction of a minimum package size we do not expect population-wide health effects as there is conflicting evidence on the health impact of such a measure.

Further measures in this final option concern the infrastructure to collect and analyse ingredients, which could have long-term positive health impacts.

Economic impact

Without a doubt Option 5 would have the most substantial economic impact, both in terms of costs for industry and in terms of potential economic benefits such as saved healthcare costs. This is because of the idea of transferring healthcare costs to the tobacco manufacturers, who would in turn be required to increase the price of their products, leading to an overall reduction in prevalence.

Using the data available, we would expect a 25 percent reduction in prevalence, with a related reduction in revenues of €10 billion, reduction in profits of €1.7 billion, and reduced employment for manufacturers of between 13 percent and 17 percent, of 15–22 percent for wholesalers and of 50–70 percent for retailers.

Lost tax revenues would constitute around €15 billion (a reduction of around 24 percent), while direct healthcare costs of €4.5 billion and indirect costs of €5 billion to €6 billion could be saved annually.

We expect the impacts of labelling costs and changes in prevalence related to these to be along the same lines as for the other two regulatory options, but with higher one-off and ongoing costs for banning the display of tobacco products in retail stores. These have been estimated as set-up costs of between €321 million and €2,297 million, with ongoing costs of around the same level.

In addition to these impacts, other important unquantified impacts include the cost of setting up an EC laboratory to conduct ingredient work, which is likely to be transferred to industry through fees.

CHAPTER 1 Introduction

1.1 The challenge of tobacco

Despite recent reductions in the prevalence of smoking in the European Union (EU), smoking remains one of the largest avoidable causes of morbidity and premature death in the EU. In 2000 approximately 650,000 deaths, or 15 percent of all deaths in the EU-25, could be attributed to smoking (Peto *et al.*, 2006). Smoking affects non-smokers too; a 2009 estimate suggested exposure to second-hand smoke at home and at work accounted for 79,000 deaths in the EU-25 (Scoggins *et al.*, 2009). Smoking-related mortality and morbidity results in both direct and indirect costs to society through healthcare expenditure, reduced productivity and increased absenteeism from work, as well as other direct and indirect medical costs.[1]

Against this background of negative health impacts and related costs to society, governments around the world are now increasingly active in regulating the use of tobacco products and in trying to curb the harmful effects of smoking.

On the international level these efforts are reflected in the World Health Organization (WHO) Framework Convention on Tobacco Control (FCTC), which was adopted by the 56th World Health Assembly in May 2003 and came into force in 2005 (WHO, 2003a). The current 168 parties,[2] among them the EU and all but one Member State, committed themselves to implementing a wide-ranging mix of tobacco control measures as foreseen in the framework convention. These measures build on practices and policies already existing in many countries, and common measures include the following (Asma *et al.*, 2009, ASPECT Consortium, 2004, WHO, 2007a):

- **taxation of tobacco** products through excise duties;
- **smoke-free laws** that ban smoking in public places such as pubs, trains and public buildings;
- **advertising bans** that prohibit or restrict the promotion of tobacco products;
- **information, education and warning measures** that are intended to educate the public about the harmful effects of smoking;

[1] See our assessment in the later chapters of this report.

[2] As of October 2009, see http://www.who.int/fctc/signatories_parties/en/index.html (accessed 16 Nov 2009).

- **product control and consumer information** measures to regulate the ingredients and composition of tobacco products as well as their sale and packaging;
- **behavioural and medical interventions**, such as smoking cessation programmes, that seek to help smokers to quit, sometimes with the use of medical cessation aids.

1.2 Tobacco control in the EU

Member States are generally responsible for tobacco control; however, the EU has been increasingly active in the field in the last two decades. The EU has introduced measures in a number of areas, mostly based on its competencies to ensure the good functioning of the single market. The key European legislation and initiatives in the field of tobacco control are these:

1. **Tobacco Products Directive** 2001/37/EC regulating the composition and labelling of tobacco products.
2. **Tobacco Advertising Directive** (2003/33/EC) banning cross-border advertising of tobacco products in printed media, radio and on-line services, supplemented by the Audiovisual Media Services Directive (2007/65/EC) which extends this ban to all forms of audiovisual commercial communications, including product placement.
3. **Council Recommendation on the Prevention of Smoking and on Initiatives to improve Tobacco Control (2003/54/EC)** encouraging Member States to take further tobacco control action. It recommends that Member States prohibit the use of tobacco brand names on non-tobacco products or services; the use of promotional items and tobacco samples; the use and communication of sales promotions such as discounts, free gifts, a premium or an opportunity to participate in a promotional contest or game; the use of billboards, posters and other indoor or outdoor advertising techniques (such as advertising on tobacco vending machines); the use of advertising in cinemas; and any other forms of advertising, sponsorship or practices directly or indirectly intended to promote tobacco products.
4. **Council Recommendation on Smoke-free Environments** (2009/C 296/02), which was adopted on 30 November 2009, calling on Member States to act in three areas:
    - adopt and implement laws to protect their citizens fully from exposure to tobacco smoke in enclosed public places, workplaces and public transport as cited in Article 8 of the FCTC, within three years of the adoption of the recommendation;
    - enhance smoke-free laws with supporting measures such as protecting children, encouraging efforts to give up tobacco use and placing pictorial warnings on tobacco packages;
    - strengthen cooperation at EU level by setting up a network of national focal points for tobacco control.

5. **Directive to Amend the Current EU Excise Duty Legislation on Tobacco (2010/12/EU)** which, amongst other effects, foresees a gradual increase in the EU minimum taxation levels on cigarettes and fine-cut tobacco up to 2014 and 2020 respectively. The directive also aims to contribute to reducing tobacco consumption by 10 percent within the next five years.[3]

1.3 Tobacco Products Directive 2001/37/EC

Within this wider policy framework, DG SANCO is currently developing options to develop further the Tobacco Products Directive 2001/37/EC (also referred to in this report as 'the directive') with the aim of reducing tobacco-related deaths and contributing to the good functioning of the internal market. The objective of the directive is to 'approximate the laws, regulations and administrative provisions of the Member States concerning the maximum tar, nicotine and carbon monoxide yields of cigarettes and the warnings regarding health and other information to appear on unit packets of tobacco products, together with certain measures concerning the ingredients and the descriptions of tobacco products, taking as a basis a high level of health protection'.

This directive contains six articles that relate directly to the actions that businesses and Member States are to take with regard to the manufacture, presentation and sale of tobacco products:

- Article 3 on the maximum TNCO yields;
- Article 4 on the measurement methods and reporting formats used on the yields;
- Article 5 on the labelling of tobacco products;
- Article 6 on additional information that needs to be submitted by tobacco manufacturers and importers;
- Article 7 on tobacco product descriptions;
- Article 8 on tobacco for oral use.

To summarise, the directive established maximum TNCO yields for cigarettes, specified the labelling provisions, banned the use of misleading descriptors such as 'mild', 'light', and so on, and banned the marketing of oral tobacco in the EU (except Sweden). The directive was complemented by two decisions on pictorial warnings as well as three guiding documents (one on pictorial warnings, a second on harmonised reporting formats, and a third on laboratory cooperation) (DG SANCO, 2008).

The second report on the application of the directive (DG SANCO, 2007b) considered the important developments that had taken place in the field of tobacco control both at the EU level and worldwide since the introduction of the directive in 2001. These developments include: 'several shortcomings of the present Directive were detected (e.g.

[3] See http://ec.europa.eu/taxation_customs/taxation/excise_duties/tobacco_products/legislation/index_en.htm and DG TAXUDEuropean Commission, *Impact Assessment. Accompanying Document to the Proposal for a Council Directive Amending Council Directive 95/59/Ec, 92/79/Eec and 92/80/Eec on the Structure and the Rates of Excise Duty Applied to Manufactured Tobacco*, Brussels: European Commission, DG TAXUD, 2008.

unclear wording which can lead to different interpretations); the tobacco industry circumvented certain parts of the Directive and ongoing legal, international and scientific developments in tobacco product regulation require an update of the Directive' (DG SANCO, 2008).

The second report on the application of the directive therefore highlighted a number of areas with regard to which amendments to the directive are proposed (DG SANCO, 2007b):

- improve the labelling of tobacco products;
- set up a framework for ingredients evaluation and the financing of the work required to analyse the ingredient information submitted;
- strengthen sales arrangements to protect minors;
- define some principles for the establishment of a common list of ingredients;
- widen the scope of the directive to cover previously unregulated or less regulated products.

1.4 RAND Europe's assignment

Against this background DG SANCO commissioned RAND Europe to provide support in drafting an impact assessment of a number of policy options to amend the current directive. For each option RAND Europe was asked to assess the social and the health, economic and environmental impacts. At this early stage of the revision of the directive, DG SANCO suggested five policy options to be assessed, each consisting of a large number of different measures. These measures may be broadly clustered into five areas of change:

1. Adjusting the scope of the directive by including further tobacco products and paraphernalia.
2. Changes to the labelling requirements for producers.
3. Introducing reporting and registration requirements and market control fees.
4. Defining the ingredients of tobacco products.
5. Revising the sales arrangements for tobacco products.

To allow for a flexible approach in developing a final proposal and options and to structure the research process, RAND Europe based its assessment of the options on these areas of change. Table 1.1 provides an overview of how the different measures suggested group into areas of change as well as into policy options.

Table 1.1: Policy options and dimensions of change

	Dimensions of change				
Policy options	**Scope of the directive**	**Labelling requirements**	**Registration and market control fees**	**Ingredients**	**Sales arrangements**
Option 1 – No change from status quo	No change	No change	No change	No change	No change
Option 2 – Non-binding measures	The European Commission (EC) would propose a commission or council recommendation, and/or issue practical guidance documents and encourage Member States to introduce their own legal requirements and/or use the guidance documents.				
Option 3 – Minimum revision of the directive bringing it into line with scientific and international developments	Scope of the directive will be extended to include non-regulated nicotine products, non-tobacco/non-nicotine smoking products, paraphernalia and the tobacco leaf	• Make pictorial warnings mandatory • Update and enlarge warnings to 50% of both sides of the pack and place them towards the top of the pack • Replace TNCO quantitative labelling with qualitative information on contents and emissions and quit-lines	• Make reporting formats for product ingredients compulsory • Introduce fixed yearly registration fees in order to finance ingredients work; only registered products may be marketed • Introduce fines for industry in case of non-delivery of ingredients data	• Ban additives that are carcinogenic, mutagenic or toxic for reproduction (CMRs) or that form CMRs during pyrolysis, in order to establish a common list of ingredients • Introduce an additional measurement method for TNCO (the modified ISO method) and set maximum limits accordingly • Introduce maximum limits for other yields and ingredients	• Introduce minimum pack size • Harmonise legal buying age to 18 in order to avoid sales to minors • Make vending machines inaccessible to minors • Ban promotion (sheers, billboards, big packets, discount banners, etc.) at retail outlets
Option 4 – Revision of the directive bringing it into line with scientific and international developments and strengthening the protection of vulnerable groups	Includes all elements of Option 3	Includes all elements of Option 3, plus: • further increase the size of warnings to 75% of both sides of the pack • introduce generic packaging	Includes all elements of Option 3 plus: • introduce market control fees proportionate to the number of outlets the product is sold in	Includes all elements of Option 3 plus: • continuously decrease the maximum limits for TNCO and other yields and ingredients • refine the definition of ingredients to include the tobacco leaf	Includes all elements of Option 3 plus: • ban vending machines • ban cross-border internet sales including the free distribution of product samples • restrict the display of products at retail outlets
Option 5 – Revision of the directive within the objective of strengthening product regulation and full implementation of the polluter pays principle	Includes all elements of Option 4	Includes all elements of Option 4 plus: • further increase the size of the warnings on the back of the pack to 100% • Introduce inserts with supplementary information (e.g. on the potential risks)	Includes all elements of Option 4 plus: • integrate the health costs of smoking into the calculation of the fees • based on the polluter pays principle, internalise the external health costs of smoking by requiring full liability and payment of the health costs of smoking by the tobacco industry to national health systems	Includes all elements of Option 4 plus: • set up a European Community (EC) laboratory to evaluate tobacco and smoking products	Includes all elements of Option 4 plus: • introduce a standard pack size • ban the display of products at points of sale

1.5 This report

This report presents the results of RAND Europe's assessment of the potential impact of the policy measures considered by DG SANCO and consists of 15 chapters.

The following chapter, Chapter 2, sets out the research approach and research methodologies used in this study. Chapter 3 then provides background information on the health-related aspects of tobacco consumption. In that chapter we discuss current smoking prevalence across Europe, summarise the health effects of smoking as well as the related healthcare costs and then discuss how changes in prevalence would influence both mortality and morbidity. In the following chapter, Chapter 4, we focus on the economic side of tobacco consumption, providing an overview of the tobacco industry, market structures, tax revenues and illicit trade. Still focusing on the economic side of tobacco regulation, we then discuss the administrative burden and compliance costs for tobacco manufacturers and retailers (Chapter 5). Against this background we can then set out the baseline assumptions used in this report in relation to future prevalence and health trends if there is no policy intervention (Chapter 6).

The analysis then moves on to the assessment of the different policy measures in Chapters 7 to 11. For each area of change a summary of relevant evidence is presented and the health and economic impacts are assessed and summarised in tables. This information, based on policy measures, is then compiled and compared in the provisional policy options currently foreseen by DG SANCO in Chapter 12. To ensure future assessment of the success of any new policy measures implemented, Chapter 13 develops a framework for monitoring and evaluating the Tobacco Products Directive. As part of this research, RAND Europe consulted with key stakeholders in the area of tobacco policy – a summary of stakeholder engagement is presented in Chapter 14. The report concludes by providing some reflections on the challenges faced in conducting this kind of impact assessment (Chapter 15). A series of appendices finally provides additional information on the methodologies used in this report.

CHAPTER 2 Approach and methodology

2.1 Approach: supporting an impact assessment

This study has been conducted to support DG SANCO in the development of an impact assessment. The study thus takes into account, to the greatest extent possible, the EC's impact assessment guidelines (European Commission, 2009). Conducting an impact assessment type study brings with it specific challenges and limitations which have to be dealt with under tight time and resource constraints.

Assessing the impacts of a wide regulatory instrument such as one for tobacco product regulation usually means that there is not one single body of (academic) evidence available upon which to base an assessment, but rather multiple bodies of literature, knowledge and expertise. An assessment of the tobacco regulation will, for example, need to take into account scientific literature on the harmful effect of specific ingredients, economic/business literature on the labelling costs for firms and behavioural studies on the effect of promotion, marketing and health warnings. Any research will therefore need to find ways to summarise these bodies of evidence effectively and rapidly as comprehensive, systematic literature reviews for each body of evidence are not feasible within the constraints of an impact assessment.

The second, unsurprising, challenge of conducting impact assessments lies in finding and using quality data and evidence. There are a number of reasons why good data and evidence may be hard to obtain. The first lies in the very logic of an impact assessment, which accompanies new and often novel regulation. While similar policies may sometimes have been tried elsewhere, this is not always the case. It will therefore not be possible to find sound and sufficient evidence from which to judge whether a specific intervention works or not – it simply hasn't been tried before. An assessment must rely on the extrapolation of findings from smaller-scale trials, or must be based on informed reasoning. Secondly, there is often a substantial time lag before official statistics become available for analysis, which leads to the often unsatisfactory situation that somewhat dated data have to be used to assess current and future trends. For this impact assessment this was the case for information about smoking prevalence, as well as for data about industry structure and employment. In a situation of scarcity of data and knowledge, studies have to rely to a larger extent than is desirable on data that have been provided by stakeholders and partners interested in tobacco regulation, which has consequences for the reliability of these data sources.

Finally, impact assessments contain a considerable degree of uncertainty as they are designed to assess future actions and impacts. At the European level, this is further

complicated by the diversity of the EU regarding, for example, the organisation of healthcare systems. Regulations may be transposed slightly differently in different countries, and the same policy measure may be implemented in very different national contexts, in which there may be different smoking patterns and other tobacco control measures in place.

Against this background, this study combines a range of methodologies to establish both a baseline scenario and an assessment of future action:

1. **Evidence and literature reviews** were conducted for each area of change as well as on cross-cutting issues informing both the selection of data sources and the identification of the key impacts of the changes to tobacco product regulation.
2. **Modelling of health impacts and healthcare costs.** To establish a baseline scenario and to assess future impacts on morbidity and mortality, we developed a forecast of future mortality, morbidity and related healthcare costs, assuming an average time lag of 17 years until reductions in prevalence result in substantive mortality and morbidity impacts.
3. **Macroeconomic modelling.** The impacts on the tobacco producing and retailing sectors may be thought of as being much more directly linked to changes in consumption and prevalence trends. We therefore forecasted prevalence trends and estimated changes to industry employment, revenues and tax revenues in relation to changes in prevalence.
4. **Administrative burden measurement.** To meet the impact assessment guidelines requirements for assessing the administrative burden for industry (European Commission, 2009), we conducted a measurement exercise including a number of key informant interviews and a questionnaire that was given to key trade associations and manufacturers.
5. **Multi-criteria framework.** To compare different policy options, we used a multi-criteria decision-making framework and a scoring mechanism to allow for a comparison between policy options.

These methods are described in more detail in the following sections of this chapter.

2.2 Evidence and literature review

In order to review the evidence available on the different areas of change and options proposed within them, the RAND Europe research team carried out a number of literature and evidence reviews, the results of which have been presented throughout the substantive chapters of this report. Given the timescales and resources available for this research project, it was not possible to conduct full systematic reviews into the different areas of change. Instead we conducted rapid reviews of evidence, the design of which draws on some aspects of the systematic review methodology.

2.2.1 Sources of evidence

The team made use of the following databases and search engines in order to find relevant articles to include in its evidence and literature reviews:

- Web of science
- EBSCOhost
- EconLit
- MEDLINE
- OECD (source)
- PubMed
- Google Scholar
- Globocan
- Google – for grey literature published by governments and international organisations (WHO, OECD).

2.2.2 Key terms

The above sources were searched for relevant articles and documents using a combination of key words appropriate to each area of change or option within these areas of change. The bullet points below illustrate some of the search terms that were used for finding relevant literature on warning labels:

- labelling + tobacco
- labelling + cigarette
- health warnings + tobacco
- health warnings + cigarette
- pictorial warnings + tobacco
- pictorial warnings + cigarettes.

While it is acknowledged that a number of these terms are sometimes used interchangeably, and that other key terms must be considered, these key search terms were used as the starting point for the search. RAND tested and developed these terms by using an iterative approach:

- using variants of successful terms, searching identified sources for key words that we employed in our searches;
- searching the bibliography of identified sources for other relevant sources to review;
- widening the list of search terms as the research progressed in order to incorporate newly identified key terms.

In its search, the team focused on gathering relevant papers that were systematic reviews or meta-analyses, as well as official reports from sources such as WHO or the Organisation for Economic Cooperation and Development (OECD), in order to capture as wide a range of evidence as possible. Where the results of studies or research reported in these papers were of particular relevance (e.g. if they contained quantitative estimates), these were also extracted in order to review their methodology and suitability for inclusion in this report.

In addition studies providing correlations at the individual and population level were included.

2.2.3 Inclusion criteria

Table 2.1 summarises the inclusion criteria that were used for the different literature and evidence reviews carried out as part of this study, arranged by category (i.e. settings, study designs, etc.):

Table 2.1: Selection criteria

Settings
• All regional/national/local settings in industrialised countries (studies focusing on developing countries were excluded)
• **Study designs**
• Randomised controlled trials • Non-randomised parallel group studies • Before and after studies • Cohort studies • Case control studies • Cross-sectional studies • Case studies • Qualitative designs • Questionnaire surveys • Systematic reviews and meta-analysis
• **Aims of the studies included**
• Examine effects of tobacco policies • Examine costs of tobacco policies • Examine cost-effectiveness or cost-benefit of tobacco policies • Examine challenges in implementation of tobacco policies
• **Included outcomes**
• Attitudes, beliefs, perceptions • Smoking uptake • Smoking prevalence • Quitting smoking and staying quit • Quantity of cigarette smoked • Health status • Healthcare costs
• **Included reporting formats**
• Studies published in peer-reviewed journals • Funder published research reports • Grey literature

2.2.4 Capturing relevant information from the sources identified

Qualitative information

Once relevant sources of evidence were identified for the different areas of change, the individual researchers in charge of each area reviewed the evidence and filled in a template that the RAND research team designed in order to capture the most relevant information from each source. The template included information relating to such areas as:

- the implementation of the relevant tobacco control measures (e.g. how pictorial health warnings are implemented across Member States and if some Member States have gone beyond the requirements of the directive);

- any evidence of developed countries outside the EU having implemented a given measure and how (e.g. evidence of countries implementing larger pictorial warnings or banning vending machines);
- any evidence about the effectiveness of these measures (e.g. impact of banning vending machines on youth tobacco uptake and impact of pictorial warnings on tobacco consumption);
- data sources identified (e.g. cohort survey, focus groups, systematic reviews).

For a complete list of questions that featured in the template, please refer to Appendix A of this report.

Quantitative information

In addition to the collection of qualitative information about the sources of evidence identified, the research team required quantitative evidence about the impact of different measures in order to get an understanding of the potential health and social impacts of the different measures proposed. For this to be as comprehensive as possible, the research team made use of a matrix to collect quantitative evidence of potential measures in the different areas of change. Table 2.2 shows how individual researchers collected this information.

Table 2.2: Table to map the evidence from papers identified

Reference	Methodological design	Results

The above steps enabled the research team to scan systematically for relevant sources of information and to produce a comprehensive list of sources to review. This allowed us to produce a robust account of the current state of play in the different areas of change as well as estimations of impacts of the different options within each of these areas, where evidence permitted.

2.3 Modelling of health impacts and healthcare costs

In order to assess the baseline and to model the impact of each of the alternative policy options, we adopted a longitudinal perspective. Although the effects of tobacco regulation might be immediate for smoking *behaviour* in the population, they will have a noticeable impact on *mortality*, *morbidity* and *costs* only several decades into the future. A longitudinal perspective is therefore appropriate in the context of tobacco regulation and health and healthcare costs.

For each individual person, the exact time lag after which the impact of a change in smoking behaviour becomes noticeable (in terms of morbidity, mortality and healthcare costs) will be different. For some the effect may be immediate, for others it may take several decades to occur, and for some it will never occur. Because our interest lies in assessing the impacts of the policies at the population level, rather than at the individual level, we do not attempt to assess impacts at the individual level or at many different points

in time (i.e. we do not distinguish between 'immediate' and 'delayed' impacts). Hence we assume an average time lag (across all individuals) of about 17 years. Recent research by Kabir *et al*. (2007) shows that in the state of Massachusetts a peak in lung cancer rates occurred in the early 1980s, about 20 years after a peak in tobacco consumption occurred (in the early 1960s). In this case it took another decade (until the early 1990s) before lung cancer rates started to drop noticeably. Although this evidence suggests a time lag of at least 20 to 30 years for lung cancer, for other diseases (in particular cardiovascular disease) the time lag may be substantially shorter. Our assumed average time lag of 17 years is based on the results shown by Kabir *et al*. (2007), but is adjusted downwards to take into account the more immediate effects for cardiovascular disease.

Thus, any reductions we currently observe (e.g. smoking-related mortality) are considered to be the result of smoking behaviour (in turn affected by tobacco regulation) over many decades in the past. This implies that any downwards (or upwards) trends in smoking-related mortality, morbidity and costs will persist over the coming years. This is true for the baseline scenario, as well as for all other policy scenarios considered in this study.

2.3.1 **Data**

In this section we provide an overview of all data sources used. We shall elaborate on the exact use of the data for our estimation in subsequent sections.

Variable	Source	Notes
Lung cancer deaths by Member State and gender	Globocan 2002 database, retrieved on-line at http://www-dep.iarc.fr/	Globocan 2002 presents estimates for the year 2002, based on the population size in 2002 and disease rates from the most recent data available, generally 2–5 years earlier.
Lung cancer 1-year prevalence by Member State and gender	Globocan 2002 database, retrieved on-line at http://www-dep.iarc.fr/	Globocan 2002 presents estimates for the year 2002, based on the population size in 2002 and disease rates from the most recent data available, generally 2–5 years earlier.
Aerodigestive (oesophageal) cancer deaths by Member State and gender	Globocan 2002 database, retrieved on-line at http://www-dep.iarc.fr/	Globocan 2002 presents estimates for the year 2002, based on the population size in 2002 and disease rates from the most recent data available, generally 2–5 years earlier.
Aerodigestive (oesophageal) cancer 1-year prevalence by Member State and gender	Globocan 2002 database, retrieved on-line at http://www-dep.iarc.fr/	Globocan 2002 presents estimates for the year 2002, based on the population size in 2002 and disease rates from the most recent data available, generally 2–5 years earlier.
Direct and indirect costs of tobacco consumption in Germany for 2003	Neubauer *et al*., 2006	Smoking attributable costs were estimated by the authors using various sources of raw data from Germany. We refer to Neubauer *et al*. (2006) for a detailed overview of the estimation methodology.
Comparative price levels (purchasing power parities) for all Member States	www.oecd.org	Comparative price levels are defined as the amount of currency units (euros in this case) necessary to buy the same basket of goods in each of the countries.
Effect of quitting smoking on mortality	Doll *et al*. (2004)	
Deaths from all causes, lung cancer, all other cancer and COPD, by age, sex, year and country	WHO mortality database	WHO mortality database contains mortality and population data from 1950 until 2007, approximately, for all developed countries.
Population figures by age, sex, year, and country		

2.3.2 Key assumptions of the approach

We have assumed that (as a result of the 17-year time lag) the baseline and other scenarios would start to diverge around the year 2027, on average. We stress, again, that this is an *average* for people at advanced age who stop smoking today. The effect on mortality, morbidity and costs may occur earlier, but for young people who stop smoking today the effect may occur later. In addition, for heart disease and stroke (caused by smoking) the effects may occur several years earlier, but for lung cancer several years later.

In order to compare the baseline and each of the policy alternatives, we first made predictions regarding mortality, morbidity and costs due to smoking, for the year 2027. Following our line of reasoning above, these predictions are identical throughout all scenarios (including the baseline).

We then estimate the change in (predicted) mortality, morbidity and costs for the year 2027 under each of the policy scenarios, while fixing the baseline scenario at exactly the predicted estimates (i.e. zero change). We define the estimated differences (for the year 2027) between the policy scenarios and the baseline as the average annual (17-year lagged) impact of the policy.

We conduct this exercise separately for the following Member States, together encompassing 73.7 percent of the EU population (and 75 percent of all EU lung cancer deaths):

- France
- United Kingdom
- Germany
- Italy
- Spain
- The Netherlands
- Poland.

Our choice of countries for analysis was guided by a number of considerations. First, we prioritised relatively large European countries in an attempt to reflect the experiences of a large proportion of the European population. Secondly, we attempted to cover diversity of trends and levels in mass adoption of tobacco and, consequently, in smoking-related mortality. Thirdly, when given more than one option, we preferred to select the countries with stronger statistical systems and more reliable data.

As a result, our final selection includes the largest countries of Europe, demonstrating significant diversity in trends and level of smoking-related mortality. Central and Eastern Europe is represented here by a single country: Poland. Given the broad similarities of experiences of smoking, epidemic in different Central and Eastern European countries (as demonstrated by Peto *et al.*, 2006), the large size of Poland's population and its developed statistical system,[4] this choice may be considered satisfactory from the point of view of representativeness of a 'regional' picture.

For the remaining 20 Member States (representing 26.3 percent of the EU population and 25 percent of all EU lung cancer deaths), we were not able to predict future mortality, morbidity or costs from smoking in any meaningful way. As a result, we do not report country-specific estimates for these countries.

However, we do include estimates on the burden of tobacco consumption for these countries in the overall EU-27 estimates on mortality, morbidity and costs. For these estimates we made the following assumptions:

- Belgium, Denmark, Ireland, Greece, Cyprus, Luxembourg, Malta, Austria, Portugal, Finland and Sweden will see similar *relative* trends in mortality over the

[4] See country-specific 'Background' and 'Documentation' sections on Human Mortality Database website (http://www.mortality.org/) to form the impression of the quality of mortality and population statistics of different Central and Eastern European countries.

next 17 years as the average of the trends for France, UK, Germany, Italy, Spain and The Netherlands. The absolute number of deaths due to smoking for the year 2007 (to which we apply these relative trends) in each of the former 11 countries is derived from the average of the latter 7, proportional to the number of lung cancer deaths.

- Bulgaria, Czech Republic, Estonia, Latvia, Lithuania, Hungary, Romania, Slovenia and Slovakia will see similar *relative* trends in mortality over the next 17 years to those in Poland. The absolute number of deaths due to smoking for the year 2007 (to which we apply these relative trends) in each of the former 9 countries is derived from the Polish estimate, proportional to the number of lung cancer deaths.

It is important to note that these assumptions relate only to the *relative trends*; that is, for those countries where a lack of data prevented us from estimating country-specific trends we imputed estimated trends of other countries. However, for these countries we still used country-specific lung cancer deaths (for the year 2007), and then applied imputed (relative) trends.

We deliberately did not impute trends for Eastern European Member States based on Western European Member States. Because Poland was the sole country from the eastern part of Europe where we were able to forecast a trend, this inevitably means that the imputation of relative trends for the Eastern European Member States is based on only one country (Poland).

2.3.3 Steps of the approach

We shall now discuss each of the separate steps in the analysis.

Predicting future trends in cause-specific mortality due to smoking

As a first step we conducted country-specific estimates of the number of deaths attributable to smoking. We implemented a method developed by Peto (1992) which has been widely used for estimation of smoking-related mortality.

Application of the method proceeds through the following five stages:

1. Calculation of the number of deaths from lung cancer for each country through the application of the American non-smokers' age and sex-specific lung cancer death rates (from the second wave of the American Cancer Society Cancer Prevention Study) to population figures for each particular country.
2. Calculation of the proportions of smokers and non-smokers in each country, assuming that the observed death rates from lung cancer are a weighted sum of the rates for smokers and non-smokers.
3. Calculation of the proportion of smoking-related deaths in each country (also called an etiologic fraction) for causes other than lung cancer, using the proportion of smokers obtained at a previous step, and cause-specific relative risks of smokers to non-smokers obtained from the American Cancer Society Cancer Prevention Study. It is worth noting that the actual relative risks are halved in this estimation. Halving of relative risks is essentially an arbitrary procedure, but it has been

proposed as a method of producing conservative, rather than inflated, estimates of smoking-related mortality.

4. Calculation of smoking-related deaths in each country from causes other than lung cancer, achieved by multiplying the etiologic fraction by the total number of deaths from a given cause. This procedure renders the number of excess – that is, smoking-related – deaths from these specific causes.
5. Calculation of death rates for mortality attributable to smoking by dividing the number of smoking-related deaths by the average population, for each country.

The method allowed us to obtain death rates for smoking-related mortality for each country at six points in time: 1951–53, 1962–64, 1973–75, 1984–86, 1995–97 and 2005–07.

Further details about the underlying assumptions and application of the estimation method may be obtained from Staetsky (Staetsky, 2009).

As a second step, for each country we fitted a series of estimation curves through six data points, as mentioned above, and extrapolated the trend for two additional 11-year periods. We thereby obtained death rates from smoking-related causes for the years 2018 and 2029, assuming the continuation of the trend observed in the years 1950–2007.

As a final step, we calculated the number of deaths related to smoking expected to happen around the years 2017–18 and 2027–29, provided that the population size and structure in those years remains identical to that for the years 2005–07. Given certain limitations to the historical data, it was not possible to estimate the number of deaths for all countries at the same endpoints. Therefore, our projections for France and the UK apply to the years 2017 and 2027, while those for the other five countries apply to the years 2018 and 2029. In the remainder of the analysis shown in this report we shall refer to the year 2027. Given the great uncertainties inherent in long-term forecasts, we do, however, not expect the two-year time difference to have a substantial impact on our results.

Predicting future trends in morbidity for lung cancer, aerodigestive cancer and COPD

To predict future trends in morbidity due to smoking, we first obtained estimates on current mortality (number of deaths) and morbidity (1-year prevalence) for lung cancer and aerodigestive cancer, for which smoking is a risk factor.

Using the ratio between the one-year prevalence and the number of deaths, we then obtained estimates on prevalence for lung cancer and aerodigestive cancer due to smoking.

Table 2.3 shows for each county the ratios we used for lung cancer and the mortality and morbidity estimates they are based on. Table 2.4 shows the same information for aerodigestive (oesophageal) cancer. Note that in all cases the one-year prevalence is less than the number of deaths. This may be explained by the fact that many people have died within one year after having been diagnosed.

For COPD we used a similar approach, using data from WHO. However, the WHO data on COPD deaths and prevalence are not available for individual countries. Hence, we used the same ratio (COPD prevalence / COPD deaths) for all countries. Because our predictions of future deaths are country specific, we still obtain separate estimates on

COPD prevalence by Member States, even though we assume the ratio between prevalence and deaths is uniform across all Member States.

Unfortunately, we were not able to locate detailed country-specific ratios (between deaths and prevalence) for cardiovascular diseases. Also, since only part of all deaths from cardiovascular disease are caused by smoking, which makes it even more challenging to estimate the prevalence of cardiovascular disease specifically caused by smoking, we did not attempt to estimate morbidity from cardiovascular disease due to smoking. As a result, our morbidity estimates (based on cancer and COPD) are likely to underestimate the total morbidity (including cardiovascular disease) due to smoking.

Table 2.3: Association between lung cancer mortality (annual number of deaths) and morbidity (prevalence)

Country	Mortality	Prevalence	Ratio Prevalence/Mortality
France			
- male	21,760	13,124	0.603
- female	4,465	2,598	0.582
Germany			
- male	29,909	13,714	0.459
- female	9,666	4,520	0.468
The Netherlands			
- male	7,079	3,609	0.510
- female	2,161	1,153	0.534
Italy			
- male	26,990	14,455	0.536
- female	5,788	3,335	0.576
Spain			
- male	16,253	7,710	0.474
- female	1,870	943	0.504
Poland			
- male	16,354	7,569	0.463
- female	3,960	1,873	0.473
United Kingdom			
- male	21,959	7,385	0.336
- female	13,390	4,678	0.349

Source: Globocan 2002 database, retrieved on-line at http://www-dep.iarc.fr/

Table 2.4: Association between aerodigestive (oesophageal) cancer mortality (annual number of deaths) and morbidity (prevalence)

Country	Mortality	Prevalence	Ratio Prevalence/Mortality
France			
- male	3,824	2,705	0.707
- female	722	500	0.693
Germany			
- male	3,316	1,739	0.524
- female	987	223	0.226
The Netherlands			
- male	815	399	0.490
- female	346	166	0.480
Italy			
- male	1,752	938	0.535
- female	499	251	0.503
Spain			
- male	1,577	842	0.534
- female	247	137	0.555
Poland			
- male	1,113	427	0.384
- female	260	85	0.327
United Kingdom			
- male	4,441	1,755	0.395
- female	2,753	1,096	0.398

Source: Globocan 2002 database, retrieved on-line at http://www-dep.iarc.fr/

Predicting future costs

To estimate the costs of smoking in 2027, we applied the most detailed cost estimates related to smoking, broken down by source and disease, available from the literature, a study conducted by Neubauer *et al.* (2006). Because these estimates were only available for Germany for the year 2003, we first extrapolated the estimates to the year 2010, assuming a 3 percent increase in indirect costs and 8 percent increase in direct costs. These inflation factors are consistent with annual increases in GDP (indirect costs) and healthcare expenditure (direct costs) in Germany over the last decade. We expressed all costs relative to the number of cause-specific deaths due to smoking. This latter way of expressing costs allowed us to relate the predicted number of deaths (in the previous step of the analysis) to cost estimates. Table 2.5 (first row) shows the number of cause-specific deaths in Germany due to smoking. Subsequently, the table shows the total estimated costs, broken down by direct/indirect cost and disease. The lower panels of Table 2.5 show these costs expressed on a per-death basis. For example, the total costs of hospital care for neoplasms due to smoking are estimated as 24,312 euros per fatality.

Table 2.5: Costs in Germany related to smoking

	Neoplasms	Cardiovascular diseases	Respiratory diseases
Deaths (2003)	46,315	45,821	22,053
Direct costs (Germany, 2003, x 1 million euro)			
Hospital care	1,126	1,747	663
Ambulatory care	312	853	489
Rehabilitation	112	120	68
Prescribed drugs	144	1,015	647
Indirect costs (Germany, 2003, x 1 million euro)			
mortality	3,436	658	444
morbidity(*)	3,138	2,230	3,476
(*) incl. work days lost and early retirement			
Ratio Direct costs / Deaths (euro, 2003)			
Hospital care	24,312	38,127	30,064
Ambulatory care	6,736	18,616	22,174
Rehabilitation	2,418	2,619	3,083
Prescribed drugs	3,109	22,151	29,338
Ratio Indirect costs / Deaths (euro, 2003)			
mortality	74,188	14,360	20,133
morbidity(*)	67,753	48,668	157,620

Source: (Neubauer, S *et al.*, 2006).

After inflating these costs to 2010, we then extrapolated the German estimates to each of the six other Member States, using the most recent (February 2010) comparative price levels (purchasing power parities) as published by the OECD, shown in Table 2.6. Comparative price levels are defined as the amount of currency units (euros in this case) necessary to buy the same basket of goods in each of the countries.

Table 2.6: Comparative price levels for seven Member States

	Comparative price level (Germany = 100)
France	104
Germany	100
The Netherlands	101
Italy	103
Spain	90
Poland	63
United Kingdom	87
	Comparative price level (Germany = 100)
France	104
Germany	100
The Netherlands	101
Italy	103
Spain	90
Poland	63
United Kingdom	87

Source: (OECD, 2010).

It is important to note that all our cost estimates are expressed in 2010 prices (euros), even though they apply to the predicted 2027 quantities.

Modelling the effect of policies aimed at smoking cessation on mortality

To model the effect of smoking cessation on mortality we made two key assumptions. First, we assumed an average 17-year lag between implementation of (new) smoking cessation policies and noticeable effects on morbidity, mortality and costs. Secondly, we assumed that stopping smoking, at any age, will on average reduce the risk of dying from smoking by one half. Both assumptions are supported by a large body of literature (see: Doll *et al.*, 2004, Kabir *et al.*, 2007). To illustrate these assumptions, suppose new EU regulations would lead to an average 1 percent reduction in the current number of regular smokers across all age groups. In our analysis, this would lead to a 0.5 percent reduction in the predicted mortality, morbidity and costs of smoking by the year 2027.

2.3.4 Limitations

There are several limitations to our estimates. First, our approach aims to take into account existing trends in mortality from smoking. Predicting what will happen in the future, based on extrapolations from the past, may lead to substantial uncertainty in the forecasted estimates, especially when these forecasts are made for several decades into the future. Nevertheless, to understand fully the likely impact of *additional* policies, it is important to take into account the likely effect of *existing* policies, which makes it necessary to build the baseline scenario around current and future mortality.

Because, in our forecasts, mortality is expected to decline substantially over the next two decades for many Member States, our estimates of the burden of smoking (including mortality, morbidity and costs) will be likely to be lower than estimates of the current (2010) or past burden reported in other studies.

Secondly, smoking causes various diseases and for some (especially cardiovascular) diseases it is very difficult to disentangle those deaths caused by smoking from those caused by other factors. Peto's approach (which we adopted in our analysis) is, given data currently available, the state-of-the-art method. This method, however, is based on the assumption that mortality from smoking caused by diseases other than lung cancer may be derived from lung cancer mortality. We do not, however, explicitly test this assumption in this impact assessment.

Thirdly, we assume an average time lag of 17 years between a change in smoking behaviour (prevalence of smoking) and observable effects on mortality, morbidity and costs. This is very much a simplification of reality, because for some diseases (in particular, cardiovascular disease) the lag may be much shorter, and for others (e.g. lung cancer) much longer. The lag will also be likely to differ by age, and be much longer for younger people.

Fourthly, our cost estimates are derived from a single German study. Even though we used purchasing power parities to derive cost estimates for other Member States, these purchasing power parities may not fully capture differences in healthcare costs between Member States. We also assume that healthcare costs are proportional to the number of deaths due to smoking, and that this proportionality is uniform across all Member States.

Fifthly, our mortality estimates are produced on the basis of halved relative risks and are, therefore, of a conservative nature. It is also likely that all subsequent estimates for which the estimates of smoking-related mortality form a base are conservative as a result.

Finally, our morbidity estimates apply to cancer and COPD only, and therefore most probably underestimate the full burden of morbidity (including cardiovascular disease).

2.4 Forecasting future prevalence and modelling macroeconomic impacts

In order to estimate the macroeconomic impacts of a revision to the directive, we employ a four-staged approach. We progress in stages because calculations feed into each other. Specifically, in order to calculate potential impacts, we need to understand first 'what would have been' (in other words, a baseline). To do this, we use previous literature, which provides us with a strategy for how to quantify the relationship between employment and various factors that may influence employment, such as consumer demand and technology.

Once we calculate the potential relationship between employment and other factors, we can then alter the factors (specifically smoking prevalence) and calculate the difference. That is, we use potential changes in consumer demand (due to each measure's potential effect on the attractiveness of tobacco products and potential affect on price) to calculate potential employment. We then examine the difference between the baseline and employment and excise duty collection with the measures.

The stages of the economic impact assessment are therefore as follows:

1. Identify theoretical underpinnings and empirical evidence for econometric model (for employment share).
2. Identify data with relevant variables across Member States and over time and prepare data for estimation.
3. With the prepared data and estimated relationships, forecast consumption to 2027 for employment excise duties collection.
4. Estimate future changes in economic outcomes and excise duties for potential changes in consumption due to measures.

The four-staged approach, illustrated in Figure 2.1, demonstrates how we established an evidence base for our understanding of how to quantify the impacts of tobacco legislation on economic outcomes and how we approached providing quantitative estimates specific to the options currently under review.

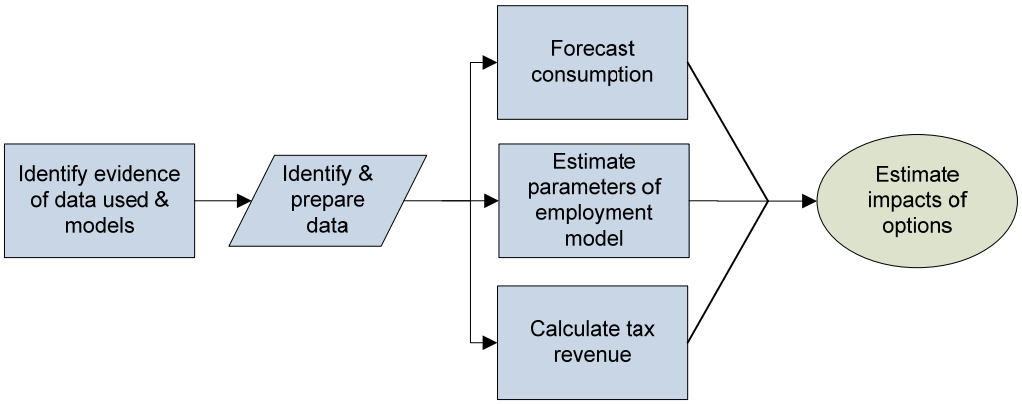


Figure 2.1: Staged approach to estimating economic impacts of options

It should be noted that in the identification and preparation of data, this included calculating healthcare costs that may be passed on to consumers for a particular measure, which may in turn affect prevalence. Furthermore, we use administration costs across all measures for which we obtained data and calculate the potential effect these costs may have on prevalence.

Factors we consider

As for factors in the employment model, we identified the following in the Eurostat 'Structural Business Statistics' (we discuss this data set in further detail below) that are consistent with the theoretical and empirical evidence:

- Firm size: *number of firms in each size category.*
- Labour cost: *average personnel cost per employee.*
- Skilled labour: *apparent labour productivity* (*gross value added per person*).
- Technological progress: *capital investment.*
- Consumer demand: *proportion of daily smokers in the population aged 15+.*

We consider the relationship between these factors and the share of employees, or the number of employees in a tobacco sector / total number of employees.

For calculating the effect that changes in prevalence may have on excise duty collections, we use tobacco consumption excise duties provided by the Directorate-General for Taxation and Customs Union (DG TAXUD). We develop a series of scenarios since there are uncertainties about how excise duty collections may change in the future. As a first scenario, we consider that the previous (median) annual rate of change in excise duty collections continues into the future. We also consider that prevalence starts to have more of an influence on excise duty collections by adding the rate of change in prevalence to the previous (median) annual rate of change in excise duty collections.

Data

In order to estimate the model for employment and calculate excise duty collections, we utilise data from Eurostat, DG TAXUD, WHO and OECD. These data sets are

particularly useful for quantitative analysis of Member States because the data are relatively harmonised and available for most of the EU countries over a number of years.

The key variable of interest in this macroeconomic modelling is the effect that the measures may have on prevalence. The data for the consumer demand proxy (i.e. smoking prevalence) come from the OECD and WHO. The demand factor is used to understand how variation across countries over time, in terms of proportion of smokers, affects the number of persons employed in a sector of the tobacco industry. The factor is, specifically, the proportion of daily smokers in the age 15+ population.

For employment factors, the data are available from Eurostat for Member States' businesses over time. Eurostat provides harmonised data in the section named 'Structural Business Statistics' (SBS). Eurostat SBS provides information for Member States from 1997 onwards by industry sectors, identified through Statistical Classification of Economic Activities in the EC (NACE) code.[5] It is worth noting that we perform three separate analyses for each of the sectors, namely manufacturing (NACE code 16), wholesale of manufactured tobacco (NACE code 51.35) and retail sales of tobacco products (NACE code 52.26). We discuss the reason for choosing these sectors in more detail in later chapters.

2.5 Assessing administrative burden

Whenever a policy measure might impose a significant administrative burden, the EU impact assessment guidelines prescribe an assessment of this burden (European Commission, 2009). The particular structure of the tobacco industry, with very few companies dominating the market for manufactured cigarettes, as well as the scope of this study, made it necessary to deviate from the standard cost modelling approach foreseen by the impact assessment guidelines and instead to follow a tailored approach to administrative burden measurement.

To assess the administrative burden and compliance costs of the baseline scenario as well as each proposed option, RAND Europe therefore consulted tobacco manufacturers and retailers throughout Europe and surveyed the relevant academic publications as well as government publications. Our understanding of administrative burden and compliance cost, as well as the methodological steps, were informed by the EC's impact assessment guidelines, impact assessments undertaken internationally and academic literature.

For assessing the administrative burden and compliance costs associated with the baseline and the alternative policy options for both manufacturers and retailers a structured process was followed. It consisted of the following:

1. Clarification of issues of interest based on the literature.
2. Data collection:
    a. literature review;
    b. formulation of cost questionnaire questions;

[5] NACE, the Statistical Classification of Economic Activities in the EC, is a standard nomenclature used to categorise economic activities.

   c. clarification of the questions with stakeholders, both manufacturers and retailers;
   d. sending out questionnaires.
3. Data analysis:
   a. deriving per company estimates both for manufacturers and retailers;
   b. scaling up to the EU level;
   c. collating results with the literature.

In the following, we shall discuss each step of the analysis in greater detail. In addition, we shall review the main limitations of the approach followed. This section spells out only the general themes of the data collection and analysis in terms of assumptions, procedures followed and potential criticism towards the results. The specific issues are discussed under each point.

1. Clarification of key issues

First, each potential regulatory measure was analysed and explored, based on academic and government literature. This led to an understanding of the potential costs and benefits for the industry as well as the identification of the stakeholders who would have to bear the costs or enjoy the benefits.

2. Data collection

Secondly, data were collected by reviewing the literature such as UK impact assessments and by surveying the manufacturers as well as the retailers in the EU. The review of the literature highlighted the data gaps – that is, the impacts of the potential regulatory measures for which data collection from the European industry is indispensible for meaningful quantitative analysis to take place. Our data collection exercise aimed at allowing all stakeholders to express their views and provide data. In spite of our best efforts, only a small set of stakeholders provided input for this report (Table 14.3).

RAND Europe developed the initial cost questionnaire of open-ended questions based on our understanding of potential costs and benefits. For example, from the academic literature and the relevant impact assessments, it was clear that labelling changes occur for regulatory as well as non-regulatory reasons (e.g. marketing); thus questions were formulated which gauged how often tobacco manufacturers change the label on cigarette packs for non-regulatory reasons and what the overall number of these changes is.

This initial cost questionnaire was piloted using semi-structured interviews with manufacturers as well as with retailer associations, which then informed the development of a final questionnaire that was applied to all stakeholders (questionnaires may be found in Appendix C). Based on this evidence, a questionnaire of open-ended questions was finalised and sent to a range of tobacco manufacturers and retail organisations initially identified by DG SANCO and extended by RAND Europe to assure a robust evidence base (Table 14.3).

The final sample of responses cannot be taken as a representative sample of the whole population of stakeholders. In the case of cigarette manufacture essentially all the relevant actors provided data, covering close to 100 percent of the EU-27 market. However, in the case of cigar manufacturers, manufacturers of other tobacco products and retailers, only a

self-selected group of companies and associations provided data (associations' responses were treated as being representative of their members' responses). We could not assure the sufficient coverage of all EU Member States or regions. Central and Eastern Europe are largely underrepresented in our sample. Approximately one month's time was allowed for respondents to compile their responses and send them back to RAND Europe, which proved to be sufficient time in most instances.

Unfortunately, the large tobacco manufacturers were not willing to provide estimates about potential future administrative costs and therefore refused to provide answers to a large number of questions. Instead, they provided information about the administrative burden of the current regulation.

3. Data analysis

Thirdly, data were aggregated for each group of stakeholders: 1) cigarette manufacturers, 2) cigar manufacturers, 3) other tobacco product manufacturers (e.g. smokeless tobacco, RYO) and 4) tobacco retailers. For each of these groups, the company-level administrative burden and compliance cost estimates were obtained, if data allowed for this. Initial costs and yearly ongoing costs were separately reported.

The overall costs for the whole EU-27 were reached by scaling up the company-level estimates. For manufacturers, scaling up was based on the market shares of companies (i.e. sales volumes), which rests on the assumption that costs are proportionate to company size. For retailers, scaling up was based on number of premises. In both cases, for scaling up the lowest cost per company solution was taken as the basis for scaling up. Nevertheless, it must be noted that the data did not allow the determination of whether some companies were more efficient than others or whether their cost differentials were economically justified (e.g. cost differences due to different member price levels).

Per company as well as overall EU, cost estimates were directly compared to impact assessments done internationally to check for data reliability.

All data were calculated and reported in 2009 euros.

Net present value of each option regarding administrative burden and compliance cost was calculated for the time period: 2009–27, and 2009 was taken as the base year. From the range of EU-27 estimates the lowest estimate was always used by assuming that the regulation would use the least-cost version and that the most cost-efficient solution would be adopted across the EU.

4. Limitations

As a result of this analytical approach and data collection, a number of potential problems will be highlighted which may have led to imprecision or overestimation of costs:

1. *Problems with the sample:* RAND Europe's industry sample is not representative even though almost 100 percent of tobacco manufacturers in Europe provided data and cigar manufacturers captured by the sample account for more than 30 percent of the overall EU market. Due to the large proportion of non-response to specific questions on the questionnaire, many estimations are based on a small number of company responses; in some cases only one company provided a quantitative estimate.

2. *Sufficient level of detail of costs:* Often the respondents only provided overall cost figures even though the questionnaire elicited a detailed cost break-down. Thus, for example, disentangling the labour costs of transmitting different types of information (e.g. TNCO yields, other test results, toxicological data) was impossible due to the high level of aggregation of the data received. In such cases other companies' average cost structure was used to assign aggregate costs to cost categories. Nevertheless, estimations based on overall cost data reported by the industry without detailed cost break-down decrease the precision and reliability of the estimations and our ability to collate and check results. It is thus not unlikely that the reported data overestimate the actual costs incurred by industry.
3. *Large variation in responses:* Per company estimates of the same compliance cost or administrative burden categories showed large discrepancies across companies, which we could not substantiate due to lack of detailed cost break-down. As a consequence, it is unclear whether these differences are due to different company characteristics or to differences in the quality of the data reported.
4. *Hypothetical scenarios:* The potential additional administrative burden and compliance cost associated with some measures were estimated on the basis of hypothetical scenarios as no historical data were available. This implies that *ex ante* cost estimates are imprecise and learning effects are difficult to establish, most likely leading to overestimated costs.
5. *Incentives:* It is likely that the tobacco manufacture and retail industries are motivated to disclose higher than actual cost figures, which would decrease the probability of additional regulation being imposed on them. This is underlined by the fact that the tobacco industry's self-reported data were always higher than the available direct comparators based on more detailed data collection in similar products (e.g. food labelling).
6. *Assumptions of scaling up:* EU-level cost may be overstated as several cost elements may not be proportionate to company size. For example, larger companies may be able to reap the benefits of economies of scale. Moreover, least cost per company may not be feasible for companies in some Member States for reasons specific to each Member State (e.g. price level of inputs).

RAND Europe aimed to counteract the methodological problems by gauging their presence in two ways:

- Comparing results to other estimates, in particular other impact assessments.
- Comparing results with each other – that is, checking for internal consistency.

2.6 Comparing measures and options

Finally, RAND Europe compiled the evidence collected in a number of overview tables per area of change and policy option. To facilitate the comparison between measures and options combining quantitative and qualitative information, we employed a comparative

framework which combines a basic multi-criteria analysis[6] along the impact categories previously identified using a scoring mechanism (see e.g.: European Commission, 2009). This approach allows us to compare the policy options by using at least some kind of standard measure, without losing the richness of the qualitative assessment. The framework summarises the evidence discussed in the previous chapters and the likely impact of each policy option, and attributes a certain assessment of the impacts to each policy option. We used the following scoring system:

++	Evidence of substantial additional health/economic/social benefits compared to the status quo.
+	Evidence of some additional health/economic/social benefits compared to the status quo.
≈	Evidence of no additional health/economic/social benefits compared to the status quo.
–	Evidence of some reduction in health/economic/social benefits compared to the status quo.
--	Evidence of substantial reduction in health/economic/social benefits compared to the status quo.
( )	Parentheses indicate that there is only a weak evidence base, even if a specific effect may be expected.
+/–	Indicates uncertainty about whether positive or negative effects may be expected, reflecting the different forecasting scenarios used.

2.7 Types of impacts assessed

The impact assessment guidelines prescribe that each proposal should assess the social (including health), economic and environmental impacts of proposed policy options. In line with the proportionality principle of conducting an impact assessment, we decided to focus the analysis of this report on the economic and health impacts, rather than systematically assessing the environmental impacts. This decision was taken after an initial scan of the literature showed some negative environmental impacts of smoking, but also that it would not be easy to assess different effects for different options. The overview of environmental impacts may be found in Appendix D.

[6] A multi-criteria analysis compares the positive and negative impacts of different policy options expressed in a mixture of qualitative, quantitative and monetary terms, and is one of the options proposed by the EC in summarising the evidence of impact assessments.

CHAPTER 3 Background for tobacco use and its health effects

3.1 Introduction

This chapter provides a summary analysis of some of the key trends in tobacco use in the EU and of the health effects that have been attributed to tobacco use.

In attempting such an analysis it is essential first to understand the challenges in measuring tobacco use. A variety of measures have been put forward in the academic literature (Hublet *et al.*, 2006), but it is most common either to measure tobacco use with consumption data, such as cigarettes per capita or grams of tobacco per capita, or else through measures of smoking prevalence. The most common method used to gather data on smoking prevalence is the survey. Surveys employ various definitions of 'current smokers' (daily and/or occasional smokers), age groupings sampled and whether or not institutionalised populations are included, and also use different sampling methodologies. In addition, some may use telephone interviews, some face-to-face interviews, and so on. Comparability is additionally challenged by the design and implementation of the surveys. The data on tobacco use obtained through surveys are influenced by response rates, the population sample, the questions and options given, the survey context, people's understanding of the questions asked in the survey and the social acceptability of smoking. Few surveys are validated using cotinine data. These differences are not only relevant across geographical areas, but also over time within countries. Consumption data, often expressed as numbers of cigarettes per capita or grams of tobacco consumed, are usually calculated from different official statistics, such as trade or tax statistics – however, again with differences in definitions and data sources between countries and years. One particular weakness of consumption data is that they exclude illicitly traded tobacco.

Recognising the challenges in a cross-national comparison of tobacco use, this analysis draws on two main data sources; the most recent Eurobarometer surveys (2009, 2010) on tobacco are used to provide a snapshot of current levels of tobacco use, and WHO's European Health for All database (HFA-DB) forms a basis for a discussion of trends over time.[7] The HFA-DB contains both consumption and prevalence data, and compiles national survey data as well as data from official national statistics on production, import and export of tobacco products. Despite efforts being made to harmonise definitions of key

[7] European Health for All database (HFA-DB). Copenhagen, WHO Regional Office for Europe, 2009 (http://www.euro.who.int/hfadb).

concepts, the HFA-DB data are still subject to differences in these definitions between countries and to changes of methodology between years. Comparisons between countries and short-term fluctuations of prevalence and consumption should therefore be interpreted with care. Nevertheless, these data are useful for a description of longer term trends. Unfortunately, neither the prevalence data nor the consumption data are comprehensive for the last 30 to 40 years, with the result that the trend data presented in the figures below use consumption data until 2000, and prevalence data only from 1990 onwards. As the methodology of Eurobarometer is more tightly controlled, and the data are more recent, this chapter also uses Eurobarometer data to provide a snapshot of current consumption patterns. A weakness of the Eurobarometer surveys which should be borne in mind is their relative low sample sizes per country.

3.2 Tobacco use in the EU

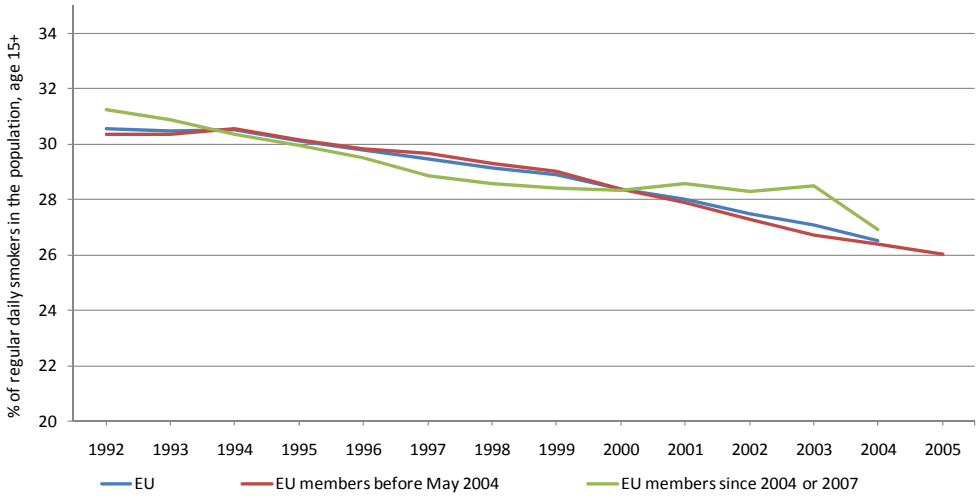
In this first section we describe current patterns and past trends in tobacco use across the EU. We first look at the EU as a whole, before examining differences between Member States and disaggregated data by gender, age and socioeconomic status.

3.2.1 Smoking prevalence is declining in the EU

The health and economic effects of tobacco use are linked to both the number of people in a population who use tobacco, and the amount that each person consumes. Thus, both smoking prevalence (the proportion of the population smoking tobacco at a given point in time) and consumption (the amount consumed per person) provide evidence of tobacco use in the EU-27. In 2009, 29 percent of the population who were 15 years or older across the EU-27 stated that they were current smokers, with an additional 22 stating that they had previously smoked but had now quit (Eurobarometer, 2010). Looking at the type of product used and frequency of smoking, we find that most smokers smoke every day; and that in particular manufactured cigarettes are used on an everyday basis, while cigars, pipes and water pipes are mainly used on an occasional basis (see Figure 3.9).

The proportion of the population affected by tobacco increases when accounting for the number of people exposed to second-hand smoke; in 2009 14 percent of non-smokers and 23 percent of smokers were exposed to second-hand smoke in their homes on an almost daily basis (Eurobarometer, 2009).

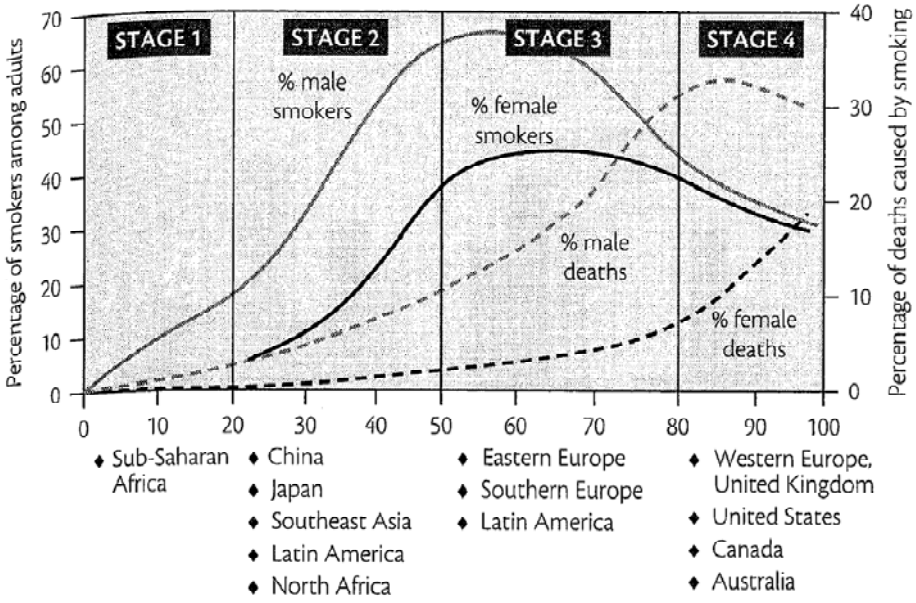
If we look at changes in prevalence over time, data across the EU suggest a decline in smoking prevalence over the last 15 years among both EU-15 and EU-12 (Figure 3.1). This indeed reflects a wider and longer term trend of reduction in smoking prevalence that may be observed since the 1980s (see also Figure 3.4 to Figure 3.7) (Asma *et al.*, 2009).



SOURCE: (WHO, 2010)

Figure 3.1: Trends of smoking prevalence across EU, 1992–2005. Percentage of regular smokers in the population, age 15+

In understanding changes in prevalence and consumption of tobacco use over time, (Lopez *et al.*, 1994) provide a widely accepted descriptive model for population-level tobacco use. Examining prevalence and mortality attributable to smoking, they describe a four-stage tobacco epidemic from the initial rise in smoking in a country's population to an eventual decline in smoking prevalence and smoking-related mortality. The four stages correspond to the initial rise of smoking prevalence among men, followed by women, and the delayed rise in smoking-related mortality among men, again followed by women. On the whole, EU Member States appear to have already peaked in smoking prevalence among the total adult population; in general, smoking is declining in Member States, although at different rates and with variation from year to year (WHO, 2007b). Mapped against Lopez's model, most Member States may be thought of as falling in stages 3 and 4 of the model, with Eastern European Member States following the same development patterns as the old Member States and consequently also moving towards stage 4 (see Figure 3.2). However, it is worth noting that this model was developed on the basis of data from the West and it has been shown that the way the epidemic developed outside the West may not be identical. The former Soviet Union and Eastern Europe provide a case in point as female smoking in some countries did not follow on as quickly from male smoking as it did in the West. In addition, rates of smoking among men remained high for decades (and in some countries are still high), rather than declining after a peak as the model would predict (Gilmore *et al.*, 2004).



SOURCE: (Lopez *et al.*, 1994) cited in (Asma *et al.*, 2009)

Figure 3.2: The four-stages model of the tobacco epidemic

3.2.2 Differences among Member States

The proportion of current tobacco users varies considerably among Member States. In 2009 smoking prevalence (regular or occasional tobacco users) was as high as 42 percent in Greece, followed by 39 percent in Bulgaria, to as low as 21 percent in Finland and 16 percent in Sweden (see Figure 3.3). Sweden, however, presents somewhat of a special case as oral tobacco use constitutes a substantial share of tobacco consumption and smoking prevalence is thus not a good indicator of overall tobacco use.

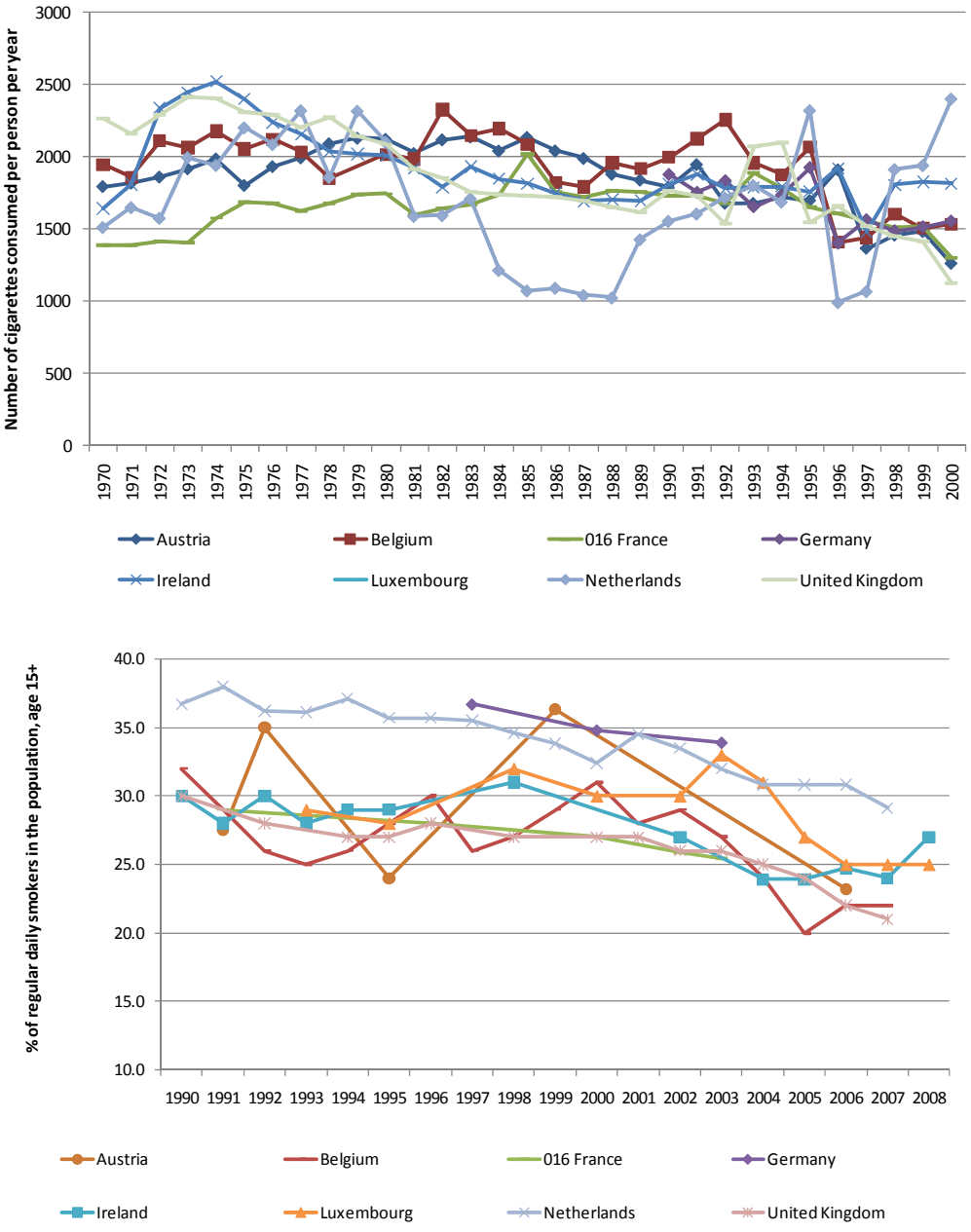
Source: (Eurobarometer, 2010) Question QD1: Regarding smoking cigarettes, cigars or pipe, which of the following applies to you?

Figure 3.3: Smoking prevalence across Europe, Eurobarometer (2009)

On looking at smoking prevalence and cigarette consumption in EU-15 countries over the past 30 years, we may observe an overall reduction in both, although there are certain fluctuations in some Member States (see Figure 3.4 to Figure 3.7). However, to some degree these may be due to methodological changes, rather than being a reflection of year-by-year variations. Varied and patchy data exist about smoking prevalence among the new Member States prior to the mid-1990s. Judging from the data available, most of the EU-10 now exhibit a similar trend of decline in smoking prevalence to that in the old Member States. Looking at the prevalence data from 1990 to 2008 (where available), we see declines of prevalence in almost all Member States.

Though the overall direction of change in smoking prevalence shows a decrease over time in the proportion of the adult population that smokes among EU-27 Member States, there is less convergence in the consumption of cigarettes at least until 2000, the last year with comprehensive data for the EU-27.[8]

[8] WHO data on cigarette consumption per capita for EU-15 Member States dates back to 1970 and are available from around 1993 for the new Member States.

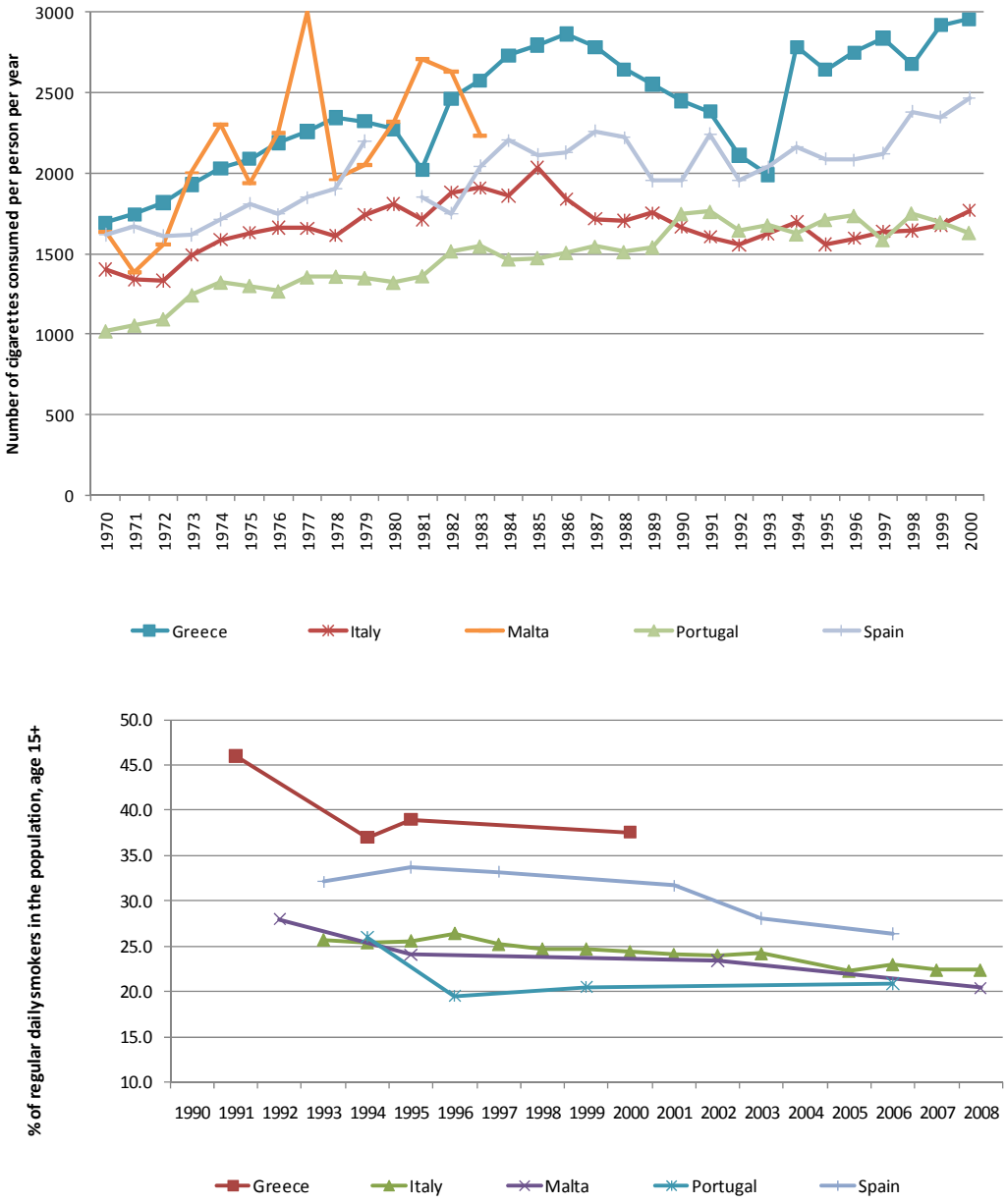


Source: (WHO, 2010)

Figure 3.4: Trends in tobacco use in West European Member States
Upper panel: per capita consumption of cigarettes, 1970–2000
Lower panel: percentage of regular daily smokers in the population, age 15+, 1990–2008

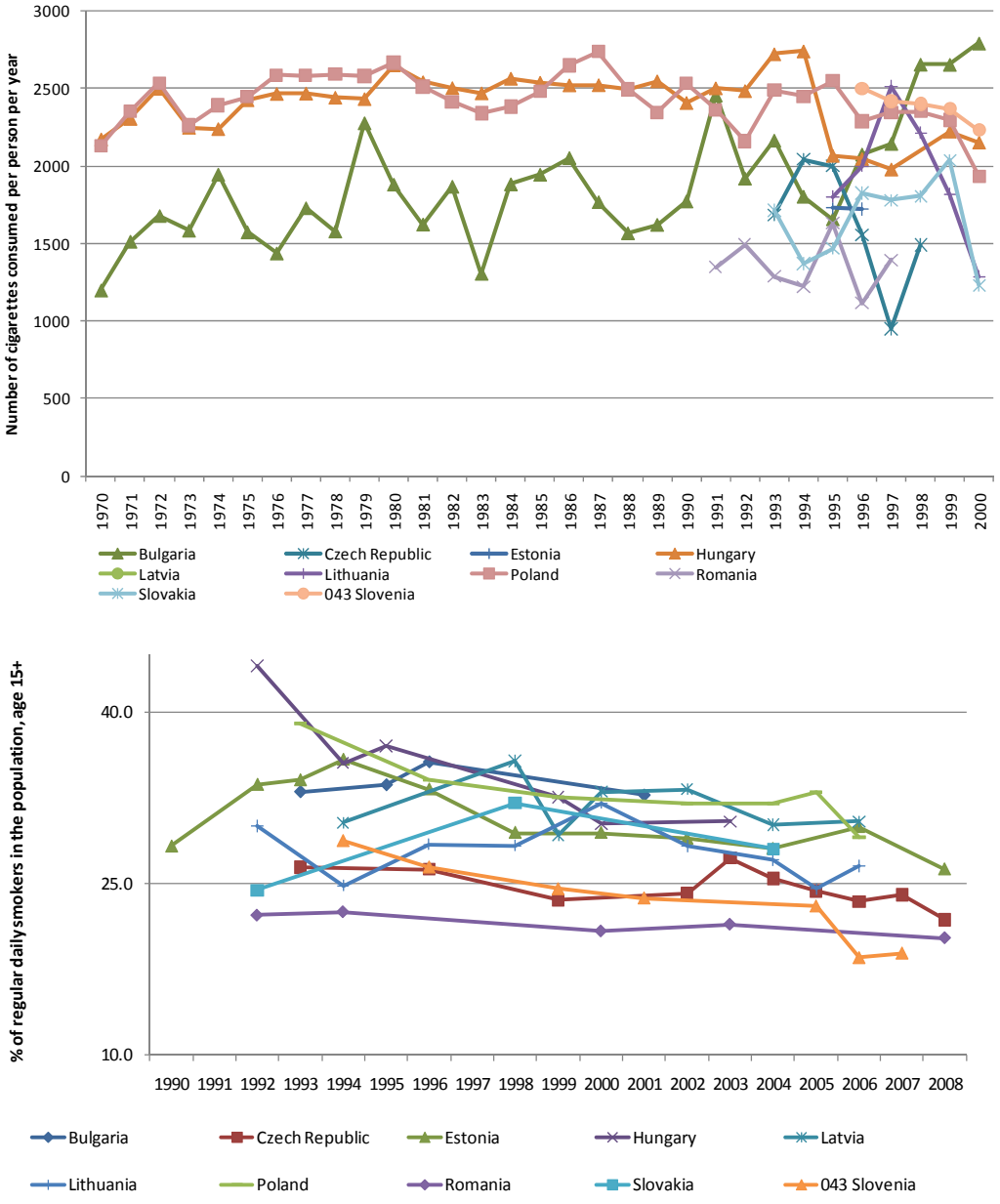
Source: (WHO, 2010)

Figure 3.5: Trends in smoking prevalence in Nordic Member States
Upper panel: per capita consumption of cigarettes, 1970–2000
Lower panel: percentage of regular daily smokers in the population, age 15+, 1990–2008



Source: (WHO, 2010)

Figure 3.6: Trends in smoking prevalence in South European Member States
Upper panel: per capita consumption of cigarettes, 1970–2000
Lower panel: percentage of regular daily smokers in the population, age 15+, 1999–2008



Source: (WHO, 2010)

Figure 3.7: Trends in smoking prevalence in East European Member States
Upper panel: per capita consumption of cigarettes 1970–2000
Lower panel: percentage of regular daily smokers in the population, age 15+, 1990–2008

3.2.3 Smoking prevalence among men and women

Over the past 30 years, tobacco use has remained more prevalent among men than women in the EU-27. In 2009 32 percent of men compared to 21 percent of women smoked daily, with 6 percent of men and 5 percent of women smoking occasionally (Eurobarometer, 2009). Comparing the data contained in the HFA-DB (see Table 3.1 toTable 3.3), we can see that prevalence rates for men are higher than those for women in all Member States except Sweden. In Sweden the sex ratio for smoking prevalence was inverted in the late 1990s, and a greater proportion of women than men smoked tobacco since that time. This is often attributed to an increased use of oral tobacco (*snus*) by males (Foulds *et al.*, 2003). Nevertheless, some Member States have fairly similar rates between men and women, most notably the UK and Ireland. The largest differences in smoking rates may be found in the new Member States, notably the Baltic countries and Romania; however, data availability is not good for these countries.

Table 3.1: Highest and lowest percentages of current male daily smokers

Countries	2000	2001	2002	2003	2004	2005	2006	2007	2008
Austria							27.3		
Belgium	36	34	33	30	28	23	29	25	
Bulgaria		43.8							
Cyprus				38.1					
Czech Republic			30.9	32.2	31.1	29.6	27.7	29.6	24.9
Denmark	32	33.5	30.5	31	29	28	26	28	
Estonia	44.1		45		42		40.9		38.6
Finland	27	29	27.5	25.7	27.1	26	24.4	25.8	24
France	33		30.6	30					
Germany	38.9			37.1					
Greece	46.8								
Hungary	38.2			36.9					
Ireland			28		24.2	24.2	24.7	24.8	28
Italy	31.9	31.6	31.3	31.4		28.7	29.2	28.6	28.9
Latvia	51.3		51.1		47.3		46.6		
Lithuania	51.5		43.7		39.4	42.1	43.4		
Luxembourg	34		35	39	36	32	29	28	29
Malta			29.9						25.6
Netherlands	35.9	38.9	37.9	35.8	35.1	35.4	35.5	32	
Poland			40		38	42	37		
Portugal							30.8		
Romania	32.3			33.2					32.1
Slovakia									
Slovenia		28				24	21.4	22.4	
Spain		39.2		34.2			31.6		
Sweden	16.8	17.9	16.3	16.7	15	13.9	12.3	12.8	
United Kingdom	29	28	27	28	26	25	23	22	

* To ease readability colours indicate the level of smoking prevalence from low (green) to high (red)

Empty cells = no data available

Source: (WHO, 2010)

Table 3.2: Highest and lowest percentages of current female daily smokers

Countries	2000	2001	2002	2003	2004	2005	2006	2007	2008
Austria							19.4		
Belgium	26	22	25	25	20	16	16	19	
Bulgaria		23							
Cyprus				10.5					
Czech Republic			18.1	22.6	20.1	19.4	19.5	18.8	18.6
Denmark	29	25.5	26	25	23	24	23	21	
Estonia	19.9		17.9		21		19.5		17.1
Finland	20	20	19.9	19.3	19.5	18.2	18.9	16.6	17.6
France	21		21.5	21.2					
Germany	30.6			30.5					
Greece	29								
Hungary	23			24.6					
Ireland			26		23.6	23.6	24.7	23.2	26
Italy	17.4	17.1	17.2	17.6		16.4	17.2	16.6	16.4
Latvia	18.2		19.2		17.8		18.2		
Lithuania	15.8		12.8		14.2	9.8	14.5		
Luxembourg	26		25	26	26	22	21	22	21
Malta			17.6						15.8
Netherlands	29.2	30.2	29.2	28.4	26.7	26.3	26.2	26.3	
Poland			25		25.6	25	23		
Portugal							11.8		
Romania	10.1			10.3					9
Slovakia									
Slovenia		20.1				22	16	15.5	
Spain		24.6		22.4			21.5		
Sweden	21	19.9	19.3	18.3	17.5	18	16.7	14.9	
United Kingdom	25	26	25	24	23	23	21	20	

*To ease readability, colours indicate the level of smoking prevalence from low (green) to high (red)

Empty cells = no data available

Source: (WHO, 2010)

Table 3.3: Difference in percentages of current male and female daily smokers (male daily smokers minus female daily smokers)

Countries	2000	2001	2002	2003	2004	2005	2006	2007	2008
004 Austria							7.9		
007 Belgium	10	12	8	5	8	7	13	6	
009 Bulgaria		20.8							
011 Cyprus				27.6					
012 Czech Republic			12.8	9.6	11	10.2	8.2	10.8	6.3
013 Denmark	3	8	4.5	6	6	4	3	7	
014 Estonia	24.2		27.1		21		21.4		21.5
015 Finland	7	9	7.6	6.4	7.6	7.8	5.5	9.2	6.4
016 France	12		9.1	8.8					
018 Germany	8.3			6.6					
019 Greece	17.8								
020 Hungary	15.2			12.3					
022 Ireland			2		0.6	0.6		1.6	2
024 Italy	14.5	14.5	14.1	13.8		12.3	12	12	12.5
027 Latvia	33.1		31.9		29.5		28.4		
028 Lithuania	35.7		30.9		25.2	32.3	28.9		
029 Luxembourg	8		10	13	10	10	8	6	8
030 Malta			12.3						9.8
033 Netherlands	6.7	8.7	8.7	7.4	8.4	9.1	9.3	5.7	
035 Poland			15		12.4	17	14		
036 Portugal							19		
038 Romania	22.2			22.9					23.1
042 Slovakia									
043 Slovenia		7.9				2	5.4	6.9	
044 Spain		14.6		11.8			10.1		
045 Sweden	-4.2	-2	-3	-1.6	-2.5	-4.1	-4.4	-2.1	
052 United Kingdom	4	2	2	4	3	2	2	2	

*To ease readability colours indicate the difference in smoking prevalence from low (light blue) to high (dark blue)

Empty cells = no data available

Source: (WHO, 2010)

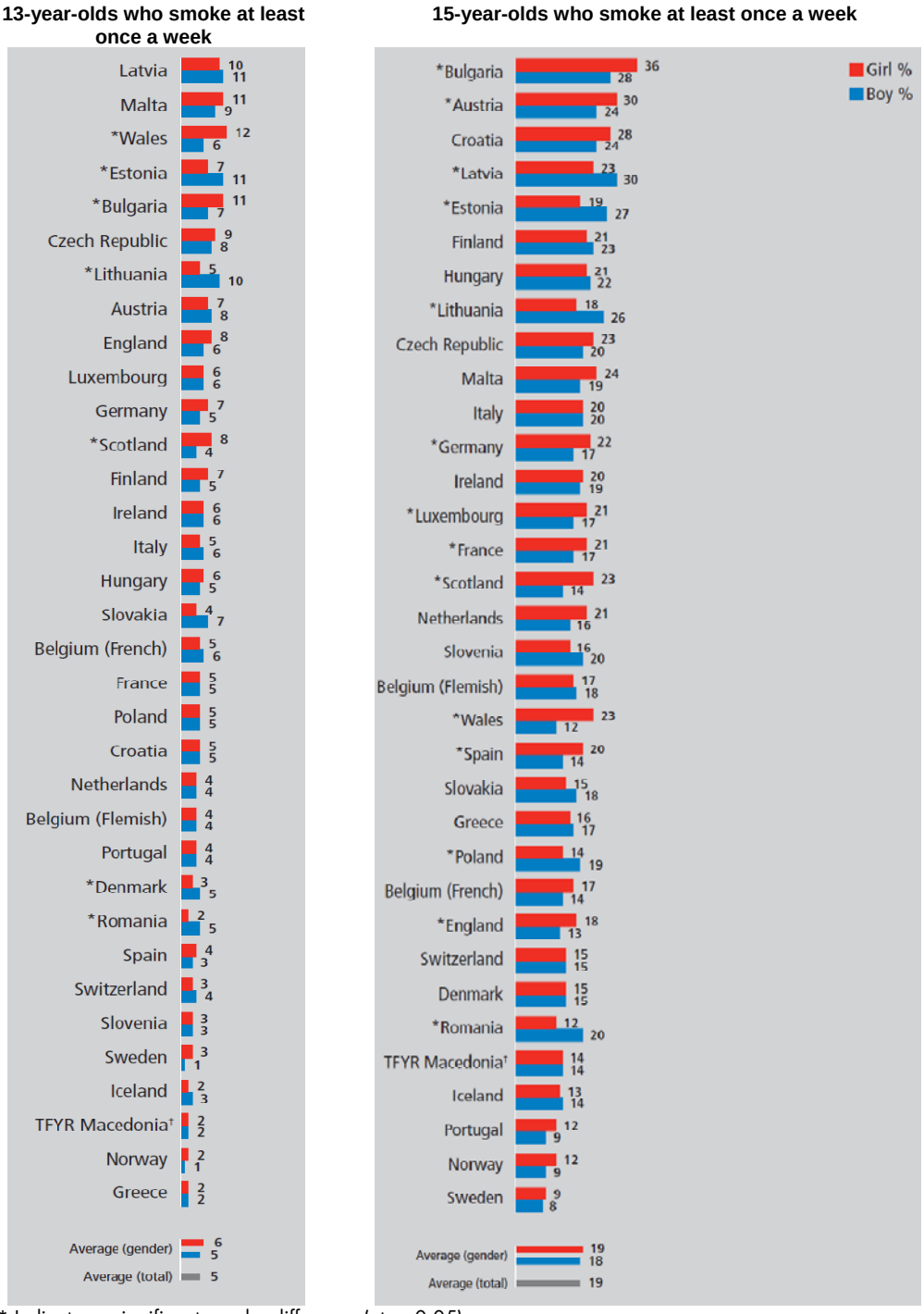
3.2.4 Young smokers

Smoking often begins during adolescence and then continues into adulthood, so that current adolescent smokers are likely to continue smoking into adulthood. Hublet *et al.* (2006) find that the younger a person is when they take up smoking, the higher the risk of habitual smoking during adulthood. To analyse smoking among adolescents, we used data reported by WHO (WHO, 2008b, 2009b), based on the Health Behaviour in School-aged Children (HBSC) survey project.[9]

In absolute levels, smoking prevalence tends to be slightly higher among girls than boys in the EU-27 as a whole. In 2005 this was true for most of the EU-15 countries among girls and boys aged 15 years. As is the situation regarding adult populations, the situation among youth is more varied in the new Member States. While some display a slightly higher prevalence of smoking rates among girls (e.g. Bulgaria and Czech Republic), most of them display higher prevalence rates among boys than girls; this is the case in Poland,

[9] For details of the HBSC survey see http://www.hbsc.org (accessed April 2010)

Latvia, Lithuania, Hungary and Estonia. If these countries follow tobacco consumption patterns evident in the EU-15, it is likely that tobacco use will become increasingly prevalent among girls (see Figure 3.8).



* Indicates a significant gender difference (at p<0.05)

Source: (WHO, 2009b), using HSBC survey data

Figure 3.8 Adolescents (between 13 and 15 years old) who smoke at least once a week (2005/06)

Between 1997 and 2005 smoking prevalence levels have diverged among 15-year-olds in the EU-27. As Table 3.4 shows, the situation is varied in the EU as a whole. Variations between countries mean that some have a falling smoking prevalence among girls and boys, some have an increasing smoking prevalence among both sexes, and some have declining prevalence for boys with increasing prevalence for girls. From 1993 to 2005 no country has recorded a continuous decline in girls' smoking prevalence. This may reflect the observation by Hublet *et al.* (2006) that girls tend to be less responsive than boys to current recommended tobacco control policies.

Table 3.4: Change in prevalence of smoking among boys and girls, 1997–2005

Decline in prevalence for both boys and girls, aged 15 years	Increase in prevalence for both boys and girls, aged 15 years	Decline in prevalence for boys and increase in prevalence for girls, aged 15 years
Denmark	Czech Republic	Austria
Finland	Estonia	Germany
France	Lithuania	Hungary
Greece	Slovakia	Portugal
Ireland		
Latvia		
Poland		
Sweden		

Source: Based on Hublet *et al.* (2006)

3.2.5 Socioeconomic differences

Inequalities in smoking prevalence between socioeconomic groups vary between EU-27 countries. Among all socioeconomic groups, individual cigarette consumption is estimated to average between 15 and 30 cigarettes a day, with consumption levels corresponding to factors affecting affordability (Lopez *et al.*, 1994). At a population level, smoking prevalence also varies between socioeconomic groups, changing in relative levels at different stages in the tobacco epidemic.

Lopez *et al.* (Lopez *et al.*, 1994) suggest that as countries progress through the tobacco epidemic, smoking prevalence will become more prominent among lower socioeconomic groups. At stage 2 in the epidemic, smoking prevalence is similar among all socioeconomic classes and potentially even higher among higher socioeconomic groups; this situation changes in stage 3 and stage 4, when there are greater declines in prevalence among higher socioeconomic groups. As the UK, Ireland, Sweden and Finland were among the first to enter the tobacco epidemic, it is expected that the inequalities in prevalence by socioeconomic group will be more pronounced there than in those countries entering the epidemic later, such as Spain and Portugal. Mackenbach *et al.* (2008) find that the relative index of inequality in current smoking by education, occupation and income is smallest in countries in Southern Europe; for instance in the Basque country of Spain there is little difference in the prevalence of smoking among lower and higher socioeconomic groups. When differentiating by sex, Portugal, Spain, Italy, Lithuania and France even show a negative index of inequality among women. Levels of inequality in current smoking prevalence are also small between men and women in new Member States, though inequalities in mortality remain high in new Member States, particularly among men.

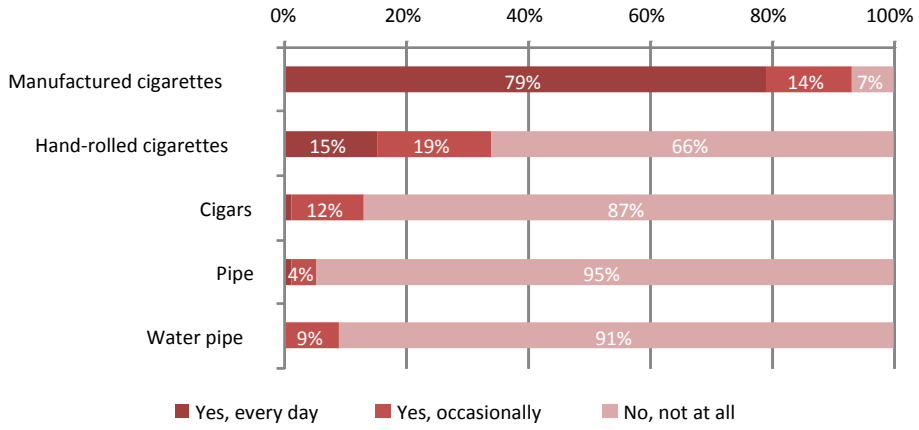
Table 3.5: Countries with the highest relative inequality of smoking between lower and higher socioeconomic groups (occupation, income and education)

Highest relative inequality among men (descending order)[10]	Lowest relative inequality among men	Highest relative inequality among women	Lowest (negative) inequality among women
1. Norway	1. Portugal (negative)	1. Slovenia	1. Portugal
2. England	2. Hungary (negative)	2. England	2. Spain
3. Czech Republic	3. Italy	3. Norway	3. Italy
4. Ireland	4. France	4. Finland	4. Lithuania
5. Sweden	5. Spain	5. Ireland	5. France

Source: (Mackenbach *et al.*, 2008)

3.2.6 Use of different tobacco products

Though the use of tobacco products other than cigarettes is low among EU-27 countries apart from Sweden, there are a variety of tobacco products on the market, as shown by recent Eurostat data (Eurobarometer, 2010). Manufactured cigarettes are the most commonly used product, followed by hand-rolled cigarettes and cigars (see Figure 3.9).



Source: (Eurobarometer, 2010) Question 3a: Do you use the following tobacco products every day, occasionally or not at all? (smokers only)

Figure 3.9: Smoking of different tobacco products within the EU-27

Tobacco products may be divided into tobacco that is: 1) rolled, combusted and smoked; 2) heated but not combusted; and 3) not heated or combusted 'smokeless tobacco'.

[10] Finland, Sweden, Denmark, UK, Ireland, Belgium, Germany, France, Italy, Spain, Portugal, Slovenia, Hungary, Czech Republic, Slovakia, Poland, Lithuania, Latvia, Estonia; missing EU-27 countries: Greece, The Netherlands, Luxembourg, Austria, Cyprus, Malta, Bulgaria, Romania.

Combustible forms of tobacco

In addition to manufactured cigarettes, smoking tobacco is found as RYO, Kretek (clove-flavoured cigarettes from Indonesia, made out of *brus*), Bidis (sun-dried tobacco wrapped in a tendu leaf), cigars, pipes (including clay pipes and chutta, Indian home-made cigars) and cheroots.

The use of hand-rolled cigarettes or RYO is more common in the EU-15 (39 percent smokers use them at least occasionally) than in the EU-12 (18 percent) (Eurobarometer, 2010). The International Tobacco Control (ITC) Survey, conducted in the UK, Canada, the USA and Australia, found that RYO are used by a much higher percentage of the population in the UK than in Canada, the USA and Australia, with 28.4 percent of the UK population found to use RYO in 2001 (Young *et al.*, 2006). In the UK RYO use increased from 1996 to 2001, a period when the taxation and price of RYO declined relative to manufactured cigarettes (Young *et al.*, 2006). Despite differing levels of use by country, in all cases RYO use was highest among younger men with lower incomes, a group defined by higher levels of nicotine addiction and stronger beliefs that RYO was less harmful than manufactured cigarettes.

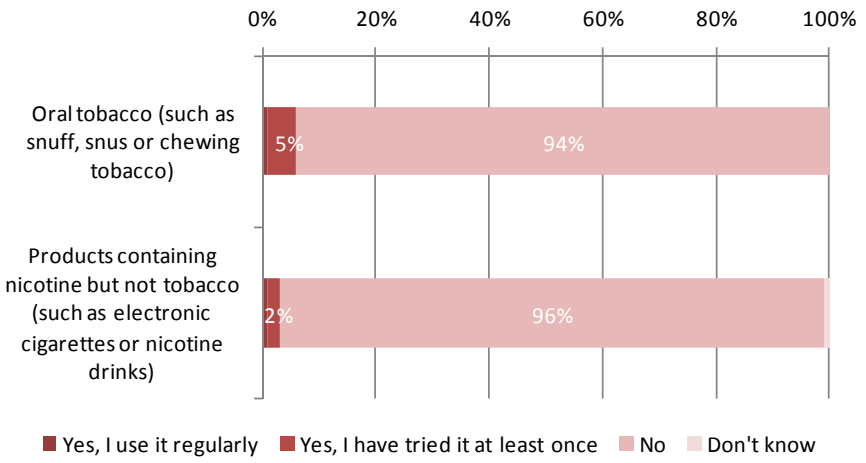
Water-pipe smoking

Tobacco that is heated but not combusted is found in Europe in the form of hookah, gaza, narghile, hubble-bubble and shisha. Water-pipe smoking has become more common in Europe since the 1990s, particularly among young adults and college students (Knishkowy and Amitai, 2005). Nevertheless, Eurobarometer data still suggest that regular water-pipe use remains fairly uncommon (only around 1 percent), and that most use is of an occasional character (Eurobarometer, 2010). Water-pipe smoking is often done as a group activity on university campuses or in families, and its increase has been linked to the perception that water-pipe use is relatively safe in terms of health impact (Knishkowy and Amitai, 2005, Maziak *et al.*, 2004). The Global Youth Tobacco Survey (GTYS)[11] found, for example, that 29.8 percent and 2.8 percent of 13–15-year-old students smoked water pipes in Latvia and Slovakia respectively (Baska *et al.*, 2008). While prevalence is rising, consumption tends to remain less frequent than cigarette smoking, with water pipes most often used once a week or less.

Smokeless tobacco

The most common smokeless tobacco products (STPs) are *snus*/snuff (a cured, finely ground flavoured tobacco found in dry and moist forms), nasal snuff and chewing tobacco (coarsely shredded flavoured tobacco). An estimated 5 percent of EU citizens have tried non-combustible forms of tobacco one or more times, and 1 percent use non-combustible forms of tobacco daily or occasionally; see Figure 3.10 (Eurobarometer 2010).

[11] The GYTS is a 56-question school-based survey developed by WHO and the Centres for Disease Control and Prevention to monitor tobacco use among youth.



SOURCE: (Eurobarometer, 2010) Question: Have you ever tried any of the following products?

Figure 3.10: Use of oral tobacco and products containing nicotine but not tobacco, EU-27

As a measure to prevent its increased use and to promote continuity across the internal market, sale of moist snuff has been banned in the EU since 1992 and continues to be banned under Directive 2001/37/EC. The only exception is Sweden, as granted in its Act of Accession. Even prior to the ban, *snus* use was heavily concentrated in Sweden. While cigarette use has been declining among both men and women since the 1970s, the prevalence and consumption of *snus* has risen in Sweden, particularly among men and male adolescents (Fagerström and Schildt, 2003, SCENIHR, 2007), see also Table 3.6.

Table 3.6: Comparison of cigarette and snus consumption in Sweden, 1980 and 2000

	1980		2000	
	Cigarettes	**Snus**	**Cigarettes**	**Snus**
Prevalence in the population (16 – 84 years)	36% men, 21% women		17% men, 21% women	19% men, 1% women (1999)
Tonnes consumed	6675 tonnes	2512 tonnes	4479 tonnes (1999)	5691 tonnes (1999)

Source: (Fagerström and Schildt, 2003))

Outside Sweden smokeless tobacco is found as dry snuff in Germany and the UK, tobacco gum in Sweden and Denmark and chewing tobacco in the Nordic countries. *Gutkha*, a ready-made form of chewing tobacco wrapped in a betel pepper leaf, is widely used by men, women and children in the south Asian sub-continent. In general, chewing tobacco is also used among immigrant populations of south Asian origin resident in the EU-27. In the UK specifically, 19 percent of Bangladeshi men and 26 percent of Bangladeshi women reported using chewing tobacco (SCENIHR, 2007).

Finally, there are a number of products on the market that do not necessary contain tobacco, such as electronic cigarettes and products that have been marketed for their possible harm reduction potential (Stratton *et al.*, 2001), such as nicotine replacements,

antidepressants that reduce nicotine cravings and medical devices. These will be discussed in the next section.

3.3 The health effects of tobacco use

The negative health effects of tobacco use are well documented and the use of tobacco has been associated with around 655,000 annual deaths in the EU, and a further 13 million people suffering ill health as a result of smoking (ASPECT Consortium, 2004, Lopez *et al.*, 1994). In this section we summarise the key health impacts of smoking and discuss the importance of tobacco as a leading risk factor.

3.3.1 Toxicology of tobacco use

Tobacco products contain a variety of chemical compounds; for instance, in mainstream cigarette smoke the number of chemical compounds is estimated to be in the thousands. There are various ingredients within tobacco products that affect individual health, including those with toxic, carcinogenic, physiological and/or metabolic properties (Stellman and Djordjevic, 2009). The effects of these compounds vary depending on the method of exposure (e.g. if combustion is involved, whether exposure is active or environmental), the combination of compounds and the duration and intensity of exposure.

3.3.2 The link between tobacco use and morbidity and mortality

The evidence relating to the health impacts of tobacco use is strong and precise. There is clear and undisputed evidence that tobacco use harms individuals and has a negative effect on population health. There is a strong dose–response relationship between tobacco use and its effects on health as such; health risks increase with the length of time and the intensity of consumption of tobacco. Correspondingly, health risks associated with smoking tobacco decrease over time following cessation of smoking (Stratton *et al.*, 2001). The causal relationships between smoking tobacco and morbidity and mortality first emerged in the 1950s when five case-control studies associated smoking with lung cancer (Doll R., 1950, Levin *et al.*, 1950, Mills and Porter, 1950, Schrek R., 1950, Wynder and Graham, 1950). However, it was not until the presentation of two reports in the 1960s that it became widely accepted that smoking was a major cause of lung cancer: Royal College of Physicians of London (1962) and Advisory Committee to the US Surgeon General (1964). Since that time, the negative effects of smoking tobacco on morbidity and mortality have become widely accepted in academic literature (Danaei *et al.*, 2005, Doll, 1999, Jha *et al.*, 2006). As outlined by the US Surgeon General (U.S. Department of Health and Human Services, 2004) and the IARC (International Agency for Research on Cancer) Working Group in 2002, smoking tobacco causes a variety of diseases, including the following:

1. **Cancers:** It is now commonly accepted that smoking tobacco is a multi-site carcinogen (IARC, 2004, U.S. Department of Health and Human Services, 2004). In addition to the 80–90 percent increased risk of premature mortality from lung cancer that may be attributed to smoking, studies confirm that smoking tobacco also causes cancer of the lower urinary tract (renal pelvis and bladder), upper aero-digestive tract (oral cavity, pharynx, larynx, oesophagus), stomach and

pancreas. Additionally, smoking tobacco is a cause of acute myeloid leukemia, cervical cancer and liver cancer.

2. **Respiratory diseases:** It has become well established that smoking tobacco leads to COPD, chronic bronchitis, emphysema, pulmonary tuberculosis, asthma and pneumonia (U.S. Department of Health and Human Services, 2004).
3. **Vascular diseases:** In addition to cancers, the causal relationship between smoking tobacco and cardiovascular diseases is now also well established (U.S. Department of Health and Human Services, 2004). Cardiovascular diseases attributable to smoking tobacco include ischaemic heart disease, hypertension, myocardial degeneration, pulmonary heart disease, aortic aneurysm, arteriosclerosis, vascular disease and peripheral cerebrovascular disease.
4. **Reproductive effects:** Smoking tobacco increases the risk of reduced lung function in the foetus and low birth weight, as well as foetal death and stillbirths. Concerning pregnancy, smoking is found to increase the risk of premature rupture of the membranes, pre-term delivery, placenta previa and placental abruption (U.S. Department of Health and Human Services, 2004). Smoking tobacco reduces fecundity, which also negatively affects reproduction.
5. **Other diseases:** Beyond established links with cancer, cardiovascular and respiratory diseases and negative impacts on reproductive health, smoking tobacco has been linked to an increased risk of cataracts, adverse surgical outcomes related to wound healing and respiratory complications, hip fractures, osteoporosis in postmenopausal women and peptic ulcer in helicobacter pylori-positive individuals.

The health effects of smoking products other than manufactured cigarettes may vary from those of manufactured cigarettes, but so far research on them is less comprehensive than in the case of cigarettes. However, the health effects of smokeless tobacco, such as *snus*, differ substantially from those of smoking tobacco.

Water-pipe tobacco smoke also contains carbon monoxide, heavy metals and carcinogens. A one-hour-long session of water-pipe smoking involves 100–200 times the volume of smoke inhaled in a single cigarette. The fuels used for water-pipe smoking may also contain carbon monoxide, metals and carcinogens, and the method of sharing a water pipe creates an additional risk of transmitting communicable diseases. As in tobacco smoking, environmental smoke inhalation and active smoking of water pipes causes lung cancer, heart disease and other diseases, and is of particular risk to pregnant women and developing foetuses (WHO, 2005b). A recently updated study by the German Federal Institute for Risk Assessment arrives at the conclusion that water-pipe smoking is hardly less harmful than smoking cigarettes (BfR, 2009). The authors, however, criticise the comparison between the volumes of smoke inhaled as this is not a useful measure for comparing the harmfulness of these products.

In comparison to studies of smoking tobacco, evidence for the variety of possible health effects associated with smokeless tobacco use is limited, but has recently been evaluated by a scientific committee at the EC (SCENIHR, 2007). The committee's key findings were that STPs are carcinogenic to humans, and the pancreas has been identified as a main

target organ. These products cause local oral lesions, and the use of various STPs has been associated with a high risk of developing oral cancers, although these findings are less clear for Swedish-style moist snuff (*snus*) (see alsoLee and Hamling, 2009). There is evidence for an increased risk of fatal myocardial infarction among STP users. Some data indicate reproductive effects of smokeless tobacco use during pregnancy but firm conclusions could not be drawn (SCENIHR, 2007).

Other products, such as the so-called electronic cigarettes, or electronic nicotine delivery systems (ENDS), have only recently been put on the market and there is still a large degree of uncertainty about their potential health effects (WHO, 2009a). As ENDS do not burn organic matter, as conventional cigarettes do, they have been found to decrease the amount of almost all toxicologically relevant smoke constituents on a per cigarette and equal total particulate matter basis, compared with the conventional cigarette (Stabbert *et al.*, 2003). At the same time, the manufacturers currently do not disclose the ingredients and composition of the ENDS devices marketed. The US Food and Drug Administration analysed the chemicals in 18 varieties of ENDS cartridges marketed in the USA and reported significant variation in content and composition as well as inconsistencies between the actual and declared nicotine levels. In addition, direct delivery of nicotine to the lung may result in stronger toxicological, physiological and addictive effects than traditional nicotine replacement therapy (NRT), to which these products are often compared (WHO, 2009a).

3.3.3 Linking future mortality and morbidity to changes in prevalence

Following the methodology set out in the previous chapter, we forecasted how changes in prevalence would affect future smoking-related morbidity and mortality. The results, which will be used in Chapters 7 to 12 to assess the impacts of different policy measures, are shown below. Figure 3.11 shows the overall link between prevalence and future mortality. According to our forecasts, a 0.5 percent change in prevalence would lead to around 900 fewer deaths annually by 2027. In terms of morbidity, the forecasts in Figure 3.12, Figure 3.13 and Figure 3.14 show the results for lung cancer, aerodigestive cancers and COPD.

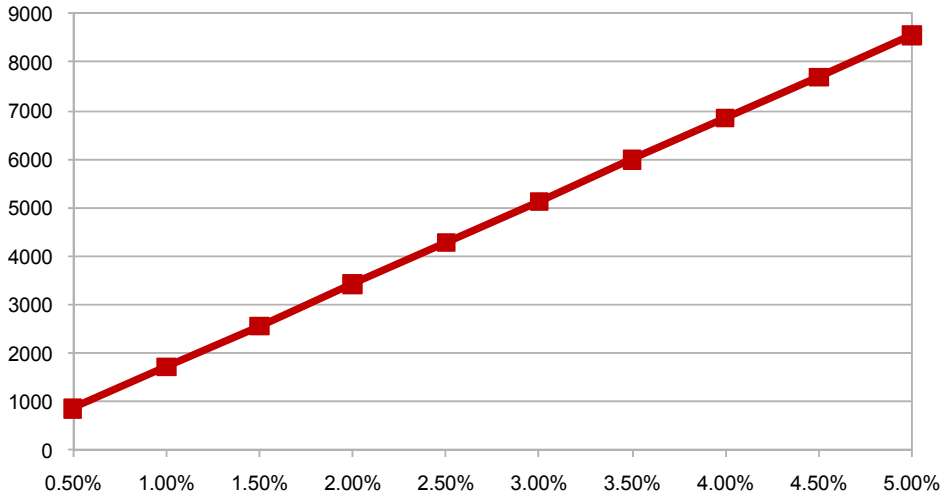


Figure 3.11: Predicted reductions in the annual number of deaths in the EU-27 in 2027, based on percentage reductions in smoking prevalence in 2010 (mortality)

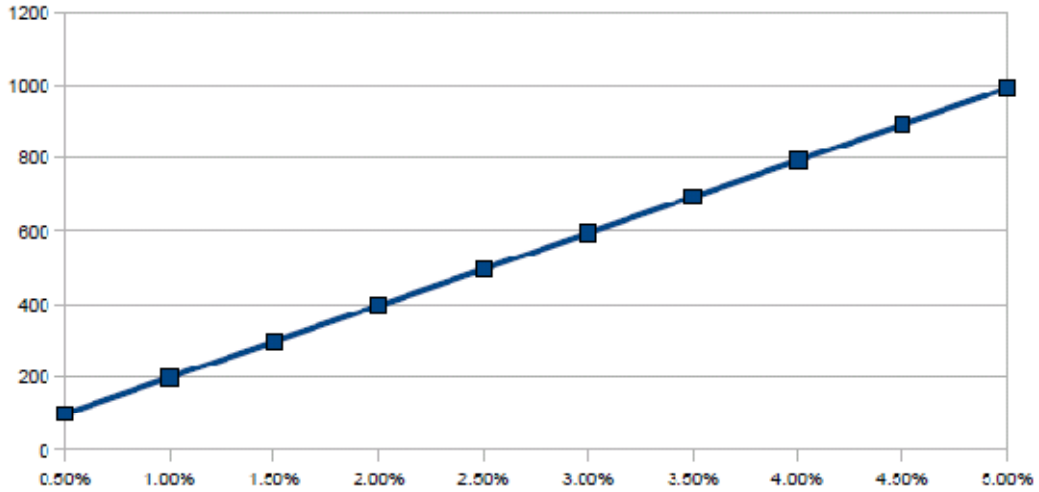


Figure 3.12: Decrease in 1-year lung cancer prevalence in 2027 resulting from percentage change in current smoking prevalence across EU-27

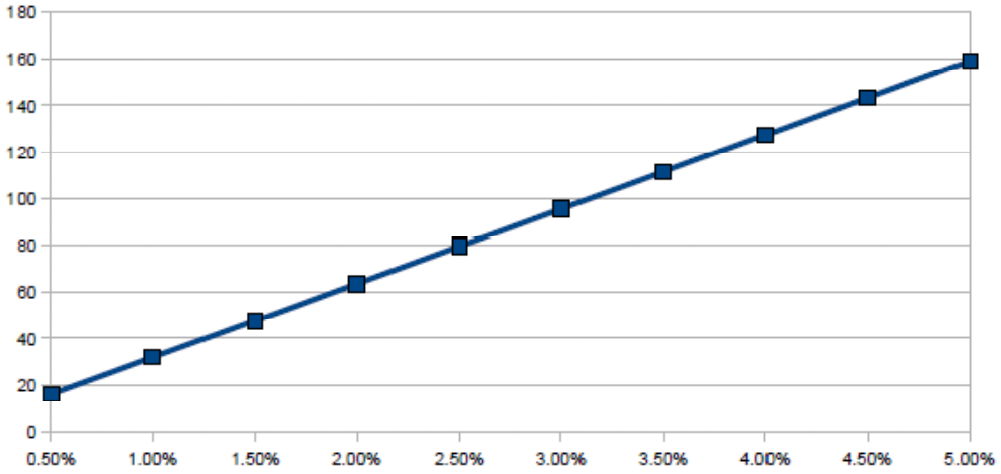


Figure 3.13: Decrease in 1-year aerodigestive cancer prevalence in 2027 resulting from percentage change in current smoking prevalence across EU-27

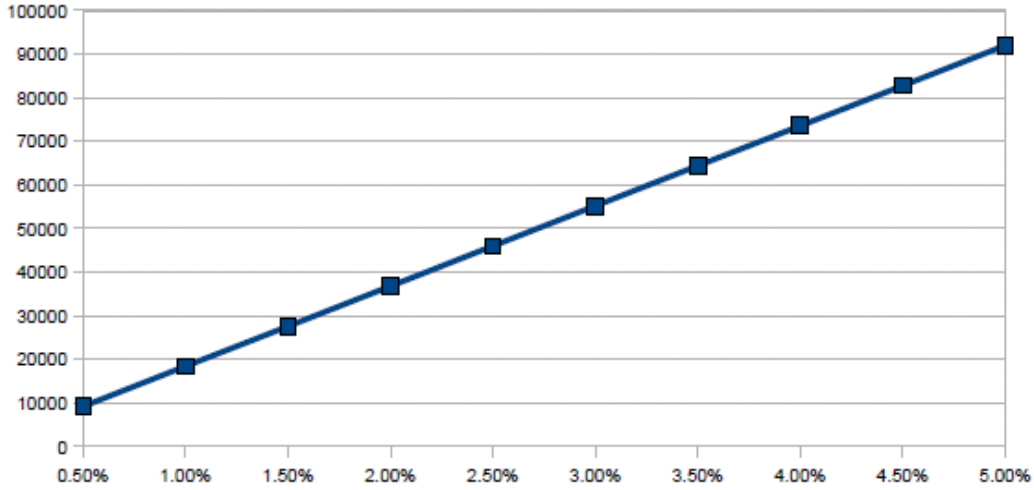


Figure 3.14: Decrease in 1-year COPD prevalence in 2027 resulting from percentage change in current smoking prevalence across EU-27

3.3.4 Tobacco use and the burden of disease

Globally, tobacco-attributable mortality is estimated to rise from 5.4 million in 2004 to 8.3 million in 2030 (WHO, 2008a). In the EU-27 tobacco is a leading driver for mortality and disease burdens. This is consistent across both the EU-15 and the new Member States; in 2002 the Member States with the greatest percentage of deaths attributable to tobacco were Hungary (26.3 percent), Belgium (23.3 percent) and Ireland (23.2 percent) (WHO, 2005a). In 2002 tobacco was the highest contributor to the burden of mortality in Belgium, Denmark, France, Hungary, Ireland, Luxembourg, Poland, Slovenia, Spain and the UK (WHO, 2005a).

Burden of disease is calculated using disability-adjusted life years (DALYs). DALYs essentially represent the sum of years of life lost and years of life lived with disability; the burden of disease measures the gap between the current health status of a given population and an ideal situation where everyone in the population lives to old age in full health. Using this concept, tobacco was the leading risk factor contributing to the total burden of disease in 16 out of the EU-27 Member States in 2002 (WHO, 2005a). Among all EU-27 Member States, tobacco is one of the top three factors contributing to the burden of disease, ranging between accounting for 5.6 percent of the population-wide DALYs in Cyprus to 20.9 percent in Hungary.

As the health effects of tobacco use are cumulative and realised over time, current burdens of mortality and disease reflect tobacco consumption in previous decades rather than current consumption. As shown in the mortality forecasts conducted in Chapter 6, changes in tobacco-related mortality follow changes in prevalence and consumption with a substantial time lag (we assumed an average time lag of 17 years). Current tobacco-related mortality thus reflects consumption patterns of past decades, and mortality may continue to rise until the reduction in prevalence in the last decade impacts on mortality rates.

As more men have used tobacco than women through the 1980s to 2000s, tobacco-attributable mortality may be expected to remain higher among men in the medium term; though, as differences in smoking prevalence are declining, sex differences in mortality attributable to tobacco may also be expected to fall in parallel.

Table 3.7: Shares of total deaths and DALYs attributable to tobacco use, 2002

Country	Estimated proportion of deaths attributable to tobacco		Estimated proportion of DALYs attributable to tobacco	
	% total	ranking*	% total	ranking
Austria	15.8	2	11.0	1
Belgium	23.3	1	15.8	1
Bulgaria	13.5	4	12.4	2
Cyprus	9.7	3	5.6	2
Czech Republic	21.8	2	15.5	1
Denmark	25.7	1	17.7	1
Estonia	17.4	3	11.9	3
Finland	13.9	3	7.7	3
France	16.2	1	12.4	1
Germany	18.3	2	13.7	1
Greece	19.3	2	12.9	1
Hungary	26.3	1	20.9	1
Ireland	23.2	1	11.8	1
Italy	18.8	2	12.0	1
Latvia	16.5	3	12.0	3
Lithuania	17.8	3	11.5	3
Luxembourg	17.7	1	11.3	1
Malta	15.4	3	9.7	3
Netherlands	23.7	1	16.7	1
Poland	25.3	1	16.6	1
Portugal	12.1	2	10.4	2
Romania	16.3	2	13.1	2
Slovakia	19.2	2	12.2	2
Slovenia	19.7	1	13.7	1
Spain	16.8	1	12.3	1
Sweden	10.8	3	8.0	2
United Kingdom	24.3	1	14.2	1

*ranking
Source: (WHO, 2005a)

3.3.5 The social costs of tobacco use

Due to the proven effects of tobacco use on morbidity and mortality rates, tobacco use has been associated with substantial costs to society. These costs may be broken down into the following categories (Collins and Lapsley, 1997); (GHK, 2010):

- direct healthcare costs (medical services, prescription drugs, hospital services, etc.);
- productivity losses (absenteeism, lost skills, unemployment, etc.);
- welfare provision (sickness benefits, unemployment benefits, nursing home or rehabilitation);
- fires and accidents (property losses, wild fires);
- research and education (public health programmes, research into smoking, education campaigns);
- intangible costs such as pain and suffering that result from loss of life or smoking-related illness.

Unfortunately, there are currently no comprehensive estimates of the social cost of tobacco use available at the European level, and estimates usually only consider specific Member States (ASPECT Consortium, 2004). Estimates available at country level vary widely depending on the income level and population size of different countries (GHK, 2010). A study undertaken by GHK on behalf of DG SANCO on the health costs of smoking looked at the various cost estimates from the literature and highlighted this point by stating that the healthcare costs estimated in high-income and populous European countries such as France, Germany and the UK could be up to 100 times higher than the costs estimated using comparable studies in less prosperous, smaller European countries (GHK, 2010).

In addition, differences in estimates may also be accounted for by the fact that they include different costs. For example, one study may include costs of nursing outside hospitals and other associated costs while other studies may estimate healthcare costs quite narrowly (GHK, 2010). These differences account for the wide range of estimates available in the literature. Table 3.8 provides a range of estimates of the social costs of smoking.

Table 3.8: Some estimates of smoking costs across the EU and various EU Member States[12]

Estimate	Country	Year	Authors
Total direct and indirect cost US$ 804 million	Sweden	2001	(Bolin and Lindgren, 2007)
Total direct and indirect cost Total costs 21 billion AUS $	Australia	1998	(Collins and Lapsley, 2002)
Total cost to the government in additional expenditures and lost revenues estimated to be well over EEK200 million greater than the tobacco tax revenues generated and reduced pension expenditures resulting from premature deaths attributable to tobacco	Estonia	2004	(Taal *et al.*, 2004)
€21 billion including €7.5 billion for acute hospital care, inpatient rehabilitation care, ambulatory care and prescribed drugs; €4.7 billion for the indirect costs of mortality; and €8.8 billion for costs due to work-loss days and early retirement	Germany	2006	(Neubauer, S *et al.*, 2006)
Public healthcare expenditure to treat smoking-attributable diseases of smokers estimated at €36.6 billion, which corresponds to 6% of total healthcare spending in the EU-27 and 0.4% of GDP Smoking-related productivity loss estimated at €12.4 billion with absenteeism accounting for 91% of that cost; productivity loss costs represent about 0.1% of EU-27 GDP Estimated costs of premature mortality attributable to smoking are estimated at €313 billion on a willingness to pay basis Altogether these estimates represent a total cost of about €363 billion in 2000, corresponding to 3.9% of EU-27 GDP	EU-27	2000	(GHK, 2010)
€98–130 billion or between 1.04% and 1.39% of the region's GDP in 2000 as conservative estimates[13]	EU-15	2000	(ASPECT Consortium, 2004)

In Chapter 6 this report relies on the work by Neubauer *et al.* (2006) to assess the costs of smoking by scaling up and adjusting the estimates for Germany to a European level. Following the methodology described earlier, in Chapter 2, the results of forecasting future direct and indirect costs in relation to changes in prevalence have been estimated to be as shown in Figure 3.15 and Figure 3.16 below. These figures show how a change in prevalence now by, for example, 1 percent will result in a reduction in smoking-related direct healthcare costs of around 90 million euros in 2027 and a reduction of indirect costs of around 108 million euros in 2027.

In the reminder of this study, the economic impacts of increased/reduced mortality and morbidity will be discussed in the relevant sections on economic impacts, even though they are closely linked to changes in the health effects of smoking and are in our model proportional to the health impacts.

In addition, no monetary value has been attributed to either mortality or morbidity in itself.[14]

[12] WHO (2005a).

[13] These estimates are conservative because they do not include such costs as those of informal care, costs related to second-hand smoke, the costs of reproductive diseases and the social costs that result from nicotine addiction. These costs also exclude intangible costs such as pain and suffering that result from smoking-related death and illnesses (ASPECT Consortium, *Tobacco or Health in the European Union. Past, Present, Future.* , Luxembourg: European Commission, 2004..

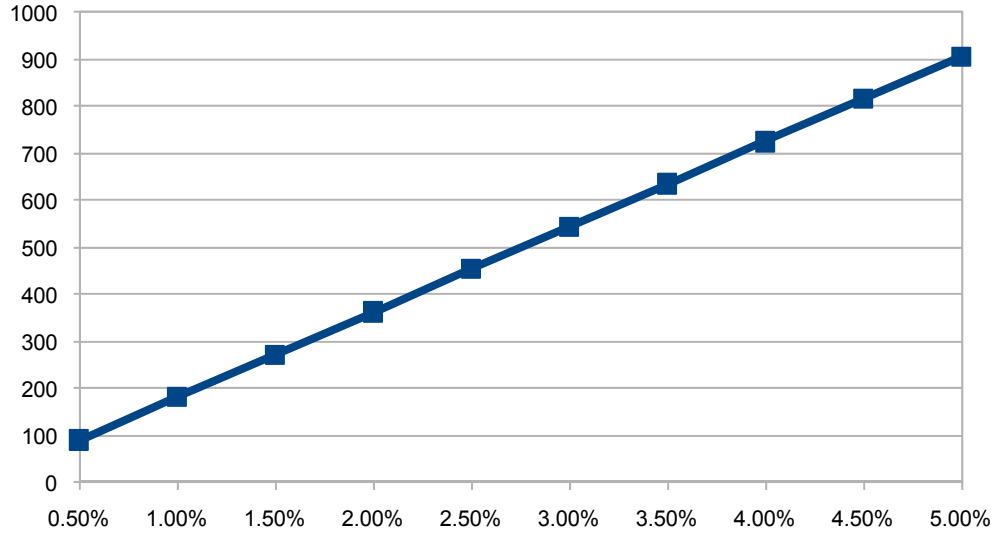


Figure 3.15: Predicted reductions in the annual direct costs of smoking (x 1 million euros) in the EU-27 in 2027, based on percentage reductions in smoking prevalence in 2010

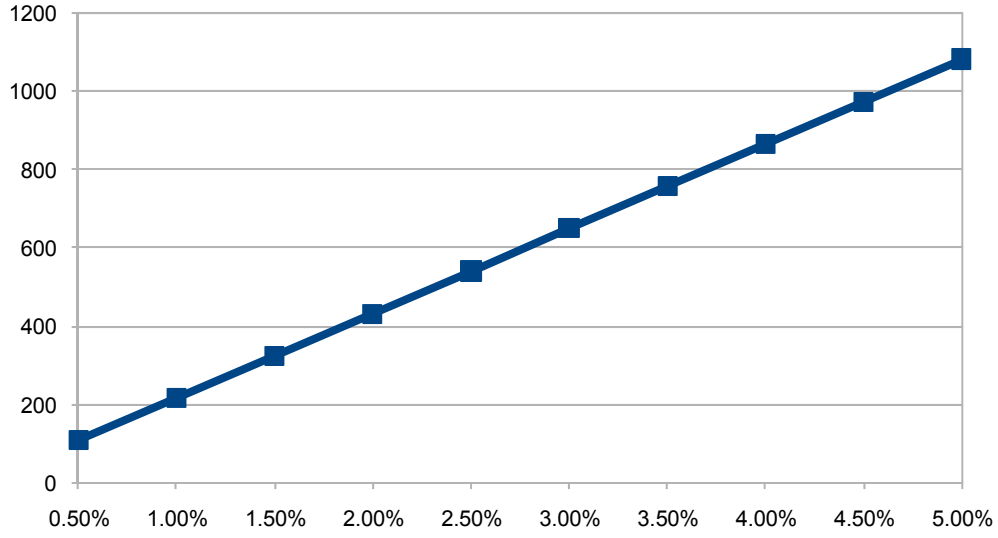


Figure 3.16: Predicted reductions in the annual indirect costs of smoking (x 1 million euros) in the EU-27 in 2027, based on percentage reductions in smoking prevalence in 2010

[14] There is, however, a wide range of techniques that could be used to do this, see Potoglou, D., P. Hunt, S. Diepeveen, B. P.B., F. Tsang, C.W. Kim and P. Burge, *The Value of Statistical Life: An International Review.*, Cambridge: RAND Europe, 2010 (forthcoming).

CHAPTER 4 Economic and financial description of the tobacco sector

This chapter describes the supply and prices of tobacco in the EU and presents the economic underpinnings for how the proposed revision of the directive could impact on macroeconomic outcomes, such as employment and excise duty collections.

In order to address these issues, we use statistical data and economic theory to:

- develop an understanding of the level of tobacco production and distribution within the EU;
- identify the main actors involved in supplying tobacco;
- discuss industry responses in this type of market structure;
- characterise the relationship between the revision of the directive and economic outcomes.

4.1 Value of tobacco industry

In this section we clarify the sectors of the tobacco industry that we examine and the value of trade in each of the sectors.

4.1.1 The sectors of industry

There are a variety of activities that may be deemed necessary to supply tobacco products to the market; however, the literature generally identifies the following groups of activities as analytically important for economic policy analysis: production, distribution and retailing of tobacco leaf and tobacco products (World Bank, 1999; (Buck *et al.*, 1995).

Each of these groups contains numerous direct activities to transform tobacco crops into final products. The types of activities include preparing the land for farming, adding chemicals or additives to tobacco, storing cigarettes in warehouses and selling cigarette packets in retail shops.

Specifically, the three main groups contain the following activities (World Bank, 2000:15; (Buck *et al.*, 1995):

- production sector: farming, leaf marketing and processing;
- manufacturing sector: production of unmanufactured tobacco and manufacturing tobacco products;

- sales sector: wholesale and retail.

In order to provide statistically describe sectors of the tobacco industry (and in later chapters to perform quantitative analysis) across countries and/or over time, there needs to be a common understanding of what constitutes a particular industrial activity and what does not (i.e. manufacturing in tobacco). Table 4.1 briefly describes each of the activities deemed a direct tobacco activity[15] and their respective NACE (Rev. 1.1) codes.

Table 4.1: Tobacco supply activities

Activity	General description	Examples	NACE (Rev. 1.1)
Farming	All tobacco works on the farm	Land preparation	1.11 – Growing of cereals and other crops
		Delivery of cured tobacco to leaf processor	
Leaf marketing and processing	All activities after tobacco leaves farm and before ageing process	Leaf auctioning	1.11 – Growing of cereals and other crops
		Leaf warehousing	
		Leaf processing	
Product manufacturing	All aspects of production	Reordering	16 – Manufacture of tobacco products
		Blending	
		Leaf cutting	
		Delivery of packed tobacco to wholesaler	
Product wholesale and retail	All activities to deliver tobacco	Selling tobacco products to consumer	51.25 – Wholesale of unmanufactured tobacco
			51.35 – Wholesale of tobacco products
			52.26 – Retail sale of tobacco

The NACE codes are useful because they provide a mechanism for providing harmonised statistics by sector. The data we provide in this chapter refer to NACE (Rev.1.1) codes 16, 51.25, 51.35 and 52.26. We use these codes to identify data that belong to a particular tobacco activity across Member States, thereby permitting us to perform quantitative analysis on harmonised data (in later chapters).

In terms of how these codes link into the process for delivering a final product to the tobacco consumer, Figure 4.1 shows how we might visually understand the process. Note that we do not suggest that this is the supply chain for tobacco, which is far more complex; this figure relates the NACE codes to the supply-chain and is therefore necessarily far more simplistic. Circles indicate a sales activity, while the boxes show an activity that physically transforms the tobacco.

[15] http://www1.worldbank.org/tobacco/toolkit.asp

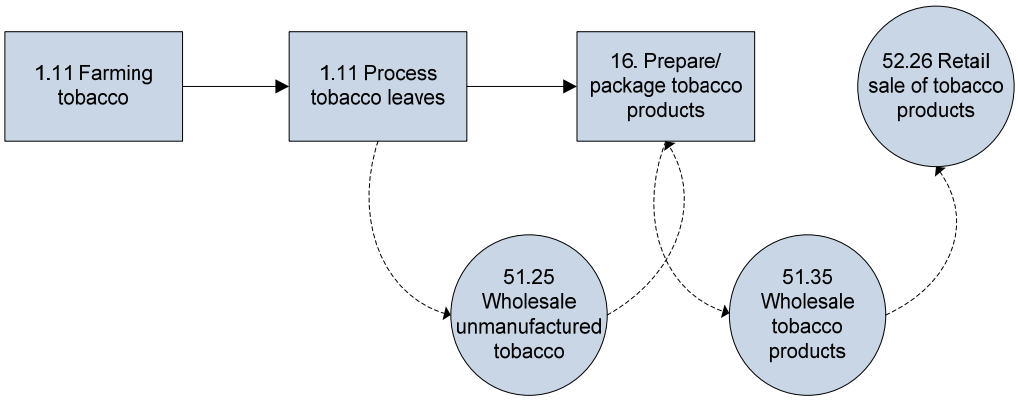


Figure 4.1: Mapping of the NACE codes into the process for delivering tobacco

It is worth noting that the NACE (Rev. 1.1) codes do not break down agricultural industries to a detailed enough level to identify 'growing of tobacco'. In 2007 an upgrade of coding occurred, and the new coding system is called NACE 2. This system does identify 'growing of tobacco' (as code A1.1.5). However, the system is not yet in place in the database needed to perform the quantitative impact assessment of the following chapters (i.e. SBS; we go into further detail about this data set below).

Apart from these direct (or core) activities to produce and distribute tobacco, there are indirect (or supplier) activities that are designed to facilitate the direct activities, such as marketing or transportation, on which we do not focus. As the World Bank Economics of Tobacco Toolkit[16] describes:

> *Individuals whose jobs are linked to tobacco through the spending of employees in the core and supplier sectors of the tobacco industry, as defined in the industry-sponsored studies, are affected little by a reduction in tobacco sales. These expenditure-induced jobs are weakly related to the tobacco industry and do not depend on the existence of the tobacco industry. For example, it is difficult to argue that the employees who work in the bank that offers auto loans depend entirely on the spending of employees in tobacco industry on automobiles...Further, the goods and services produced by the supplier sectors are not uniquely used by the core sector of the tobacco industry; these suppliers can find new customers for their goods and services without much difficulty. For example, tobacco products are heavily advertised products. A fall in demand for tobacco product advertising does not lead to a smaller advertising industry, since an advertising agency can find new products to advertise if the demand for its service from tobacco advertising falls.*

Furthermore, we do not consider analysing other goods that may be indirectly affected by a revision of the directive. There are many goods that are complementary to tobacco consumption that we might want to consider as well, such as lighters and matches. However, empirical research indicates that a fall in demand for tobacco products would not lead to a smaller industry for these goods as they are complements to hundreds of other products too;[17] therefore, we focus on the tobacco goods themselves.

[16] http://www1.worldbank.org/tobacco/toolkit.asp

[17] For example, lighting barbeques, candles, cookers, and camp fires.

4.1.2 The value of trade across sectors of the tobacco industry

A relatively small proportion of global production of tobacco leaf is developed in the EU; the Food and Agriculture Organization (FAO) predicts that the EU will account for 4 percent of global production of tobacco leaf in 2010.[18]

In order to account for the value of trade in tobacco across Member States, not just information from a selection of firms, we turn to Eurostat data. There are, however, potential problems associated with those data:

- missing values – that is, not all Member States report business statistics for the tobacco industry;
- potentially lower quality of data – that is, the validation procedures of Eurostat SBS may not be as rigorous as that of accounting firms who produce annual reports of firms.

In Table 4.2 we present data on the 2006 gross income (after adjusting for subsidies and indirect taxes), or value added,[19] in the tobacco manufacturing sector for the countries reporting to Eurostat. According to Eurostat, from the countries reporting the EU 'earns' €6.5 billion in value added from the manufacturing of tobacco. The Netherlands, Germany and the UK account for nearly 60 percent of value added in the manufacture of tobacco products in the EU.

Table 4.2: Value added in manufacturing of tobacco, 2006

	euros (million)	percent of total
Belgium	238	3.64%
Bulgaria	75	1.15%
Germany	1,488	22.75%
Spain	350	5.35%
Greece	204	3.11%
Netherlands	1,976	30.22%
Poland	260	3.97%
Portugal	206	3.15%
Romania	59	0.91%
United Kingdom	1,684	25.75%
TOTAL	6,539	100.00%

Source: Eurostat SBS

According to Eurostat, for the countries reporting the turnover of tobacco products, or production value,[20] in wholesale and retail for 2006 totalled €24.14 billion (see Table 4.3).

[18] http://www.fao.org/docrep/006/Y4956e/y4956e08.htm

[19] Value added at factor costs is the gross income from operating activities after adjusting for operating subsidies and indirect taxes. Value adjustments (such as depreciation) are not subtracted.

[20] Production value measures the amount actually produced by the unit, based on sales, including changes in stocks and the resale of goods and services. The production value is defined as turnover, plus or minus the changes in stocks of finished products, work in progress and goods and services purchased for resale, minus the purchases of goods and services for resale, plus capitalised production, plus other operating income (excluding subsidies). Income and expenditure classified as financial or extraordinary in company accounts is excluded from production value.

Much of this is in the wholesale of tobacco products in Italy, with approximately €13 billion total wholesale and retail sales.

Table 4.3: Turnover of wholesale and retail of tobacco (in € million), 2006

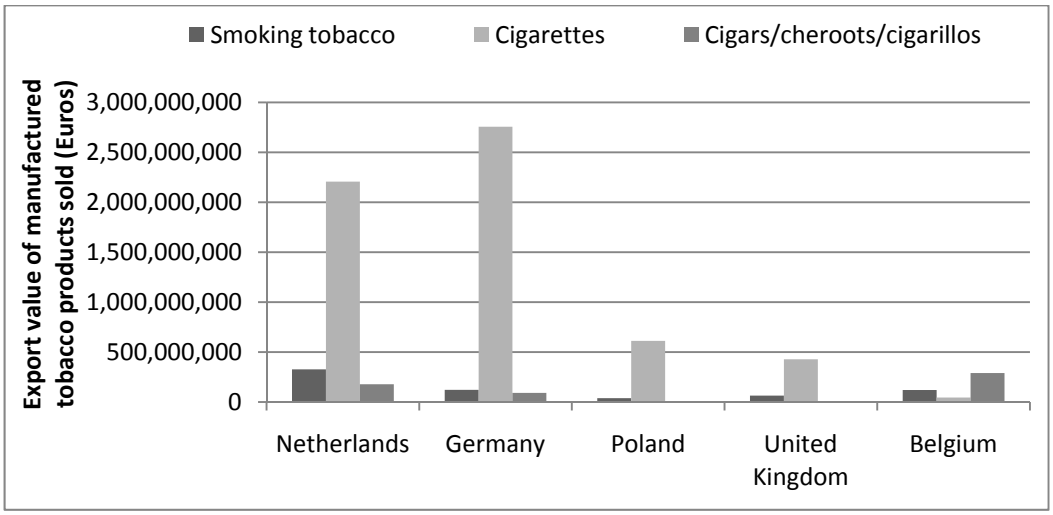
	Wholesale of tobacco products	Retail sale of tobacco products	Total
Austria	1,682	392	8.59%
Belgium	1,097	27	4.66%
Cyprus	28	1	0.12%
Czech Republic	153	49	0.84%
Germany	803	626	5.92%
Denmark	85	57	0.59%
Estonia	11	.	0.05%
Spain	754	795	6.42%
Finland	62	.	0.26%
France	289	592	3.65%
Greece	220	154	1.55%
Hungary	111	8	0.49%
Italy	10,061	2,744	53.04%
Lithuania	15	.	0.06%
Luxembourg	57	1	0.24%
Latvia	54	1	0.23%
Netherlands	343	238	2.41%
Norway	235	1	0.98%
Poland	559	54	2.54%
Portugal	59	20	0.33%
Romania	203	4	0.86%
Sweden	115	229	1.42%
Slovenia	28	11	0.16%
Slovakia	35	4	0.16%
United Kingdom	827	253	4.47%
TOTAL	17,884	6,260	100.00%

Source: Eurostat (SBS)

Export value of trade in particular tobacco products

Figure 4.2 demonstrates the top EU countries (reporting) the export value of trade in cigars/cheroots/cigarillos, cigarettes and smoking tobacco products. Germany exports the highest value of cigarettes, while The Netherlands exports a greater value overall (i.e. including all categories of products). Belgium exports a greater value of cigars/cheroots/cigarillos than cigarettes. Poland and the UK have a similar situation in that both export approximately €500 million cigarettes and €40–€65 million in smoking tobacco products.

Figure 4.2: Top five EU countries for export value of manufactured tobacco products sold (in euros) by type, 2008



Source: Eurostat (Prodcom)

4.2 Prices

In the simplest of frameworks, people demand and companies supply tobacco. In order to meet the demand for tobacco products, companies produce tobacco products by hiring workers and purchasing (or renting) land and equipment. All of these activities incur costs (e.g salary payments, mortgage). In order to pay these costs, tobacco companies charge a price to consumers. The price consumers pay is not simply the result of production costs (e.g. salary payments, land rental, tobacco processing), but also includes the taxes and duties applied to tobacco and the activities performed to increase or maintain demand (e.g. marketing, lobbying).

On the other hand, there are costs that do not enter the price. These are external costs in which persons who are not involved in the decision to consume or produce the tobacco are negatively affected, but receive no compensation. For example, the following types of costs may accrue to those who do not use tobacco products:

- physical cost of encountering output of the tobacco production process (i.e. chemicals used in farming and production, etc.);
- physical cost of encountering output of tobacco use (e.g. smoke, environmental degradation, packaging or cigarette butt litter);
- financial cost of supporting a health system with any amount of public funding (i.e. poor health outcomes related to smoking are paid for by taxes in the national health insurance system).

Equally, there are costs incurred by governments to implement tobacco control measures for which not all costs are met by those benefiting from the tobacco industry. Importantly, a policy that is designed to improve the health outcomes of individuals may also influence

the way in which the market operates and the price; therefore there may be changes to the economic outcomes of firms and consumers.

Prices are a good indicator of market activity and provide information regarding the supply and demand for products (see Box 4.1 for more on indicators). For our purposes, a revision of the directive may alter the cost of bringing tobacco to market, which may alter the prices of tobacco. This may have a variety of effects depending on the type of tobacco consumer. For example, an increase in tobacco products' prices may result in:

- some consumers reducing the amount of tobacco consumed in order to spend the same total amount on all the other goods they consume;
- some consumers altering the type of tobacco consumed to a cheaper alternative in order to spend the same amount on all goods they consume in total;
- some consumers quitting tobacco consumption altogether and thus spending more on other goods.

In any event, the impact on individuals depends on their sensitivity to price. As we discuss in greater detail later in Section 4.2.2, research finds that consumers are overall somewhat responsive to price (i.e. a 10 percent increase in the price of cigarettes decreases consumption of cigarettes by 3–5 percent), with younger people being more responsive to price than adults.

Box 4.1: Good indicators are indicative, not comprehensive

The search for and design of indicators to represent concepts, such as 'value of an industry', is the creative part of a scientific enterprise. No indicator is absolutely right; it is merely good enough for the tasks asked of it. Often the usefulness of an indicator is enormously increased just because it gains general currency.

For example, the cost of living index is not a particularly subtle or scientific measure, but it does the job and is good enough for use in a wide variety of practical contexts. Part of its success is the availability of appropriate data to calculate the value of the index accurately and consistently over time and place. So an indicator rises in value not only by being usable and acceptable, but by being easily populated with data.

Good indicators have a range of other technical qualities – they bear a constant relationship with the concept measured and are not markedly affected by extraneous factors. That is, fluctuations in value are easily interpreted so that a quantum change at one point in the scale bears a known relationship with the same quantum change at another point in the scale of value. However, the desirability of these technical characteristics increases as an indicator is required to do more and more detailed work – be more reliable and more discriminating between similar states of the concept measured.

4.2.1 Prices of different tobacco products

In order to have a sense of prices for different products, Table 4.4 provides the producer price of unmanufactured tobacco across the EU countries reporting information to the FAO. The average price per tonne of tobacco in 2007 was approximately €2,500. Cyprus

commanded the highest price, €6250/tonne; whereas Portugal had the lowest price, €910/tonne.

Table 4.4: Producer price of unmanufactured tobacco (€/tonne), 2007

Country	Price per tonne (€)
Austria	2,216.47
Belgium	2,386.35
Bulgaria	2,632.33
Cyprus	6,250.52
France	1,272.72
Germany	3,315.49
Greece	3,065.08
Hungary	1,000.09
Italy	5,576.44
Poland	1,230.04
Portugal	910.31
Romania	1,650.94
Slovakia	2,131.09
Spain	1,108.64
MEAN	2,481.89

Source: FAO Statistical Database (FAOSTAT)

This variation across countries may be due to a variety of reasons. First, the price is a function of the supply and demand for:

- the quality or type of tobacco leaf;
- the curing method.[21]

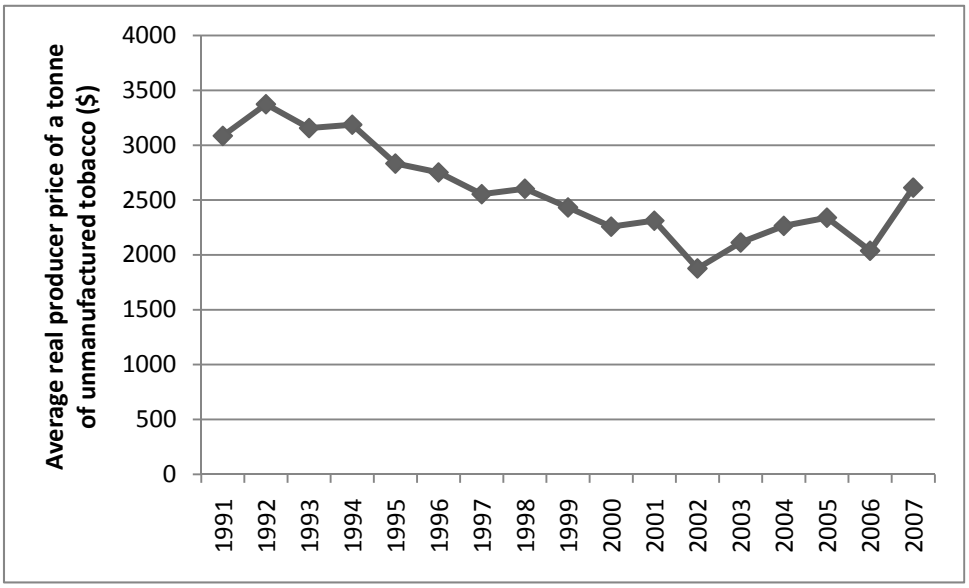
Different leaves and curing methods command different prices in the market and there may be differences across countries in terms of what type of leaf and curing method may be, or are traditionally, used.

Secondly, the price is a function of costs, and some countries may have physical land arrangements so that they can achieve greater economies of scale, which drives down the cost and thus price.

Lastly, an explanation may lie in the nature of subsidies and price may also be driven by the amount of subsidisation available to farmers in each country.

In order to understand how 2007 prices compare to previous prices commanded in the market, Figure 4.3 shows the average real price per tonne (in US $) across the EU countries reporting to the FAO. The figure indicates that there has been a general downward trend in producer prices from 1991 to 2002; since then, there has been a general increase in producer prices.

[21] There are four curing methods used to cure tobacco grown for commercial purposes: flue-curing, fire-curing, air-curing, and sun-curing (see http://www.tobaccoleaf.org/about_tobacco/index.asp?op=2, accessed on 18 November 2009).



Source: FAOSTAT. Countries include Austria, Bulgaria, Cyprus, France, Germany, Greece, Hungary, Italy, Poland, Portugal, Romania and Spain (from 1991 to 007); Belgium–Luxembourg (1991–99); Belgium (2000–07); and Slovakia (1993–2007)

Figure 4.3: Average real producer price per tonne of unmanufactured tobacco, 1991–2007

As for retail tobacco products, Table 4.5 presents the average price per pack of 20 cigarettes in the most popular price category[22] (MPPC) across 27 Member States. The table shows that the average in 2009 was €3.55, with a minimum price found in Bulgaria (€1.48) and a maximum in Ireland (€8.45).

[22] 'Most popular price category' refers to prices of the most popular brands in a market. 'The concept of the 'most popular price category' was designed more than 30 years ago, when national markets were dominated by one brand that was clearly 'most popular' http://europa.eu/rapid/pressReleasesAction.do?reference=IP/08/1149 (accessed 4 Jun 2010).

Table 4.5: Retail price per pack of 20 MPPC (in €) by Member State, 2009

Country	Average retail price per pack (€)
Belgium	4.74
Bulgaria	1.48
Czech Republic	2.41
Denmark	4.29
Germany	4.71
Estonia	2.06
Greece	3.00
Spain	3.00
France	5.30
Ireland	8.45
Italy	3.70
Cyprus	2.82
Latvia	2.09
Lithuania	1.77
Luxembourg	3.44
Hungary	2.35
Malta	3.59
Netherlands	4.74
Austria	3.60
Poland	1.70
Portugal	3.40
Romania	1.93
Slovenia	2.35
Slovakia	2.10
Finland	4.40
Sweden	5.04
United Kingdom	7.39
MEAN	3.55

Source: DG TAXUD, Excise Duty Tables – Manufactured Tobacco; shows the situation on 1 July 2009

4.2.2 Responsiveness of consumers to changes in price

In order to understand how a policy may impact on consumers or producers, researchers often attempt to identify the price elasticity of demand and the price elasticity of supply. Price elasticity is the change in demand or supply for a change in price (see Box 4.2 for further explanation).

Box 4.2: Elasticities of demand are measures of responsiveness to price

The concept of price elasticity of demand is used in economics to describe the sensitivity of consumption to changes in the monetary price of a product (i.e. the percentage change in consumption resulting from a 1percent increase in price). For example, a price elasticity of tobacco demand of –0.5 means that a 10percent increase in price would reduce tobacco consumption by 5percent.

There appears to be a general consensus about the degree to which consumers alter their cigarette demand in response to a price increase. Generally speaking, research finds that a 10 percent increase in the price of cigarettes decreases consumption of cigarettes by 3–5 percent (see: Chaloupka and Warner, 2000, Gallus *et al.*, 2006, Townsend, 1996).

Chaloupka and Warner (2000: 1547) state 'the price elasticity estimates for overall cigarette demand from recent studies fall within the relatively wide range from –0.14 to –1.23, but most fall in the narrower range from –0.3 to –0.5'. This is further supported in Townsend (1996: 132) in which 'estimates have varied between about –0.2 and –0.9 and have clustered about –0.5'. In more recent work focusing on Europe exclusively, Gallus *et al.* (2005) find the price elasticities of demand were –0.46 and –0.74 for local and foreign cigarette brands respectively. Another, more comprehensive, meta-analysis of literature analysing price elasticity of cigarette demand finds that the median price elasticity (of 156 papers in the top 36 journals) is precisely –0.47 (Gallet and List, 2003).

Young people's responses to price

There are studies that focus on age groups, in which there is support for the inverse relationship between price sensitivity and age; that is, younger people are more sensitive to price changes than older people. Table 4.6 shows that young people respond to a 10 percent price increase by reducing their cigarette consumption by between 5 percent and 9 percent, potentially a reduction double that of all adults.

Table 4.6: Range of elasticities of demand for cigarettes

Source	Elasticity	Years of analysis	Group type
Evans and Farrelly (1998)	–0.58	1976–92	Young adult (18–24 years)
Evans and Huang (1998)	–0.50	1985–92	Young people
Tauras and Chaloupka (1999)	–0.79	1976–93	17–35 years
Lewit *et al.* (1997)	–0.87	1990–92	9th graders (ages 13–14)
Chaloupka and Wechsler (1997)	–0.68	1992–94	8th, 10th, 12th graders

Source: Chaloupka and Warner, 2000

Price-induced switching to other tobacco products

In terms of switching to other product types, one study using German data over the period 1991 to 2004 finds that a 10 percent increase in the price of cigarettes increases the consumption of loose tobacco by 12.3 percent, indicating that these products are substitutes and there is a partial switch to cheaper loose tobacco after a price increase for cigarettes. A key implication of this study is that the price differentials between tobacco products should be reduced in order to maximise the public health benefits of high tobacco prices (Hanewinkel *et al.*, 2008).

4.2.3 Market structure

Market structure influences the responses of businesses to a policy or regulation. As such, it is worth understanding which market structure characterises the tobacco market. To do this, a key indicator may be used: market share or market concentration ratios. A market concentration ratio is measured as the proportion of quantity or value of output generated by top businesses in the total market.

We are unable to locate this information across the EU; however, we are able to locate concentration ratios for the UK. Table 4.7 shows the proportion of output and value produced by the top businesses across some markets in the UK in 2004. The table indicates that the manufacture of tobacco products – NACE (Rev 1.1) code 16 – had one of the largest shares of the market concentrated in the hands of the top five businesses: 100 percent in terms of value added. In terms of output, in 2004 the top five tobacco

manufacturers produced nearly double that of the top five alcohol beverage businesses, in their respective industries.

Table 4.7: UK market share of top businesses, 2004

	Top 5 businesses (as % of the total)		Top 15 businesses (as % of the total)		Ranking positions for the top 5 businesses	
	Output	Gross value added	Output	Gross value added	Output	Gross value added
Alcoholic beverages	50	68	78	99	28	8
Soft drinks and mineral waters	75	76	93	90	10	3
Tobacco products	99	100	99	100	2	17

Source: (Mahajan, 2006); estimates of gross value added and total output at 2004 current basic prices

As for market structure that tobacco production represents, Table 4.8 shows the various market structures (i.e. perfect competition) and their corresponding characteristics. Importantly, a market structure with a five-firm concentration ratio over 40 percent is deemed an oligopoly (Mahajan, 2006) and, as we saw in Table 4.7, the top five UK tobacco manufacturing firms are approximately 100 percent.

Table 4.8: Market structure types and characteristics

Type of market structure	Number of businesses	Freedom of entry	Nature of product	Five-firm concentration ratio	Supply response to price controls[23]
Perfect competition	Very many	Open, unrestricted	Various	0%	Highly responsive, consumer driven
Monopoly	One	Closed, restricted	Unique	-	Highly unresponsive, firm driven
Monopolistic competition	Many	Open, unrestricted	Differentiated	<40%	Relatively responsive
Oligopoly	Few	Limited, restricted	Similar	>40%	Relatively unresponsive

In a market with few firms and barriers to entry,[24] prices are generally set by firms and adjust in response to competitors' prices. Because of this, prices are fairly rigid. That is, in the absence of a policy intervention a competitor would match a price *decrease* but not a price *increase*, because that could divert customers away. Therefore firms gain little from altering prices, which remain fairly stable over time.

As for how these market structures generally respond to policy, supply is relatively unresponsive to price floors and price ceiling interventions.

Regarding taxation, there are opportunities to absorb (not pass on the tax increase to prices) or pass through price increases beyond the tax increase ('more than full pass-through').

Thus, we cannot assume that:

- increasing costs will necessarily not be transferred to the consumer;

[23] Price controls are price ceilings (maximum price) and price floors (minimum price) set by government.

[24] Barriers include substantial restrictions on advertising, product consumption in public locations, etc.

- declining sales will necessarily lead to declining profits.

Importantly, for a revision in the directive we need to consider that attempts to increase industries' costs may not lead to changes in price, in which case there may be no change in consumption. Conversely, there may be more than full pass-through in which industry increases price beyond the increase in cost.

If, however, the revision of the directive is related to other types of strategy, such as advertising or product differentiation, then theoretically an impact may be seen in oligopoly markets (see Box 4.3, a description of strategies used by firms in oligopoly markets when facing price floors[25] or price ceilings[26]).

Box 4.3: Strategies of firms in oligopolistic markets

There are three key strategies of firms in an oligopoly market when their governments introduce price controls (e.g. price floors, price ceilings). These are as follows:

- **Use non-price competition.** Specifically, oligopolies will advertise, differentiate their products and/or try to create barriers to entry for other firms.
- **Acquire other firms.** Firms may seek to integrate the supply chain (horizontally or vertically) more because it becomes relatively more attractive, even if costly, than it was before the introduction of a regulation. The key for this to be a successful strategy is to strike a balance between competition and cooperation.
- **Regain control of prices.** Firms in an oligopoly may join together to control prices again, following a price control policy.

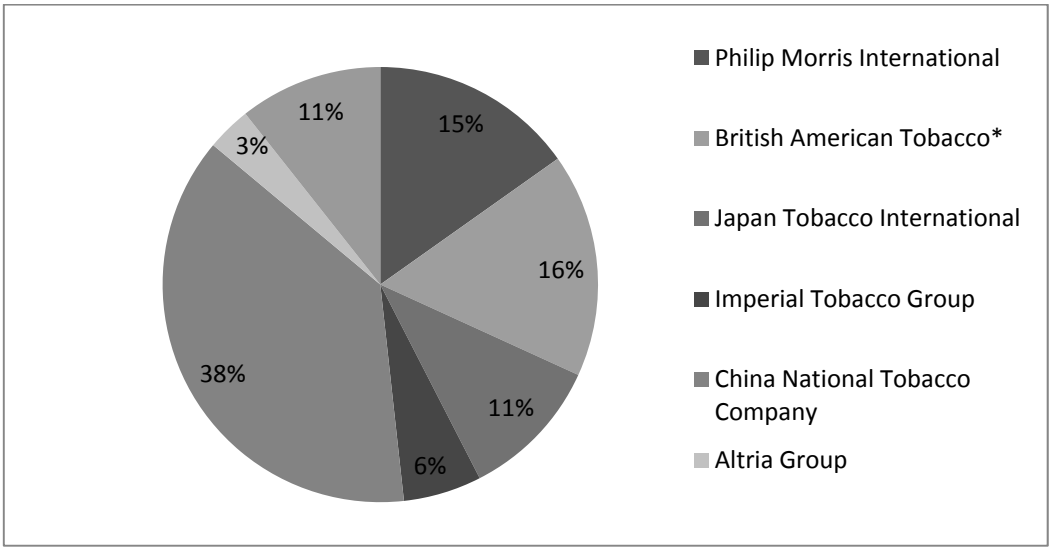
Governments seeking to affect demand of a product should consider that firms in oligopoly markets (and not other structures such as perfectly competitive markets) may use these three broad strategies to avoid reductions in demand for their products and maintain or increase profits.

4.2.4 Description of the top businesses involved in manufacturing and sales of tobacco products

The global industry for tobacco, particularly cigarettes, is largely concentrated in the hands of five companies (see Figure 4.4). With a share of nearly half the entire tobacco market, the China National Tobacco Company is the largest company involved in the tobacco industry. It is owned and managed by the Chinese government, and currently sells only in China.

[25] An example of a price floor often proposed is a minimum wage.

[26] An example of a price ceiling often proposed is a maximum rent for apartments.



Source: Morgan Stanley, Consumer Retail Conference, 2008, slides p. 6

* Including subsidiaries and associates

Figure 4.4: Global market share in sales of tobacco products, 2007

Below we summarise details from each of the main tobacco companies in order to provide a description of the key players in the supply of tobacco products:

- **China National Tobacco Company (CNTC):** sells 1.5 trillion cigarettes annually, all in China.
- **British American Tobacco (BAT):** BAT is a leader in over 50 markets around the world with over 300 brands, and employs nearly 54,000 people. This company focuses on its Global Drive Brands, which include Dunhill, Kent, Lucky Strike and Pall Mall; and includes ready-made cigarettes, cigar, RYO, pipe and STPs.[27] In 2008 BAT earned £12,122 million in revenue, of which 39 percent was revenue generated from Europe. From 2007 to 2008 profit from operations grew by 23 percent to £3,572 million (BAT annual report, 2008). During 2008 the acquisition of the cigarette and *snus* businesses of Skandinavisk Tobakskompagni (ST) and the purchase of the cigarette assets of Tekel, the Turkish state tobacco company, improved revenue growth (*ibid.*).
- **Philip Morris International (PMI):** PMI is a spin-off from Altria Group from 28 March 2008, and in 2008 sold tobacco products in over 160 countries. PMI owns over 150 brands with 1,900 variants, although it is best known for its Marlboro brand.[28] It is a company with revenue in 2008 of $63,640 million and net income of $6,890 million. In 2008 the company held an estimated 15.6 percent share of the total international cigarette market outside the USA. In September 2009 Swedish Match AB sold its South African operation, Swedish

[27] http://www.bat.com/group/sites/uk__3mnfen.nsf/vwPagesWebLive/DO52ADK2?opendocument&SKN=1&TMP=1

[28] http://www.philipmorrisinternational.com/PMINTL/pages/eng/ourbus/Our_brands.asp

Match South Africa (Proprietary) Limited (SMSA) to PMI; SMSA is the market leader in the South African pipe tobacco and snuff categories, which represent an estimated 31 percent of total tobacco consumption.[29]

- **Japan Tobacco International (JTI):** This company owns and manages three of the top five international cigarette brands – Winston, Camel and Mild Seven – as well as other cigarette brands and tobacco products in over 120 countries around the world. The other tobacco products include Hamlet cigars, Old Holborn and Amber Leaf RYO tobacco and Gustavus Snus. In 2007 JTI sold 385 billion cigarettes (cigarette equivalent units), generating US$8 billion in net sales. During the fiscal year ended 31 March 2009 the company had net sales of ¥6,832,307 and net income of ¥123,400, a 48.3 percent decrease from 2007. JTI is the international tobacco business of Japan Tobacco, the world's third largest industry player, with a global market share of 11 percent (Figure 4.4) and market capitalisation of approximately US$32 billion.[30] JTI employs 23,000 people in 40 offices and 30 factories and R&D centres around the world.
- **Altria Group:** Altria sells brands such as Marlboro, Copenhagen, Skoal and Black & Mild through its operating companies, Philip Morris USA, US Smokeless Tobacco Company and John Middleton. In 2008 Altria Group had revenue of $19.5 billion and net income of $4.9 billion.[31]
- **Imperial Tobacco Group (ITG):** The company has sales in over 160 countries and a portfolio of brands, led by Davidoff. In 2008 ITG had volumes of 292 billion, revenue of £5,238 million and net income of £1,157 million.

As these points illustrate, these large firms tend to provide cigarettes, rather than tobacco for cigars or pipes.

In terms of specifically European business, the key four firms reported a total net revenue of nearly €42 billion in 2008 (see Table 4.9).

Table 4.9 Corporate summaries, European business statistics, 2008

	British American Tobacco	Philip Morris*	Imperial	Japan Tobacco International*
Net revenue	€6,043	€20,822	€4,011	€11,012
Profit	€1,542	€3,221	€1,930	€367
Cigarette volumes	260bn	243.5bn	124.6bn	114.8bn
Share of its business in Europe (in terms of operating income)	31%	46%	73%	n/a

Source: 2009 annual reports for BAT, PM, JTI and ITGl

*Profits refer to operating income

[29] http://www.philipmorrisinternational.com/PMINTL/pages/eng/press/pressreleaseTemplate.asp?ID=1304129

[30] http://www.jti.com/About/about_history

[31] http://www.altria.com/download/pdf/investors_AltriaGroupInc_2008_AnnualRpt.pdf

Note: PMI and JTI figures converted from dollars to euros using average 2008 conversion of £1=$1.46. Information for PMI refers to the EU. Information for JTI includes 'Western Europe (including Switzerland, France and Germany)'.

4.2.5 Gross turnover associated with manufacture, wholesale and retail sale of tobacco products across European countries

Utilising Eurostat data, we present gross turnover[32] per capita associated with the manufacture and sale of tobacco products, across countries that reported, in Table 4.10. The table indicates that on average retail sale generates the lowest turnover per capita while wholesale of tobacco products generates the highest gross turnover per capita.

Table 4.10: Gross turnover per capita (€), by sector and country, 2006

	Manufacturing	Wholesale of tobacco products	Retail sale of tobacco products
Austria	.	283.13	253.81
Belgium	128.62	310.04	31.87
Bulgaria	101.18	.	.
Cyprus	.	274.00	3.91
Czech Republic	.	174.42	29.36
Germany	252.91	158.36	30.87
Denmark	.	47.90	18.79
Estonia	.	50.57	.
Spain	20.00	90.45	195.69
Finland	.	35.77	.
France	.	20.20	18.57
Greece	48.63	257.70	53.30
Hungary	.	157.39	4.47
Italy	.	235.33	55.67
Lithuania	.	28.80	.
Luxembourg	.	2950.42	19.19
Latvia	.	94.13	1.31
Netherlands	355.94	267.23	41.32
Norway	.	61.64	0.65
Poland	100.48	65.41	1.99
Portugal	42.48	159.61	12.49
Romania	42.39	96.85	0.97
Sweden	.	21.66	64.66
Slovenia	.	33.94	36.94
Slovakia	.	81.83	5.01
United Kingdom	222.49	21.71	23.72
Average	131.51	239.14	41.12

Source: Eurostat (SBS)

[32] 'Turnover comprises the totals invoiced by the observation unit during the reference period, and this corresponds to market sales of goods or services supplied to third parties; it includes all duties and taxes on the goods or services invoiced by the unit with the exception of the VAT invoiced by the unit to its customer and other similar deductible taxes directly linked to turnover; it also includes all other charges (transport, packaging, etc.) passed on to the customer. Price reductions, rebates and discounts as well as the value of returned packing must be deducted' (http://epp.eurostat.ec.europa.eu/cache/ITY_SDDS/en/sbs_esms.htm, accessed 31 May 2010.

4.2.6 Number of enterprises involved in tobacco across European countries

In terms of the number of enterprises[33] operating in the manufacture, wholesale and/or retail sales of tobacco products in 2006, Eurostat data suggests there were approximately 67,000 within the EU and Norway (see Table 4.11). Note that these enterprises are not necessarily separate legal entities; some of them may be owned by the same parent company. In any event, the highest reported numbers of tobacco manufacturing enterprises in 2006 were in Germany and Spain, the highest reported numbers of wholesale enterprises were in Greece and Poland, and the highest numbers of retail sale enterprises were in Italy and Spain.

Table 4.11: Number of tobacco enterprises, by sector and country, 2006

	Manufacturing	Wholesale of tobacco products	Retail sale of tobacco products	Total
Austria	1	14	3,228	3,243
Belgium	33	79	198	310
Bulgaria	33	.	.	33
Cyprus	.	17	10	27
Czech Republic	4	47	1,992	2,043
Germany	46	214	4,961	5,221
Denmark	7	20	159	186
Estonia	0	5	5	10
Spain	55	32	11,542	11,629
Finland	1	11	4	16
France	9	40	4,701	4,750
Greece	6	395	1,980	2,381
Hungary	.	23	436	459
Italy	.	144	26,786	26,930
Lithuania	1	9	8	18
Luxembourg	1	15	11	27
Latvia	3	18	8	29
Netherlands	20	65	1,165	1250
Norway	1	8	9	18
Poland	21	599	525	1145
Portugal	4	294	733	1031
Romania	17	145	128	290
Sweden	19	61	1,802	1,882
Slovenia	.	5	78	83
Slovakia	.	13	10	23
United Kingdom	10	80	3,911	4,001
TOTAL	292	2,353	64,390	67,035

Source: Eurostat (SBS)

Interestingly, the UK and The Netherlands, two countries with less than 10 percent of firms, generate over 50 percent of gross income in the EU for manufacturing tobacco (gross income is seen in Table 4.10). The countries comprising less than 1 percent of the total enterprises (thus reporting one or zero enterprise) are Austria, Estonia, Finland,

[33] 'The enterprise is the smallest combination of legal units that is an organisational unit producing goods or services, which benefits from a certain degree of autonomy in decision-making, especially for the allocation of its current resources. An enterprise carries out one or more activities at one or more locations. An enterprise may be a sole legal unit' (Eurostat: Metadata in Euro SDMX Metadata Structure (ESMS)).

Lithuania, Luxembourg and Norway. This may indicate a greater scale of operation or greater productivity in these countries.

4.2.7 Employment across European countries

A revision of the directive may alter the attractiveness and increase the costs of tobacco products. The result that this may have on employment is uncertain. On the one hand, change in attractiveness and costs may not affect profit margins in a way that affects employment (i.e. measures may induce companies to make efficiency savings). On the other hand, companies may need to start cutting their costs (i.e. reduce the number of full-time workers) in order to remain competitive. In the short term, companies may try to reduce labour costs because capital (i.e. land, infrastructure) is fixed – that is, land and capital assets have longer contracts and take a long time to sell off to another buyer.

The general composition of employment in the tobacco industry lies in the activities of manufacturing, wholesale and retail sales, with relatively limited employment in wholesale of unmanufactured tobacco (see Figure 4.5); however, as described earlier in this chapter, the data for employment with NACE codes referring to agriculture are not available.

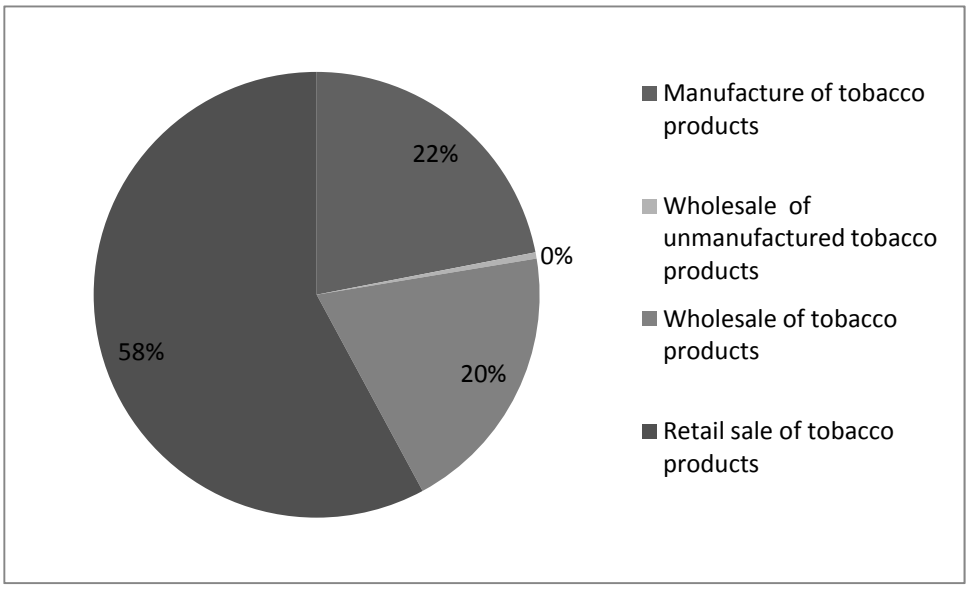


Figure 4.5: Composition of number of persons employed in tobacco industry, across the EU and Norway, 2006

As the three key areas of employment are manufacturing, wholesale of manufactured products and retail, we describe the *levels* of employment across Member States in more detail below in order to provide an indication of the absolute numbers. For the impact analysis, we use the proportion of employed persons in each sector to the total employed persons in each country over time (see Table 4.12 for these data).

As seen in Table 4.12:, there are approximately 47,000 persons employed in the manufacturing of tobacco products. The largest proportions of these employees reside in Germany (24.5 percent), Poland (14.9 percent), the UK (9.7 percent), Spain (9.7 percent) and The Netherlands (9.5 percent).

Approximately 200,000 people are employed in the sale of tobacco products (see Table 4.12:). With many more individual enterprises involved in the retail sale of tobacco

products than in other sections (as seen in Table 4.11), it is not surprising there are many more people employed in this activity of the tobacco market. The Eurostat data suggest the largest proportions in retail sale reside in Italy, Germany and Spain. Table 4.11 also suggests that there are differences in the nature of employment across sales activities, and any revision to the directive that affects one sector more than another may have a differential impact across Member States.

Table 4.12: Number of persons employed, by sector, 2006

	Manufacturing	Wholesale of tobacco products	Retail sale of tobacco products	Total
Austria	.	198	9,881	10,079
Belgium	1,877	872	394	3,143
Bulgaria	6,324	.	.	6,324
Cyprus	.	242	20	262
Czech Republic	.	2,811	3,633	6,444
Germany	11,543	8,681	20,108	40,332
Denmark	.	221	865	1,086
Estonia	.	134	.	134
Spain	4,556	2,680	20,734	27,970
Finland	.	195	.	195
France	.	1,041	9,548	10,589
Greece	2,520	3,397	5,838	11,755
Hungary	.	1,560	849	2,409
Italy	.	1,452	50,509	51,961
Latvia	317	.	.	317
Lithuania	.	157	.	157
Luxembourg	.	221	27	248
Latvia	.	327	44	371
Netherlands	4,473	1,711	5,048	11,232
Norway	292	173	27	492
Poland	7,009	4,127	1,489	12,625
Portugal	1,140	1,561	1,150	3,851
Romania	2,471	5,082	472	8,025
Sweden	.	467	3,966	4,433
Slovenia	.	117	129	246
Slovakia	.	559	372	931
United Kingdom	4,586	4,106	14,937	23,629
TOTAL	47,108	42,092	150,040	239,240

Source: Eurostat (SBS)

4.3 Tax rates and revenues in tobacco

Tobacco revenues are a function of the quantity and price of tobacco products – any element of a revision in the directive that affects price and demand may impact on governments' budgets and therefore may have an economic implication.

As described in (Buck *et al.*, 1995), 'although strictly speaking tax revenue is a transfer between different groups in the population and therefore not an economic cost, from the government's perspective tobacco tax revenue is a significant and useful source of finance'. That is, generally, collection of excise duties may be considered shifts in financial holdings from one group to another.

It should be noted that as people shift from purchasing tobacco to purchasing other goods and services or saving their money, governments' overall revenues increase again. We discuss here the short-term effect the proposed policy changes could have on governments' tobacco tax revenue.

In 2007 European governments collected approximately €67 billion in excise duties relating to the consumption of tobacco (see Table 4.13). On average, each country accrued €2.5 billion in excise duties from the consumption of tobacco.

Table 4.13: Excise duties collected from the consumption of tobacco (€ million), by country, 2007

Country	Excise duties collected (€ millions)
Belgium	1,536.20
Bulgaria	688.55
Czech Republic	1,049.63
Denmark	898.09
Germany	14,108.00
Estonia	133.66
Greece	2,650.00
Spain	7,141.00
Ireland	37.00
Italy	10,195.00
Cyprus	180.50
Latvia	92.29
Lithuania	119.11
Luxembourg	49.43
Hungary	910.17
Malta	2.04
Netherlands	1,288.00
Austria	1,446.16
Portugal	684.92
Romania	1,263.72
Slovenia	301.01
Slovakia	782.61
Finland	622.00
Sweden	1053.18
United Kingdom	11,764.62
Switzerland	1,049.63
Norway	6,815.00
AVERAGE	2,531.23
TOTAL	66,861.52

Source: DG TAXUD, NTL Tables

4.4 Smuggling of tobacco products

In both economic and public health terms, tobacco smuggling is an issue. Price is a factor of consumption, as indicated in the literature on elasticities, and the availability of cheaper smuggled products may encourage increases in consumption (with implications for health, given the health impacts of tobacco outlined in Chapter 9). In the formal economy, government revenues may fall because smuggled products are not subject to taxation and manufacturers/wholesalers/retailers may experience lower revenue and/or profits because consumers are diverted to the informal economy.

According to DG TAXUD, the cigarettes seized over the course of 2006 would have provided the EU and Member States with more than 230 million euros of tax revenue (European Commission, 2007).

The European Anti-Fraud Office (OLAF) reports that approximately 5.3 billion illegal cigarettes were seized by law enforcement agencies across the EU in 2008.[34] In 2008 cigarettes were the second most detained item (23 percent) at European borders, following CDs/DVDs (44 percent). According to DG TAXUD, 'compared to previous years, the overall amount of articles has increased enormously, mainly due to much more articles detained in the CD/DVD/cassettes and cigarettes categories' (European Commission, D.T., 2008).

There is some academic research at country level. Research in France finds that 14–20 percent of total tobacco sales involve cross-border or smuggled cigarettes (Lakhdar, 2008). The study also finds nearly one cigarette out of six was bootlegged or smuggled (Lakhdar, 2008). In the UK studies indicate that the illegal market share for cigarettes was 13 percent in 2005–06, which was attributed mainly to bootlegging and the counterfeit trade (Joossens and Raw, 2008)HM (Treasury, 2006).

[34] http://ec.europa.eu/anti_fraud/press_room/pr/2010/01_en.html

CHAPTER 5 Administrative burden of the current tobacco directive

Regulating the manufacture, presentation and sale of tobacco products, as described in the current directive, results in an administrative burden for the businesses involved in the production and for Member States' competent authorities. In this chapter we describe the key administrative burden implications of the current regulation for businesses affected and EU Member States. In addition, this chapter provides the background for the assessment of policy measures and options in the later chapters by discussing general themes of regulatory compliance. The current regulation and any future changes to it are likely to have cost impact in the following areas:

1. Labelling and packaging of tobacco products.
2. Reporting on tobacco products.
3. Member States' reporting and information provisions.

Each of these three areas is discussed in more detail in the following sub-sections. The final assessment of these costs is informed by a number of key informant interviews with business representatives, a survey of businesses and a review of the few existing studies that have assessed the cost impacts of tobacco regulation as well as other relevant literature (e.g. on food labelling costs).

5.1.1 Overview of administrative burden for business

In general, regulation imposes compliance costs on business, citizens and other organisations which are defined, quite broadly, as costs incurred as a consequence of legislation – that is, all direct costs incurred by addressees in order to comply with the policy measure, including administrative cost. A much smaller set of costs is administrative costs, which are defined as 'the costs incurred by enterprises, the voluntary sector, public authorities, and citizens in meeting legal obligations to provide information on their action or production' (European Commission, 2009). Administrative burdens are defined as those administrative costs that a company incurs solely because of being legally obligated to provide information to the relevant regulator or to third parties (European Commission, 2009). Information obligations are to be understood in a broad sense and include reporting, labelling, registration and monitoring. Administrative burdens primarily refer to labour costs, but may also mean the costs of equipment that is required to generate or transmit the information.

The Tobacco Products Directive contains a number of information obligations. Table 5.1 lists the key information obligations contained in the current directive.

Table 5.1: Information obligations of business under Directive 2001/37/EC

	Description	Frequency	Recipient	Article
1	The result of tests assessing the TNCO yields of cigarettes done by approved laboratories must be reported.		Member States	Article 4
2	The results of any other test required by Member State legislation must be reported.	Annually, upon change of product	Member States	Article 4
3	The TNCO yields of cigarettes should be printed on the pack.	Per pack	Consumers	Article 5
4	Unit packs of tobacco products must carry health warnings.	Per pack	Consumer	Article 5
5	A list of all ingredients, and quantities thereof, used in the manufacturing of those tobacco products by brand name and type must be reported.	Annually	Member States	Article 6
6	A statement setting out the reasons for the inclusion of such ingredients in those tobacco products must be submitted. It shall indicate their function and category.	Annually	Member States	Article 6
7	The toxicological data available to the manufacturer or importer regarding these ingredients in burnt or unburnt form as appropriate, referring in particular to their effects on health and taking account, *inter alia*, of any addictive effects must be reported.	Annually	Member States	Article 6

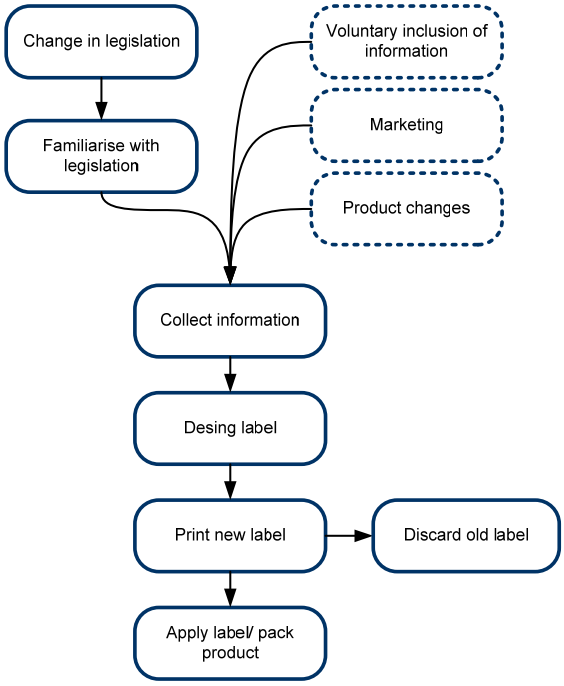
The information obligations may be roughly divided into information about the product that will be communicated to the consumer on the packets of tobacco products (labelling), and information about the characteristics of the product that will be transmitted to the Member States (reporting).

5.1.2 Businesses' administrative burden in labelling tobacco products

The costs of labelling requirements occur primarily at company level; this is particularly the case for the manufacturers of tobacco products. They occur either in-house or as costs for outsourced services (Golan *et al.*, 2000). In understanding the cost implications of labelling changes, it is important to note that labels are not changed for regulatory reasons alone, and tobacco products would be labelled in the absence of any regulations. From food labelling research it is known that changes in regulation are an important driver of labelling changes, but that labels are usually changed by producers at regular intervals for marketing purposes – to reflect changes in the recipes of the product or for various other reasons. In food labelling the life cycle of a label may range from a few months for highly marketed, branded products – such as cereals or soft drinks – to a few years for niche products and commoditised products such as sugar, salt or flour (EAS, 2004). In the tobacco industry the cycles appear to be longer, with labels being changed approximately

every two years for cigarette stock keeping units (SKUs), and every five to seven years for cigar SKUs for non-regulatory reasons.[35]

The administrative burden of labelling regulation is thus not defined as the total costs of producing a label, but only as the additional costs of including any new specific requirements on the label. Figure 5.1 gives an overview of the basic steps of producing a label.



SOURCE: Own compilation

Figure 5.1 Key steps in the labelling process

These steps may translate into a number of specific costs, which will depend on the extent of change to existing requirements and the timing of these changes. These costs may include those incurred by the following:

1. The company will have to familiarise itself with the changes in regulation, either through in-house expertise or contracting.
2. The information to be put on the label will most probably need to be collected – that is, the ingredient information as well as the textual/or pictorial health warnings.

[35] For this report, as it is coming practice when discussing the costs of labelling, SKUs are the reference point as labelling costs are incurred at the level of stock keeping units. A SKU is an item that is unique because of some characteristic (such as brand, size, colour, model) and is thus stored and accounted for separately from other items; in particular, it will have different packaging. If a tobacco product is, for example, sold in 27 Member States in two different package sizes, this will result in a total of 54 SKUs (i.e. two packages for each country) reflecting language and potentially regulatory differences. A company would therefore need to change 54 different packages/labels if labelling requirements change. This also means that the price of changes per package or per cigarette will depend on how many cigarettes are sold per SKU.

3. The label needs to be redesigned to accommodate the additional information.
4. The label or package will need to be printed, potentially requiring the use of new printing equipment (cylinders and embossing tools). In any case, this equipment is replaced on a regular basis, so additional costs only will need to considered.
5. Manufacturers may have a stock of old labels and or packages, which they may have to discard if there is no transition period for a new regulation.

There are two areas of cost implications of labelling requirements under the current directive: 1) the TNCO yields of cigarettes should be printed on the package, and 2) unit packs of tobacco products must carry health warnings. RAND Europe gathered evidence from cigarette as well as cigar manufacturers on the administrative burden of these two sources of cost (for more details about data collection see Section 2.5). As there is no requirement and no standardised and widely accepted measurement method for TNCO yields of cigars, this particular question was not explored with regard to cigar manufacturers. Initial administrative burden of the directive was not explored as measuring that proved to be analytically challenging – for example, the size of the market has changed since the introduction of the directive and EU Member States had different national regulation prior to the introduction of the EU-level regulation.

Three large European cigarette manufacturers reported that the administrative burden each of them faces on an ongoing basis regarding TNCO yield labelling ranges from 1.5 million euros per annum to 3.1 million euros per annum (Table 5.2). This translates into 730–1560 euros per SKU. The wide range of costs is due to the differences in company sizes, production processes (e.g. technology used to print labels put on the pack) and labour costs. This range of per company costs implies an EU-27-wide overall administrative burden for cigarette manufacturers of between 4.8 million euros per annum and 9.8 million euros per annum. Scaling up company-level data to the EU-27's market is based on the market share of companies – that is, sales volumes taking into account the least-cost solution as lower margin and average solution as higher margin. The reason for allowing such variation is that the data did not allow us to determine whether some companies were more efficient than others or if their cost differentials were economically justified.

The cigarette manufacturers reviewed here reported that the administrative burden they face on an ongoing basis regarding the display of textual health warnings ranges from 7.8 million euros per annum to 17.5 million euros per annum (Table 5.2). This translates into 2,000–9,720 euros per SKU a year. Once again cost differences are driven by company size, production process and labour cost. By implication, the overall annual administrative burden for cigarette manufacturers in the EU-27 amounts to between 30.4 million and 50.2 million euros per annum.

The cigar manufacturers who provided responses reported that the administrative burden each of them faces on an ongoing basis regarding the display of textual health warnings ranges from 300,000 euros per annum to 900,000 euros per annum. This translates into 160–330 euros per SKU a year.[36] Cost differences are driven by differences in company

[36] The reasons behind the wide gap in per SKU administrative burden of cigarette and cigar manufacturers could not be explored in detail. It is possible that smaller SKU volumes in the cigar industry explain the smaller costs.

size, production process and labour cost. This range of per company costs suggests an EU-27-wide overall administrative burden for cigar manufacturers of between 2.8 million euros and 5.2 million euros per annum.

The above company-level estimates of administrative burdens are based on information provided by manufacturers according to detailed cost categories such as prices of embossing tools and frequency of change of machinery. Companies varied greatly in terms of costs of standard inputs they use, such as embossing tools, as well as in terms of crucial aspects of their production process such as number of cylinders used per label and frequency of machinery change. The validity of such information could not be assessed and the reasons for the inter-company variation could not be explored.

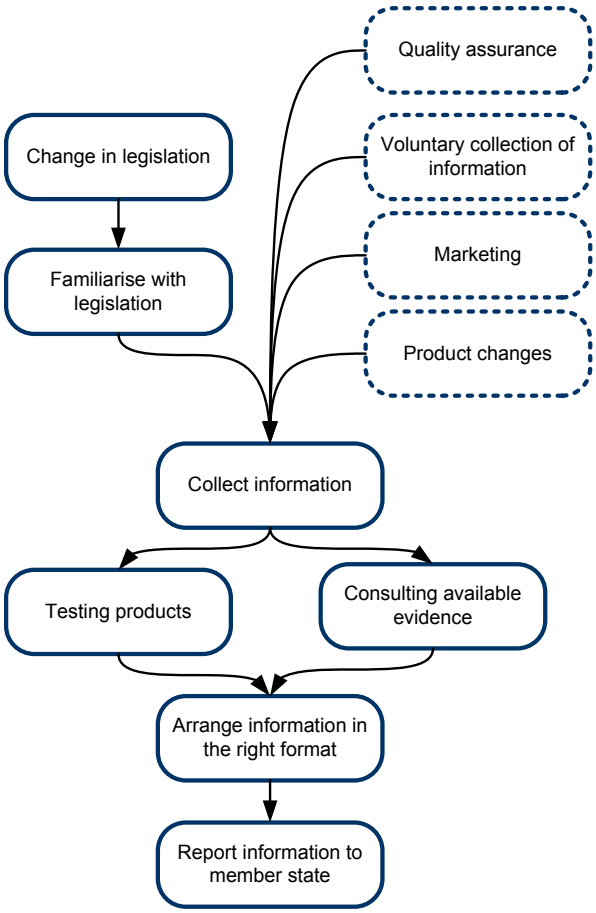
A particularly problematic aspect of the above calculations was getting estimates on the proportion of business-as-usual costs to administrative burdens. Manufacturers reported that their internal cost-accounting systems do not allow for precisely differentiating costs due only to regulation; their estimates for labelling costs due solely to regulation (i.e. administrative burden) ranged between 30 percent and 50 percent of overall labelling costs.

Table 5.2: Ongoing administrative burden under the current directive regarding labelling, euros/year, 2009

	TNCO yield			Textual warnings		
	Per cigarette (euro cents)	per SKU (euros)	EU-27 (million euros)	Per cigar (euro cents)	Per SKU (euros)	EU-27 (million euros)
Cigarette manufacturers	0.0006–0.0013	730–1560	4.8–9.8	0.0041–0.0068	2000–9720	30.4–50.2
Cigar manufacturers	Not applicable	Not applicable	Not applicable	0.4–0.7	160–330	2.8–5.2
Other tobacco product manufacturers	Not available	Not available	Not available	Not available	Not available	Not available

5.1.3 Businesses' administrative burden of reporting on tobacco products

A second element of administrative burden for manufacturers of tobacco products is the cost of reporting on tobacco products. This entails two major cost elements: 1) testing tobacco product; and 2) submitting information on the results of tests, as well as further aspects of ingredients of tobacco products, to Member States (information obligations numbers 1–2 and 5–7 in Table 5.1). The costs of laboratory testing may occur in-house or laboratory services may be procured from external providers. Testing and submission costs occur only upon changes in the product composition, or if new products are introduced. Thus the frequency of such changes will be an essential element of our administrative burden estimates. Moreover, products are tested and information on ingredients is collected for marketing purposes (e.g. to gauge consumer response to certain flavours) as well as for reasons of internal quality assurance (e.g. controlling the quality of the production process). Therefore not all costs may be classified as an administrative burden.



SOURCE: own compilation

Figure 5.2: Key steps in the reporting process

These steps may translate into a number of specific costs:

1. The company will have to familiarise itself with the changes in the legislation, either through in-house expertise or by contracting in expertise.
2. The information to be reported to Member States will potentially need to be collected (i.e. TNCO yields data and ingredient information). This information may be collected in two ways:
   - 2.1 products must be tested by approved laboratories either in-house or externally;
   - 2.2 available evidence on ingredients (e.g. health impacts, addictiveness) must be consulted or new evidence collected.
3. Information collected must be put in the format required by Member States.

From the cost areas discussed in this sub-section, the one referring to TNCO yields is not applicable to cigars; therefore this question was not explored regarding cigar

manufacturers. The measuring of the initial administrative burden of the directive was not explored as it proved to be challenging analytically – for example, the size of the market had changed since the introduction of the directive and EU Member States had different national regulation prior to the introduction of the EU-level regulation.

The large cigarette manufacturers reported that the total administrative burden each of them faces on an ongoing basis regarding TNCO yield testing and other tests required by Member States ranges from 0.2 million euros to 6.9 million euros per annum. Quantitative cost estimates were obtained for laboratory costs (0.2–6 million euros a year) and labour costs (0.005–0.9 million euros a year) related to information transmission to the relevant authorities. In every case the laboratory costs represented the predominant part of the total administrative burden. The average number of TNCO measurements per SKU per annum was reported to be 24 (i.e. twice per month per SKU).

The above wide range of per company costs is due to different product portfolios, testing processes (e.g. infrastructure used for testing) and labour costs. This range of per company costs implies an EU-27-wide overall administrative burden for cigarette manufacturers of between 1.1 million euros and 10.2 million euros per annum (Table 5.3).

Cigarette as well as cigar manufacturers reported on the administrative burden each of them faces on an ongoing basis in submitting the list of ingredients used, the reasons for their inclusion and the toxicological data available. The costs per company and the EU-27-wide cost figures are reported in Table 5.3. For some responding companies, the major part of administrative burden was labour costs, basically relating to searching evidence available and submitting the information collected. Laboratory and research costs were the biggest cost element for companies that conducted their own research on, for example, the toxicological impact of ingredients.

Scaling up company-level data to EU-27 level has been done in the same way as in the case of administrative burden of labelling requirements.

Table 5.3: Ongoing administrative burden of cigarette and cigar manufacturers from reporting on tobacco products, million euros/year, 2009

	Cigarette manufacturers			Cigar manufacturers		
	Per cigarette (euro cents)	Per company	EU wide	Per cigarette (euro cents)	Per company	EU wide
Testing TNCO yields and other test required by Member States	0.0002–0.0001	0.2–6.9	1.1–10.2	Not applicable	Not applicable	Not applicable
List of ingredients	0–0.001	0.05–7.3	0.2–10.2	0.03–0.1	0.001–0.2	0.2–0.7
Reasons for inclusion	0	0.001–0.1	0.003–0.2	0.009–0.05	0.0007–0.1	0.07–0.3
Toxicological data available	0	0.001–0.4	0.06–0.7	0.004–0.1	0.0002–0.3	0.03–0.7

The above company-level estimates of administrative burdens are based on information provided by manufacturers according to broad cost categories such as staff time spent in

preparing reported information or external laboratory costs. More detailed information on production costs could not be obtained in spite of RAND Europe's best efforts. A particularly problematic issue in this respect is that the amount of business-as-usual costs could not be quantified in most of the cases; therefore the figures above may be overestimations. This should be noted particularly in the case of reporting information on ingredients where laboratory costs were included by RAND Europe's calculations, resulting in a wide range of per company costs. It is unclear which proportion of these administrative costs is due to the regulation and is not serving other purposes (e.g. supporting the general knowledge base of the company) as industry did not disclose such information.

5.1.4 Overview of administrative burden for EU Member States

The current regulatory framework involves administrative costs for the EU Member States emanating mostly from information and reporting requirements towards the EC. The reporting requirements for Member States contained in the current directive are listed in Table 5.4. They predominantly concern the collection and aggregation of information from business and industry and the communication of the aggregated information to the EC, the general public and consumers.

Table 5.4: Member States' reporting and information obligations

#	Description	Frequency	Recipient	Article
1	Provide a list of approved laboratories, specifying the criteria used for approval and the methods of monitoring applied and whenever any change is made	Complete list once, upon changes to the list	EC	Article 4
2	Communicate all data and information submitted by the tobacco manufacturers and importers pursuant to Article 4	Annually	EC	Article 4
3	Communicate all data and information submitted by the tobacco manufacturers and importers pursuant to Article 6	Annually	EC	Article 6
4	Communicate the text of provisions of domestic law which they adopt in the field governed by this directive.	Once, and upon change	EC	Article 14
5	Dissemination of information submitted by the tobacco manufacturers and importers pursuant to these articles, taking into account any information which constitutes a trade secret (in particular when concerning a specific product formula)	Annually	Public/consumers	Articles 4 and 6
6	Publish the list of ingredients for each product, indicating TNCO yields	Annually	Public/consumers	Articles 4 and 6

The administrative burden is likely to arise from obligations 2, 3, 5 and 6, defined in Table 5.4, which are related to relaying information from tobacco manufacturers to the general public and the EC. By 2009, however, only nine Member States had forwarded the

information to the EC, and only one had made the information available to the general public using an on-line database tool.[37]

In preparation for the electronic submission of ingredient data, the European Executive Agency for Health and Consumers (EAHC) (60 percent) and a consortium of 13 Member States (40 percent) funded the development of EMTOC (Electronic Model Tobacco Control), a European web application which enables safe submission of the lists of tobacco ingredients to the authorities concerned (RIVM, 2010). The total cost of the project was around €335,000, but the roll-out of the electronic format will result in some additional set-up costs from the provision of help desk advice (DG SANCO, 2009b). Some of the running costs will, however, be recovered through a recommended submission fee of €200 (paid by each tobacco company that uses the system).

Besides the reporting requirement, Member States bear the costs of implementing the directive nationally, although these are not administrative burdens. These costs mainly concern the following (UK Department of Health, 2002):

1. The accreditation and monitoring of laboratories conducting measurements of cigarette yields.
2. Expenses for making public the information about constituents of tobacco products.
3. Enforcing the regulation 'on the ground' through inspections and necessarily prosecutions.

No comprehensive cost estimates of implementing the current directive in the Member States are available. There is, however, some evidence from a UK impact assessment conducted prior to the implementation of the directive in the UK, stating that implementation costs are estimated to be small for the UK (UK Department of Health, 2002):

- Laboratory costs are around £388,000 a year.
- Minimal costs for the dissemination of information using existing communication routes and mechanisms.
- Short initial burden for local authorities enforcing the legislation, but a high level of compliance expected so that costs are expected to be minimal.

[37] Exchange with EC officials.

CHAPTER 6 Baseline scenario

In assessing the impacts of changes to the Tobacco Products Directive it is important to assess the baseline scenario – that is, a situation in which no additional policy measures would be taken. In the following section we shall therefore forecast future prevalence, smoking-related morbidity and mortality and related healthcare costs, and also employment and excise duty collection if current trends continue.

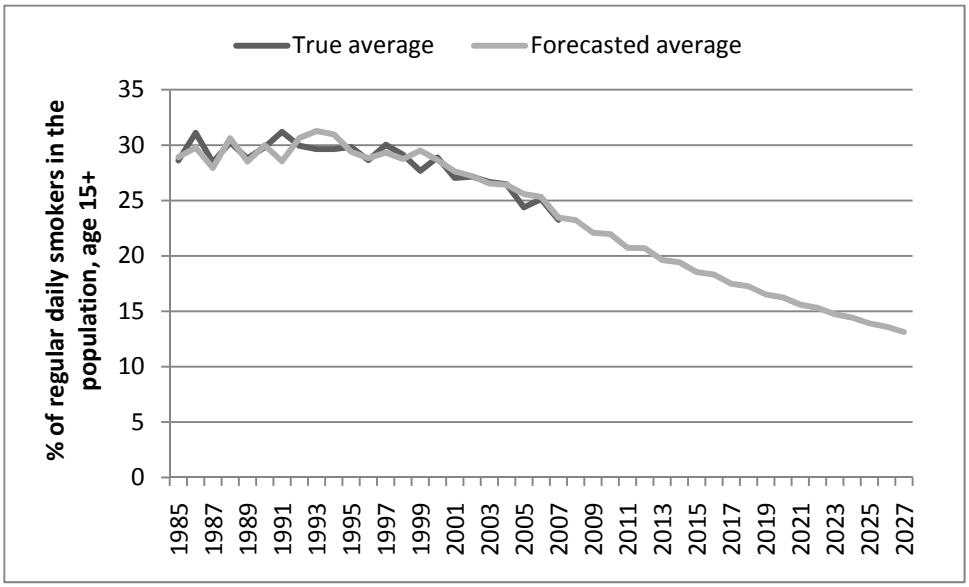
6.1 Smoking prevalence

For the baseline scenario we assumed that current prevalence is some function of previous prevalence rates. Rather than simply assuming a single average of the past change in prevalence, we improve on the assumption by testing each year of smoking prevalence figures (per country) against the previous ten years of smoking prevalence figures per country.

To do this, we test whether changes in prevalence in one year have any statistical relationship to changes in prevalence up to ten years previously. The testing of WHO prevalence data finds that the change in one year is based on changes over the previous ten years. For example, the change in prevalence from 2006 to 2007 is the accumulation of some proportion of the prevalence change from 2005 to 2006, some proportion of the change from 2004 to 2005, and so on. The testing provides the extent to which changes in previous years influence current changes; as would be expected, more recent changes have more relationship than changes in the distant past. In other words, a larger proportion of the forecasted change from 2006 to 2007 will include the change from 2005 to 2006 than from 1999 to 2000.

After identifying this potential relationship, we then estimate future prevalence in each country in the years 2008 to 2027. It should be noted, however, that this is a relatively simple model that takes into account previous prevalence to understand current prevalence and is therefore likely to be still imprecise because it bluntly combines changes within each year. It is beyond the scope of this study to develop a model to identify the determinants of smoking prevalence across the EU and disentangle changes within each year. For a more in-depth explanation of the methodology, see Appendix B.

Figure 6.1 demonstrates our forecast of tobacco prevalence using data compiled by WHO in the European Health for All database[38] for the countries of Europe. We plot both the 'true' average (the actual data provided by WHO) and the 'forecasted' average (the prevalence our basic model predicts). The figure indicates that our model performs quite well against the actual data (the 'true' average and 'forecasted' average are fairly similar from 1985 to 2007).



Source: WHO European Health for All database and authors' estimates. The 'true average' is the figure provided in the data. The forecasted average is the prediction of the model.

Figure 6.1: Forecast and actual average smoking prevalence in the age 15+ population, for EU-27, 1985–2027

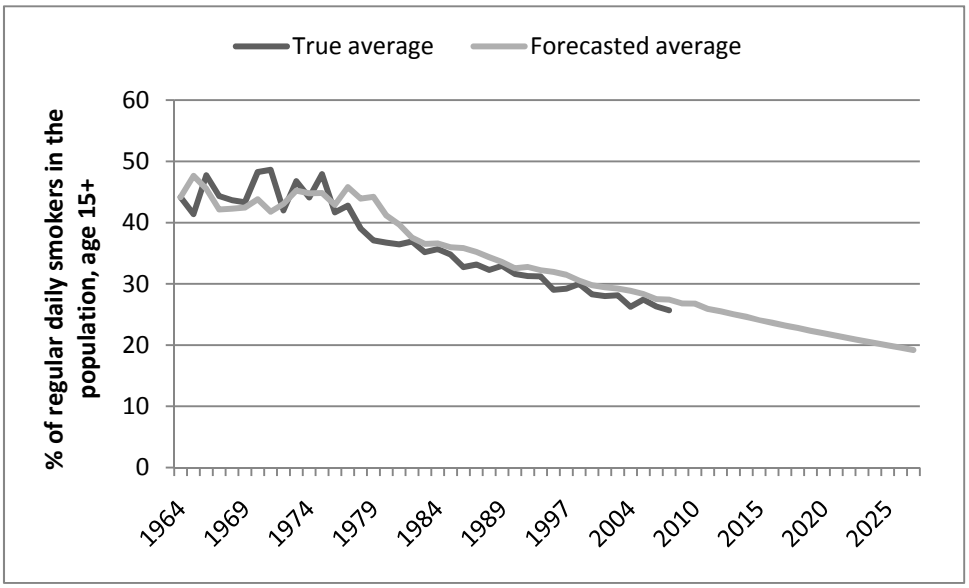
We also test the sensitivity of our findings on prevalence by using a different data set on tobacco prevalence from the OECD. This includes a larger number of countries over a longer time period and allows us to consider trends from countries outside Europe that have implemented tobacco control measures similar to those being proposed (e.g. labelling regulations in Canada). Figure 6.2 shows that our model does not perform as well as it did with WHO data (the differences between the true and forecast results are greater and consistently diverge from actual trends across years). We offer two main reasons for this divergence:

- The definitions of 'daily smoker' may have changed more over time when compared to WHO data, making it difficult for the statistical tests to identify the relationship between consumption rates over time.[39]

[38] 'The data are compiled from different sources, including a network of country experts; WHO/Europe's technical programmes; and partner organizations such as agencies of the United Nations system, Eurostat and the Organisation for Economic Cooperation and Development, and is updated twice annually' http://www1.worldbank.org/tobacco/toolkit.asp (accessed 4 Jun 2010).

[39] There are a number of changes in definitions across countries. For WHO, see http://data.euro.who.int/hfadb/definitions/def.php?w=1280&h=1024.

- There are more countries in other parts of the world with a wider variety of policies introduced, again making it difficult for the statistical tests to identify the relationship between consumption rates over time.



Source: OECD data and authors' estimates. The 'true average' is the figure provided in the data. The forecasted average is the prediction of the model. Depending on year, countries include Australia, Austria, Belgium, Canada, Czech Republic, Denmark, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Japan, Korea, Luxembourg, Mexico, Netherlands, New Zealand, Norway, Poland, Portugal, Slovak Republic, Spain, Sweden, Switzerland, Turkey, United Kingdom and United States of America.

Figure 6.2: Forecast and actual average smoking prevalence in the age 15+ population, 1964–2027

6.2 Mortality and morbidity

The health effects of current tobacco use will be experienced in the upcoming decades as there is a lag between the onset of disease and mortality due to tobacco use. Thus, though the countries entering the tobacco epidemic in later years are now showing an overall decline in overall smoking prevalence, the increases in smoking prevalence seen in the early 1990s, particularly among new Member States, will probably still be reflected in future healthcare costs and increased burden of disease and mortality.

Similarly, other trends in smoking prevalence evident during the 1990s and 2000s, such as the increasing relative proportion of women smoking compared to men, should factor into the distribution of future smoking-attributable health effects.

Finally, the relative increase in smoking prevalence among lower socioeconomic groups – particularly in countries in more advanced stages of the tobacco epidemic such as the UK, Sweden and Ireland – suggests that an increasing proportion of the health effects of tobacco use will also be experienced among lower socioeconomic groups. Thus, the burden of disease and mortality will increasingly be concentrated among these groups.

Our approach does not take into account the immediate effects of policies such as the smoking ban on morbidity and mortality, related to cardiovascular and respiratory disease.

Banning smoking in public places has been associated with a reduction in smoking prevalence and a decline in respiratory symptoms and in hospital admissions due to cardiovascular disease (Allwright *et al.*, 2005, Cesaroni *et al.*, 2008, Eagan *et al.*, 2006, Juster *et al.*, 2007, Khuder *et al.*, 2007, Pell *et al.*, 2008, Valente *et al.*, 2007). Therefore, in our estimates of morbidity we tend to err on a conservative side.

As explained in Chapter 2, all our baseline results apply to the year 2027 since this is (on average) the first year for which we expect any current changes in tobacco regulation to have a noticeable impact. Table 6.1 summarises the baseline estimates, in terms of the total number of deaths, the total direct costs and total indirect costs (both in million euros, deflated[40] to the year 2010), all due to smoking. These are annual estimates, and take into account predictions regarding rising or falling mortality rates based on past patterns.

The table shows that, for the EU-27 as a whole, baseline annual deaths due to smoking are estimated at 342,204, with total direct costs at over 36 billion euros and total indirect costs at over 43 billion euros.

Table 6.1: Summary of baseline smoking-related mortality and cost (x 1 million euros) estimates for the year 2027

Country	Total number of deaths	Total direct costs	Total indirect costs
France	37,599	4,298	5,613
Germany	58,728	6,977	7,716
Italy	30,326	3,462	4,444
The Netherlands	21,022	2,427	2,968
Poland	23,421	1,748	1,763
Spain	31,795	3,025	4,256
United Kingdom	54,843	5,620	6,375
Other Member States	84,469	8,729	10,138
EU-27	342,204	36,285	43,273
Country	Total number of deaths	Total direct costs	Total indirect costs
France	37,599	4,298	5,613
Germany	58,728	6,977	7,716
Italy	30,326	3,462	4,444
The Netherlands	21,022	2,427	2,968
Poland	23,421	1,748	1,763
Spain	31,795	3,025	4,256
United Kingdom	54,843	5,620	6,375
Other Member States	84,469	8,729	10,138
EU-27	342,204	36,285	43,273

Source: Authors' calculations.

In subsequent sections, we describe the (predicted) mortality trends underlying these figures and the estimated prevalence of selected diseases caused by smoking, and give a detailed breakdown of both direct and indirect costs.

Mortality

In this section we present (predicted) trends in mortality attributable to smoking, broken down by cause (lung cancer, aerodigestive cancer, other cancer, COPD and others). Here,

[40] As explained in Chapter 2, all our cost estimates are expressed in 2010 prices (euros), even though they apply to predicted 2027 quantities.

other causes are primarily cardiovascular and cerebrovascular diseases. Since our models predict very different trends for males and females, we present all trends separately for each.

The figures below reveal several important findings. First, the number of deaths has historically been much higher for men than for women. In the majority of countries presented here our models suggest a dramatic change in this pattern over the next two decades, with deaths among women exceeding deaths among men by 2027.

For the UK, Germany, Italy, The Netherlands and Poland, the expected decrease in male deaths is already observable over the past decade; whereas for countries such as France and Spain male death rates are currently still rising or flat. Deaths due to smoking among women have been rising steadily in all countries in the past. For some countries, such as France and The Netherlands, we expect these trends to remain strongly upward sloping, whereas for others (Italy and the UK) they are expected to level off.

The figures also show that changes in trends first occur for other diseases (mainly cardiovascular and cerebrovascular disease) and later for (lung) cancer.

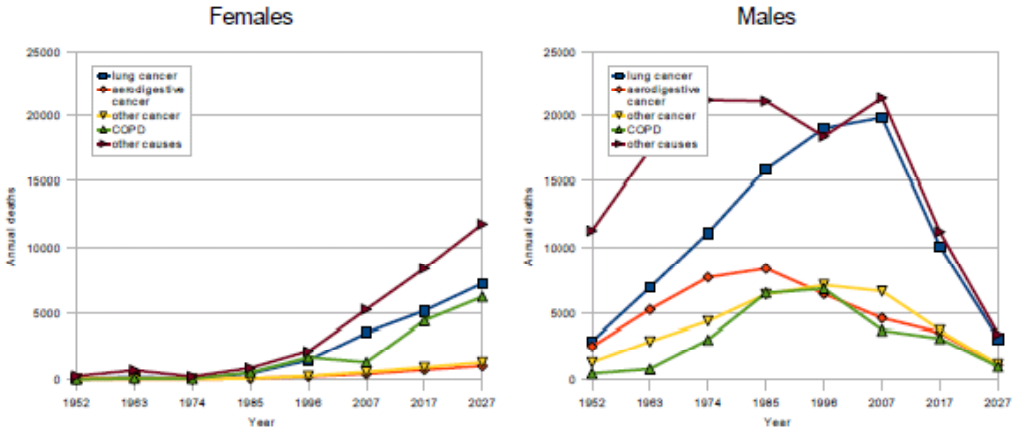


Figure 6.3: Trends in cause-specific mortality due to smoking – France (observed until 2007, predicted afterwards)

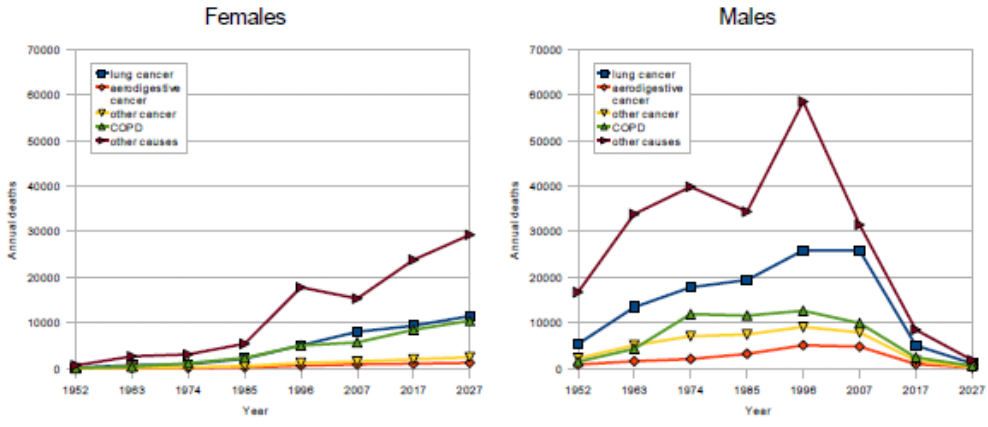


Figure 6.4: Trends in cause-specific mortality due to smoking – Germany (observed until 2007, predicted afterwards)

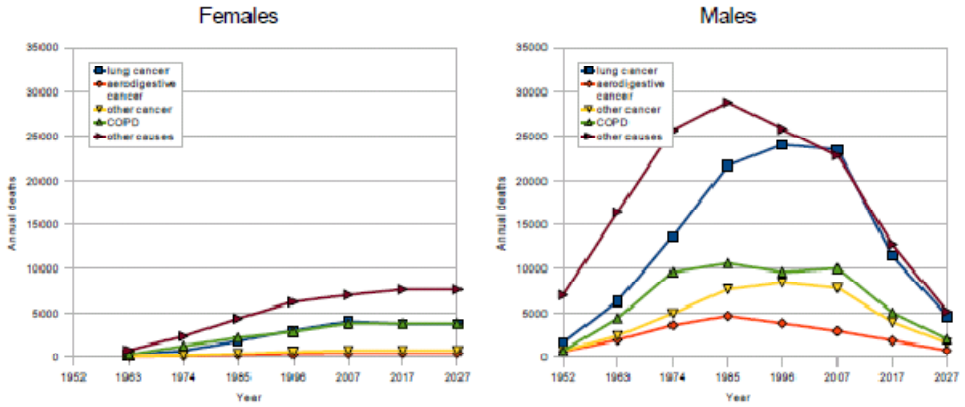


Figure 6.5: Trends in cause-specific mortality due to smoking – Italy (observed until 2007, predicted afterwards)

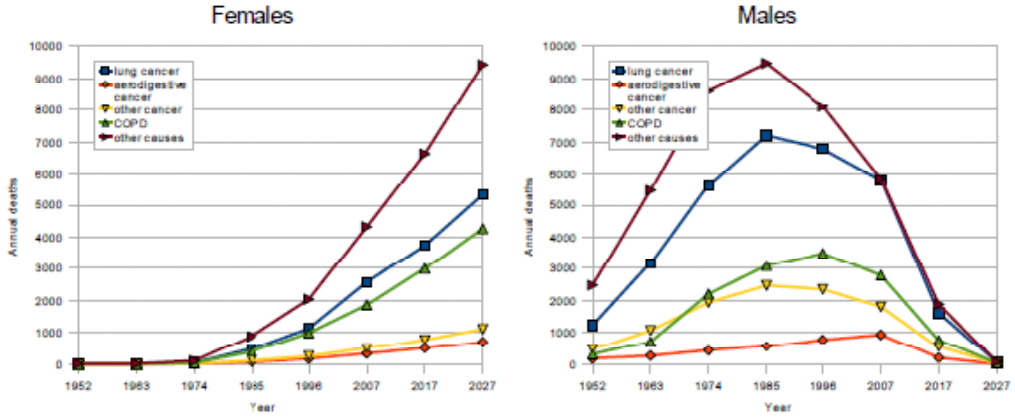


Figure 6.6: Trends in cause-specific mortality due to smoking – The Netherlands (observed until 2007, predicted afterwards)

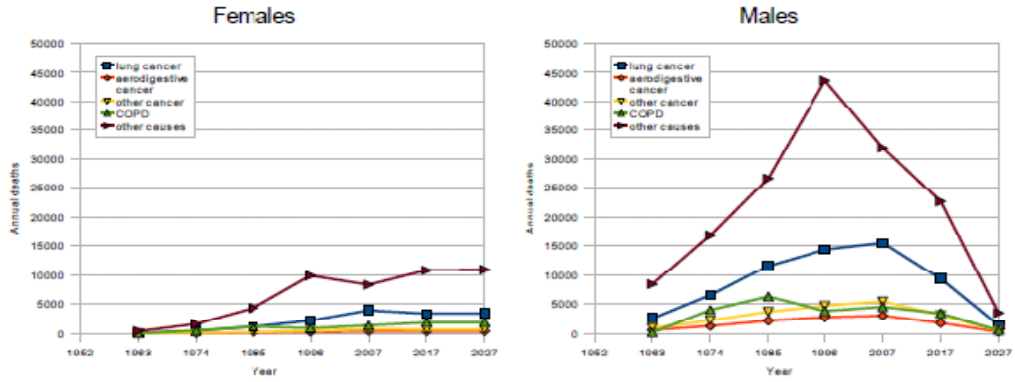


Figure 6.7: Trends in cause-specific mortality due to smoking – Poland (observed until 2007, predicted afterwards)

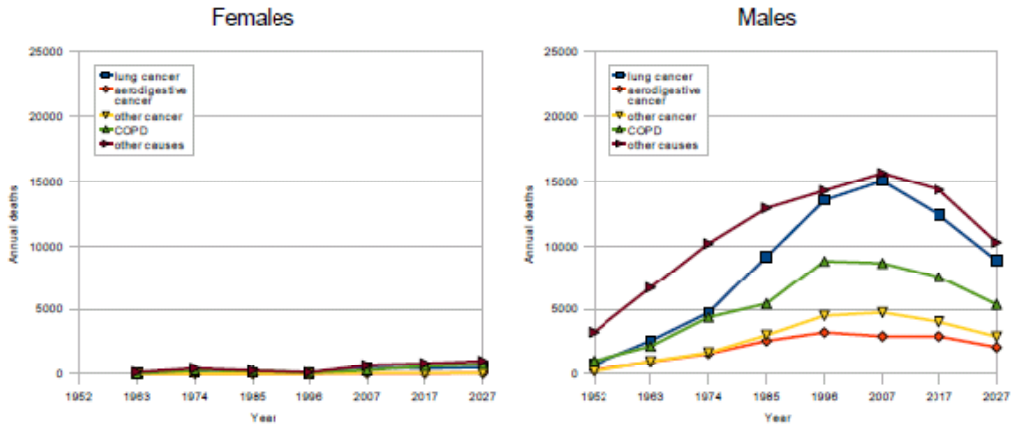


Figure 6.8: Trends in cause-specific mortality due to smoking – Spain (observed until 2007, predicted afterwards)

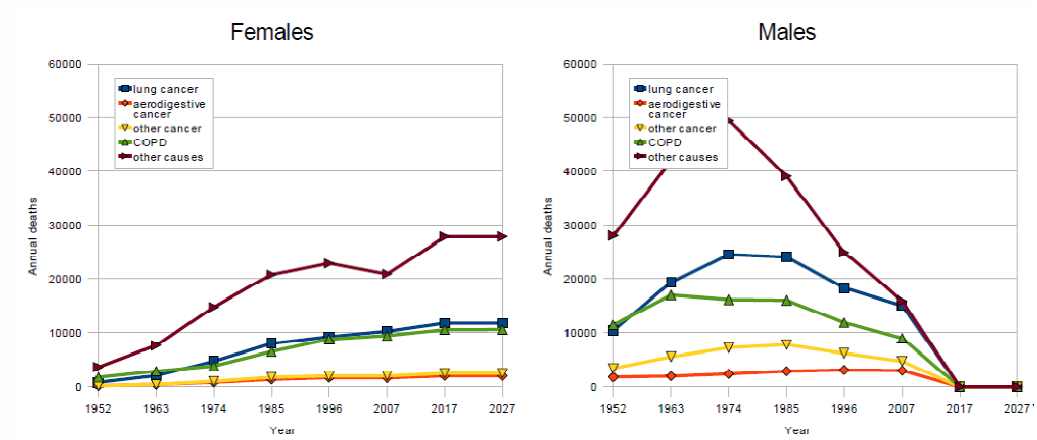


Figure 6.9: Trends in cause-specific mortality due to smoking – UK (observed until 2007, predicted afterwards)

A very significant drop in the number of deaths due to smoking is expected to take place during the first three decades of the 21st century among males in the UK, Germany, France, Italy and The Netherlands. The predicted drop, however surprising it may appear, results from the reliance of the estimation procedure for smoking-related mortality on trends in the rates of mortality from lung cancer. Lung cancer mortality has been decreasing rapidly in these countries, starting some time during the 1980s to 1990s. The dramatic drop in the number of deaths due to smoking during the last two decades of the 20th century is also observed in updated estimates produced by Peto *et al.* (2006).

Morbidity

In this section we present our findings regarding trends in the one-year prevalence of lung cancer, aerodigestive cancer and COPD. Because of the large differences between these diseases, we present all findings in tables rather than in figures. Note that the one-year prevalence figures are typically lower than the absolute number of deaths presented in the previous section because many people diagnosed with these diseases will not survive for a full year after being diagnosed. For COPD the situation is quite different, though, because

COPD is a chronic disease from which people may suffer for many years until it becomes fatal.

Due to our specific way of estimating the future prevalence of these diseases (i.e. proportional to the number of deaths caused by these diseases), trends in prevalence mimic trends in mortality; among males in France, Germany, Poland, The Netherlands and the UK a dramatic drop in the prevalence of lung cancer and aerodigestive diseases is expected toward the end of the second decade of the 21st century.

Table 6.2: Estimated 1-year prevalence (absolute numbers) of lung cancer, aerodigestive cancer and COPD, due to smoking – France

		lung cancer	*aerodigestive cancer*	*COPD*
females	1952	37	5	299
	1963	115	29	4,912
	1974	46	10	3,470
	1985	257	51	33,853
	1996	856	153	103,007
	2007	2,083	296	80,636
	2017	3,025	514	273,692
	2027	4,240	721	383,566
males	1952	1,770	1,808	28,725
	1963	4,211	3,751	49,456
	1974	6,724	5,486	187,995
	1985	9,609	5,970	402,270
	1996	11,488	4,594	421,371
	2007	11,982	3,284	230,298
	2017	6,110	2,545	193,672
	2027	1,893	789	60,022

Table 6.3: Estimated 1-year prevalence (absolute numbers) of lung cancer, aerodigestive cancer and COPD, due to smoking – Germany

		lung cancer	*aerodigestive cancer*	*COPD*
females	1952	60	3	2,973
	1963	318	15	21,084
	1974	399	19	68,281
	1985	981	46	140,250
	1996	2,361	133	307,269
	2007	3,743	195	348,026
	2017	4,359	225	519,191
	2027	5,360	277	638,438
males	1952	2,453	434	89,772
	1963	6,154	799	262,300
	1974	8,155	1,076	729,419
	1985	8,898	1,660	708,275
	1996	11,879	2,653	773,827
	2007	11,862	2,494	605,814
	2017	2,290	473	146,722
	2027	480	99	30,757

Table 6.4: Estimated 1-year prevalence (absolute numbers) of lung cancer, aerodigestive cancer and COPD, due to smoking – Italy

		lung cancer	*aerodigestive cancer*	*COPD*
females	1952			
	1963	117	13	16,616
	1974	417	49	77,261
	1985	1,039	113	134,122
	1996	1,723	152	173,437
	2007	2,315	176	230,253
	2017	2,142	192	232,566
	2027	2,142	192	232,605
males	1952	877	339	42,266
	1963	3,357	1,035	267,074
	1974	7,288	1,920	588,427
	1985	11,581	2,484	650,162
	1996	12,872	2,037	588,457
	2007	12,564	1,563	613,894
	2017	6,121	998	305,872
	2027	2,469	403	123,373

Table 6.5: Estimated 1-year prevalence (absolute numbers) of lung cancer, aerodigestive cancer and COPD, due to smoking – The Netherlands

		lung cancer	*aerodigestive cancer*	*COPD*
females	1952			77
	1963			
	1974	23	2	1,817
	1985	259	30	23,978
	1996	608	79	61,363
	2007	1,374	157	114,543
	2017	1,997	240	183,838
	2027	2,841	342	261,519
males	1952	634	84	18,781
	1963	1,619	127	44,076
	1974	2,870	209	135,211
	1985	3,670	277	189,094
	1996	3,454	385	214,174
	2007	2,953	462	170,548
	2017	825	95	47,089
	2027	29	3	1,637

Table 6.6: Estimated 1-year prevalence (absolute numbers) of lung cancer, aerodigestive cancer and COPD, due to smoking – Poland

		lung cancer	*aerodigestive cancer*	*COPD*
females	1952			
	1963	42	4	260
	1974	198	19	16,479
	1985	557	45	39,123
	1996	1,027	78	29,531
	2007	1,852	125	45,200
	2017	1,593	118	61,284
	2027	1,610	119	61,931
males	1952			
	1963	1,178	224	5,905
	1974	3,023	485	131,096
	1985	5,347	843	206,061
	1996	6,649	1,056	124,609
	2007	7,183	1,154	148,244
	2017	4,314	686	112,119
	2027	660	105	17,143

Table 6.7: Estimated 1-year prevalence (absolute numbers) of lung cancer, aerodigestive cancer and COPD, due to smoking – Spain

		lung cancer	*aerodigestive cancer*	*COPD*
females	1952			
	1963	25	3	1,510
	1974	69	10	17,017
	1985	45	8	15,185
	1996	31	4	7,774
	2007	277	31	17,507
	2017	220	28	38,220
	2027	266	34	46,172
males	1952	341	161	61,329
	1963	1,214	497	130,817
	1974	2,243	838	267,645
	1985	4,333	1,361	331,315
	1996	6,410	1,705	537,772
	2007	7,120	1,546	527,758
	2017	5,864	1,544	458,195
	2027	4,192	1,104	327,589

Table 6.8: Estimated 1-year prevalence (absolute numbers) of lung cancer, aerodigestive cancer and COPD, due to smoking – United Kingdom

		lung cancer	*aerodigestive cancer*	*COPD*
females	1952	285	81	108,380
	1963	731	173	178,035
	1974	1,656	337	238,033
	1985	2,787	550	398,556
	1996	3,215	674	535,040
	2007	3,575	658	576,745
	2017	4,113	809	645,946
	2027	4,116	809	646,496
males	1952	3,520	718	701,022
	1963	6,483	787	1,038,263
	1974	8,301	954	986,018
	1985	8,137	1,150	978,582
	1996	6,134	1,240	726,564
	2007	5,064	1,193	547,607
	2017			
	2027			

6.3 Healthcare costs: direct and indirect

Direct costs

In this section we show how (predicted) trends in mortality would extrapolate to direct medical costs, assuming all countries would experience similar smoking-related costs (per disease) to those calculated for Germany in 2003 by Neubauer *et al.* (2006) proportional to the number of deaths[41] caused by each disease (for a more detailed description of the method refer to Chapter 2).

In all estimates below, direct medical costs encompass acute hospital care, in-patient rehabilitation care, ambulatory care and prescription drug costs. For all countries acute hospital care accounts for most of the direct costs, with cardiovascular disease being the largest component, followed by cancers and respiratory disease. The cost of prescription drugs and ambulatory care is the second largest component, with a similar ranking across the three diseases to acute hospital care. The smallest cost component is rehabilitation care.

Whereas direct costs have been increasing in the past, they are expected to level off (The Netherlands) or decrease rapidly over the next decades (all six other countries). This

[41] As explained in Chapter 2, in our methodology cost estimates are assumed to be directly proportional to the number of deaths. Another way would have been to base cost estimates on morbidity estimates (assuming that most of the costs would be incurred before the terminal phase of the disease). The reason we opted for estimating costs proportional to the number of deaths, rather than morbidity, is that the (forecasted) number of deaths (due to smoking) is the central anchor point (variable) throughout the entire model. Whereas the literature (in particular Peto, 1992) is strong with regard to predicting future mortality, this is much less the case for predicting future morbidity. Hence our analyses start with forecasting future mortality and use these mortality estimates as inputs for estimating morbidity and costs.

decrease reflects the combination of the (mostly upward) predicted trends in deaths due to smoking among women and (mostly downward) predicted trends in deaths due to smoking among men.[42]

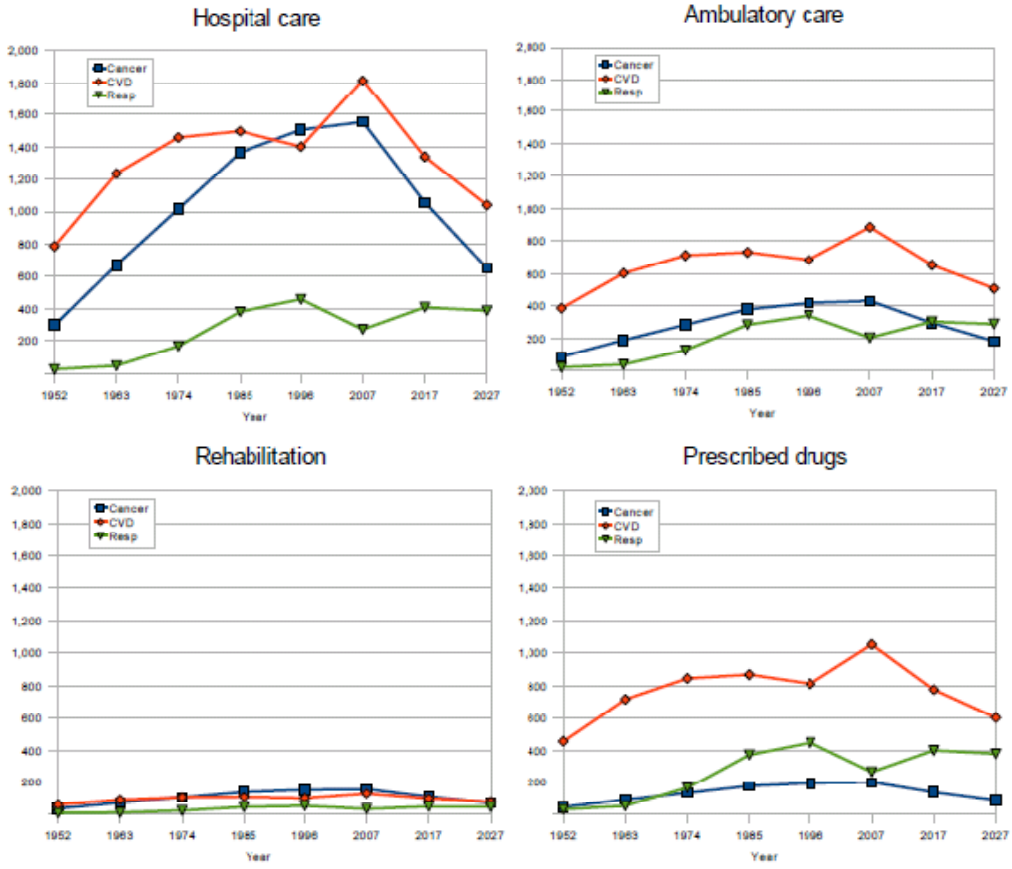


Figure 6.10: Direct medical costs due to smoking in 2010 euros (x 1 million) – France (observed until 2007, predicted afterwards)

[42] All cost estimates shown assume current medical technology (treatments, medicines, etc.) will not change in the future. Of course, it is quite possible that new (expensive) medical technologies will increase the costs of treating smoking-related diseases, or that more cost-effective treatments will become available. Forecasting the state of medical technology 20 years from now is mostly speculative, however, and therefore outside the scope of this study. Cost estimates include hospital costs, ambulatory costs, prescription drug costs and rehabilitation costs. We refer to Neubauer *et al.* (2006) for a detailed description of these costs.

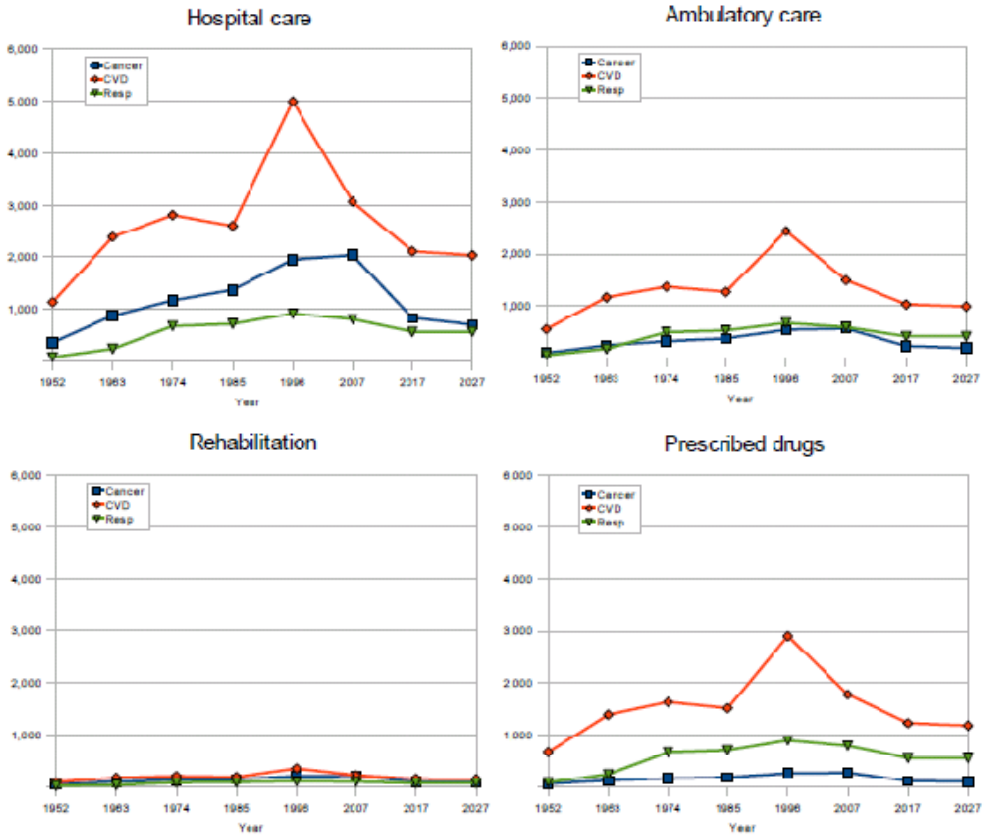


Figure 6.11: Direct medical costs due to smoking in 2010 euros (x 1 million) – Germany (observed until 2007, predicted afterwards)

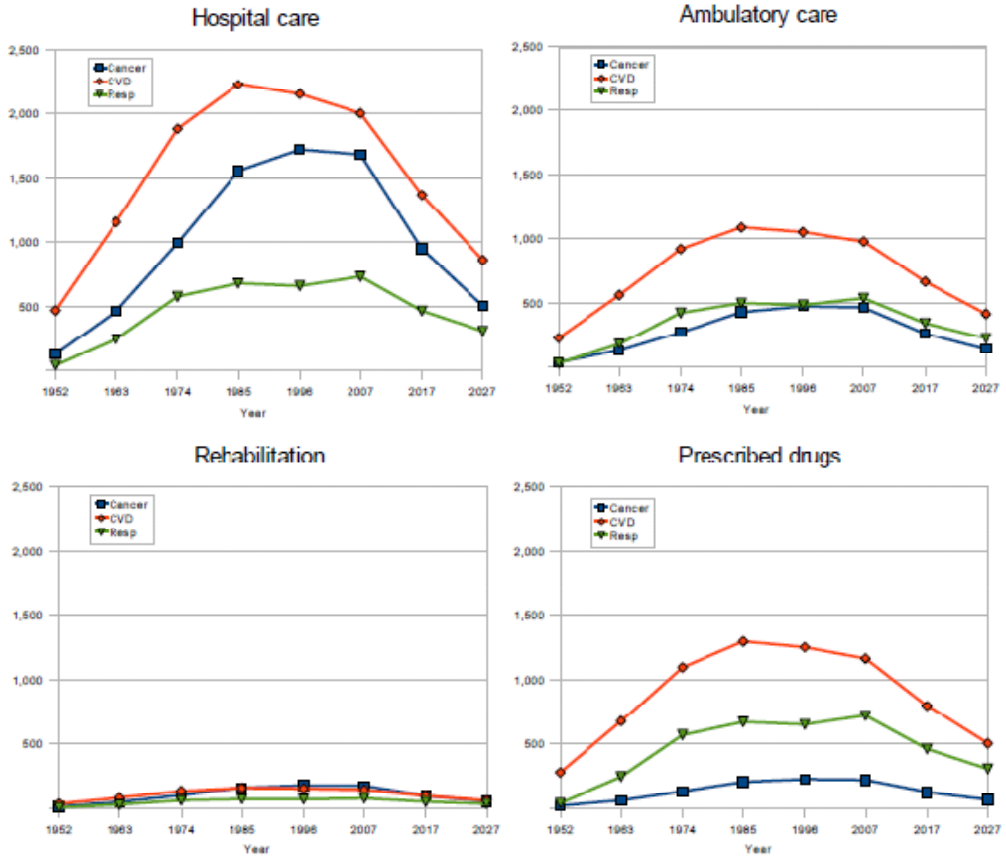


Figure 6.12: Direct medical costs due to smoking in 2010 euros (x 1 million) – Italy (observed until 2007, predicted afterwards)

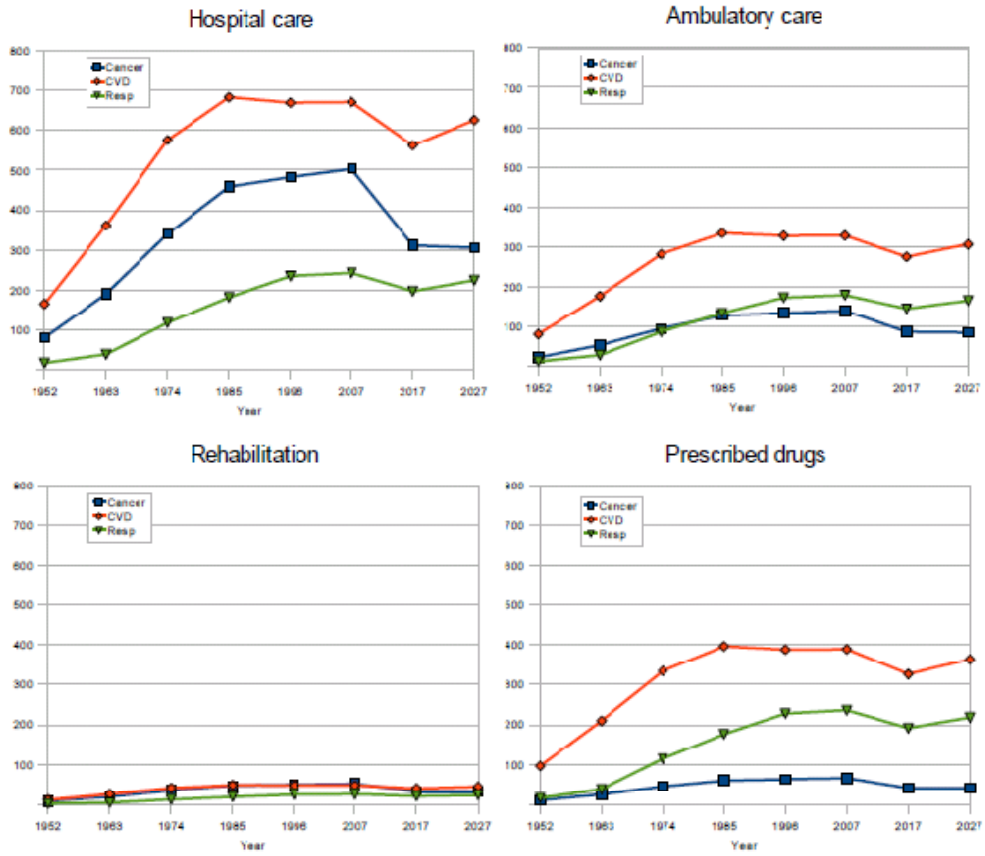


Figure 6.13: Direct medical costs due to smoking in 2010 euros (x 1 million) – The Netherlands (observed until 2007, predicted afterwards)

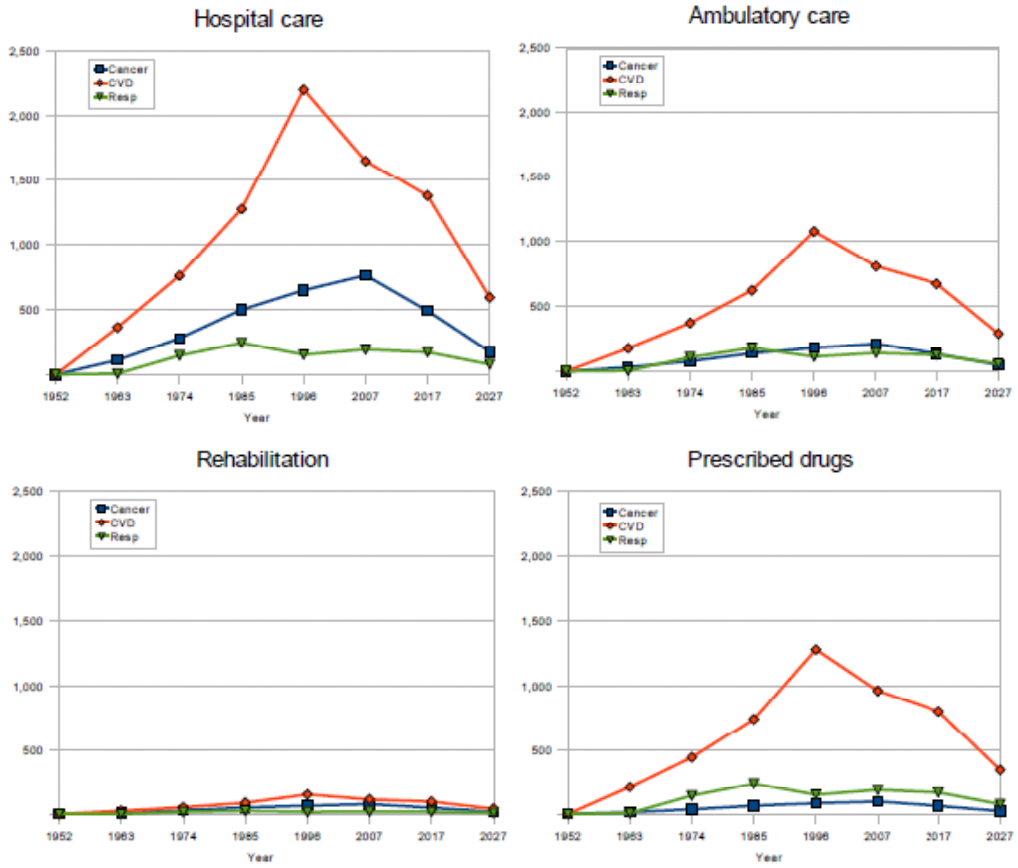


Figure 6.14: Direct medical costs due to smoking in 2010 euros (x 1 million) – Poland (observed until 2007, predicted afterwards)

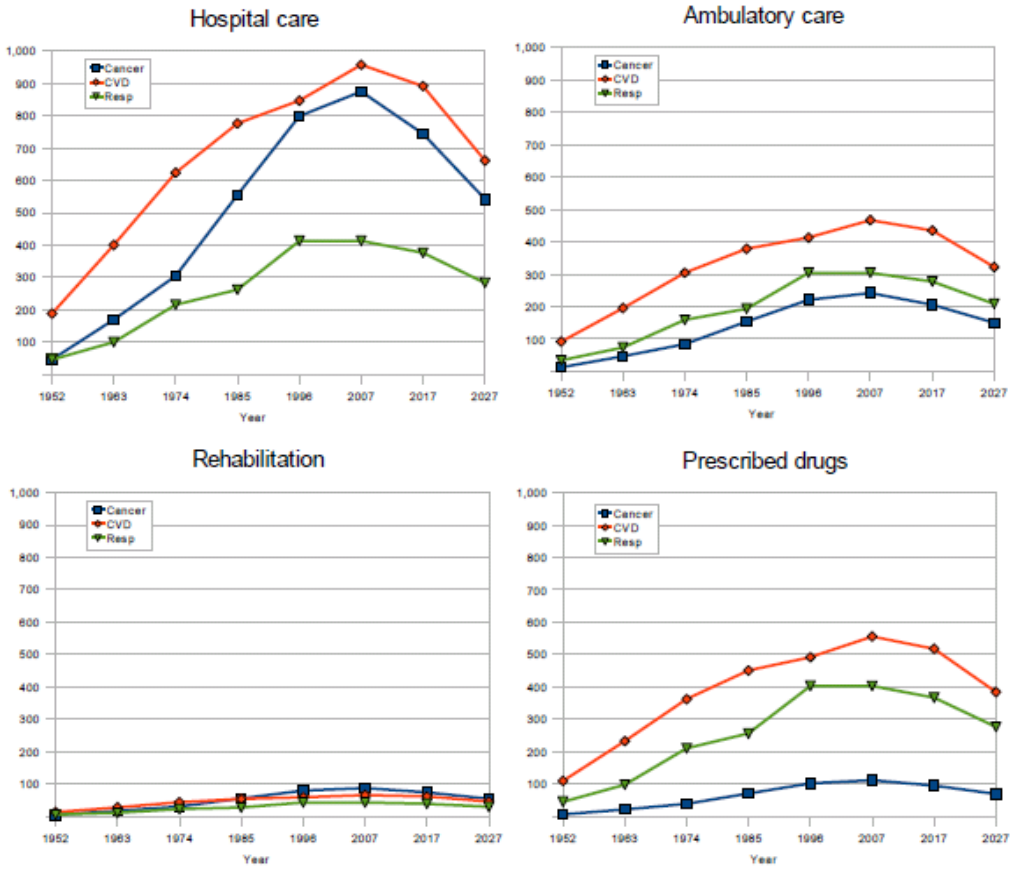


Figure 6.15: Direct medical costs due to smoking in 2010 euros (x 1 million) – Spain (observed until 2007, predicted afterwards)

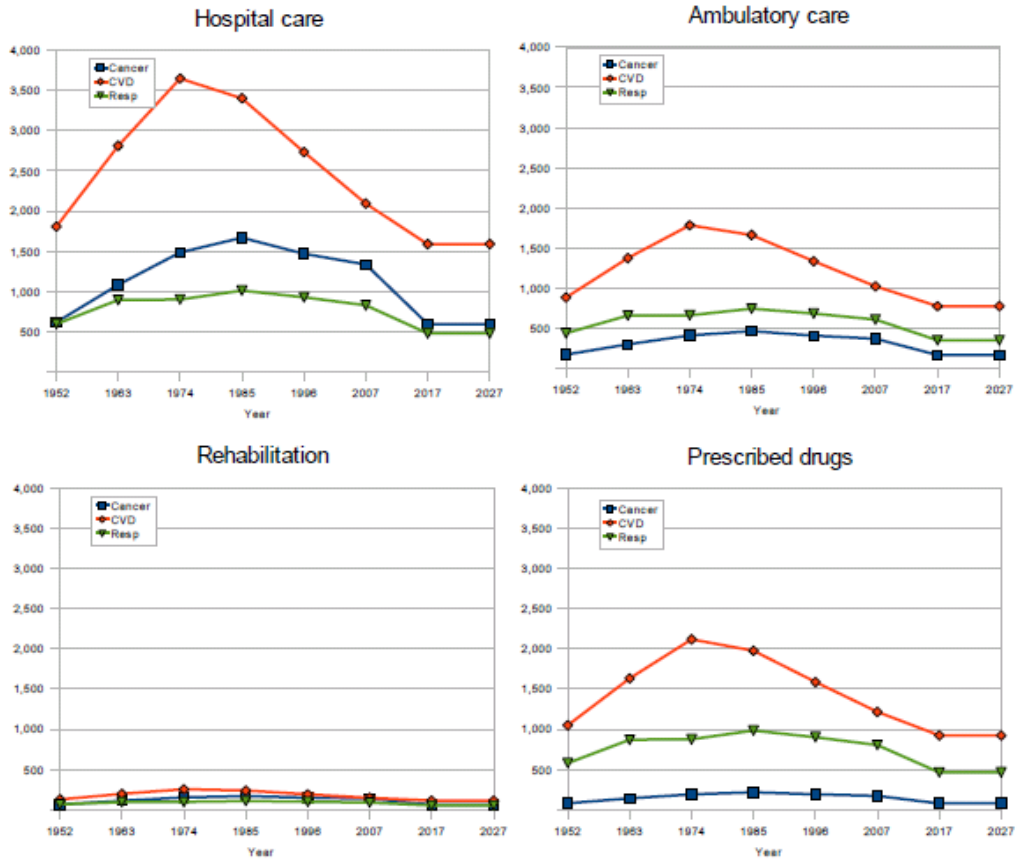


Figure 6.16: Direct medical costs due to smoking in 2010 euros (x 1 million) – UK (observed until 2007, predicted afterwards)

Indirect costs

In a similar way, we estimated indirect costs, assuming all countries would experience similar smoking-related indirect costs (per disease) to those calculated for Germany in 2003 by Neubauer *et al.* (2006), proportional to the number of deaths caused by each disease. Indirect costs encompass the indirect costs of mortality, work-loss days and early retirement.[43] We refer to Neubauer *et al.* (2006) for a full description of their approach to assessing these costs (for a more detailed description of the method see Chapter 2). All costs have been extrapolated to other countries using OECD purchasing power parities.

Interestingly, indirect costs related to mortality are mostly driven by cancer, whereas direct costs are mostly driven by cardiovascular disease, as shown in the previous section. Indirect costs related to morbidity (work-loss days and early retirement) are driven more equally by each of three disease categories.

[43] Thus other costs – for example, costs of second-hand smoking and costs to the smokers' families – are not included in these estimates.

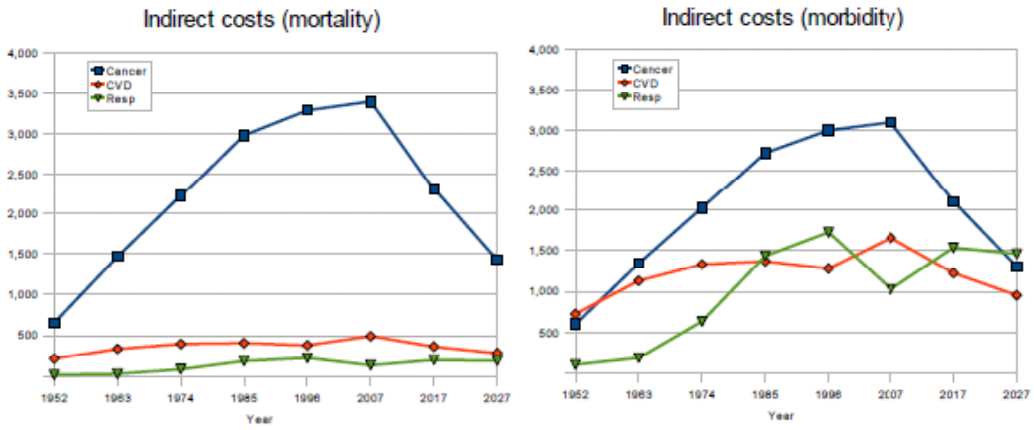


Figure 6.17: Indirect costs due to smoking in 2010 euros (x 1 million) – France (observed until 2007, predicted afterwards)

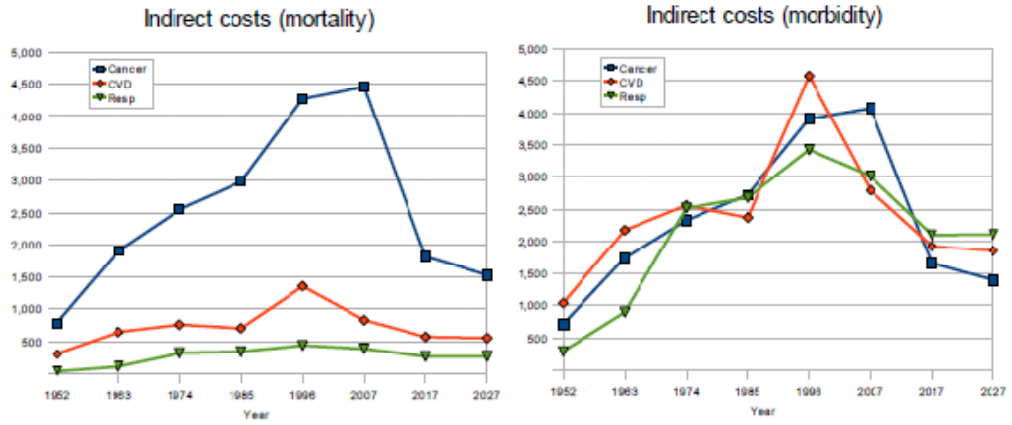


Figure 6.18: Indirect costs due to smoking in 2010 euros (x 1 million) – Germany (observed until 2007, predicted afterwards)

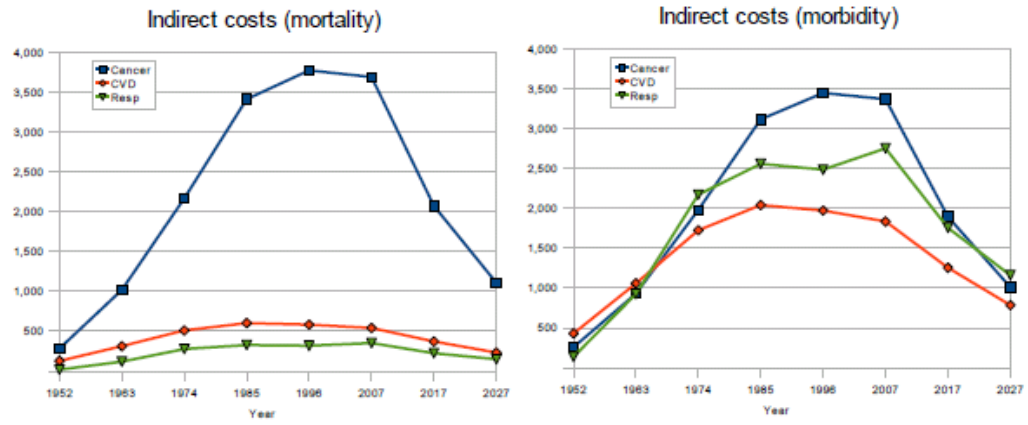


Figure 6.19: Indirect costs due to smoking in 2010 euros (x 1 million) – Italy (observed until 2007, predicted afterwards)

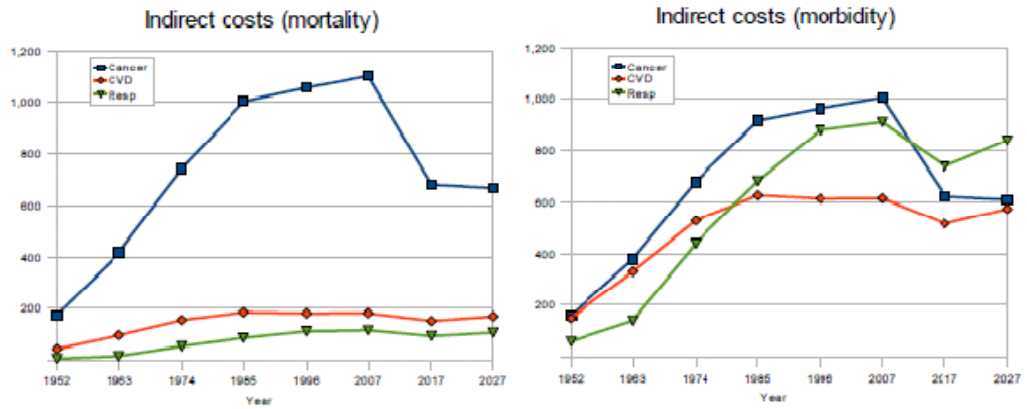


Figure 6.20: Indirect costs due to smoking in 2010 euros (x 1 million) – The Netherlands (observed until 2007, predicted afterwards)

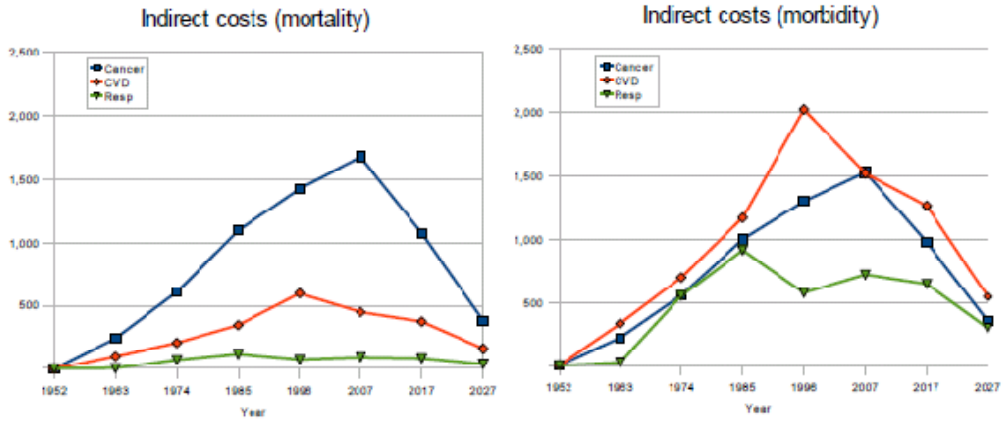


Figure 6.21: Indirect costs due to smoking in 2010 euros (x 1 million) – Poland (observed until 2007, predicted afterwards)

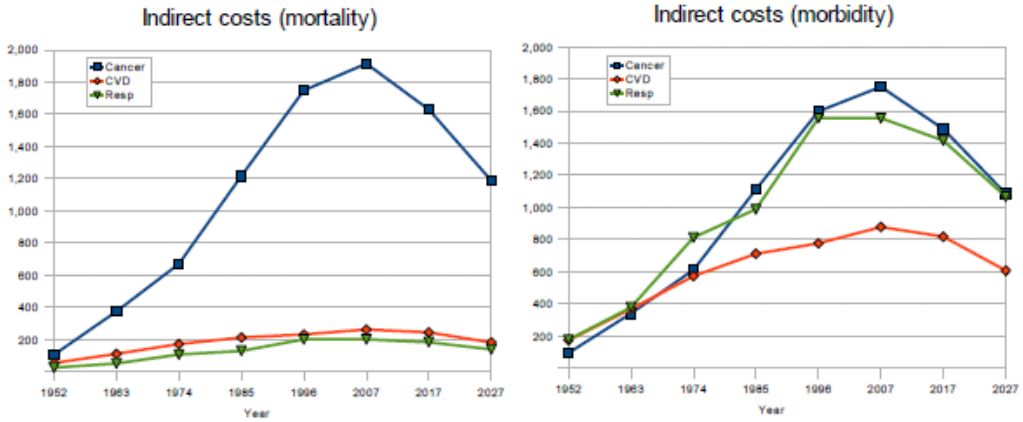


Figure 6.22: Indirect costs due to smoking in 2010 euros (x 1 million) – Spain (observed until 2007, predicted afterwards)

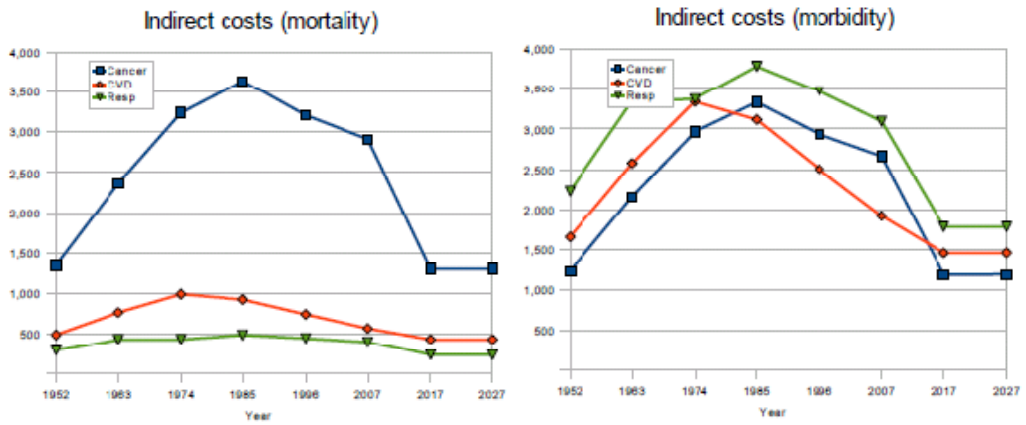


Figure 6.23: Indirect costs due to smoking in 2010 euros (x 1 million) – UK (observed until 2007, predicted afterwards)

6.4 Employment

Chapter 4 provided a descriptive overview of tobacco manufacturing and sales across some Member States of the EU. According to statistics, Germany, Greece, Italy, The Netherlands, Poland and Spain are the main countries involved in the production and distribution of unmanufactured and manufactured tobacco. Of those working in tobacco manufacturing and sales, a relatively large proportion are in retail sales in Italy, Spain, Germany and the UK.

This section and the subsequent section present the findings of a modelling exercise to understand the relationship between prevalence (a focus of a revision in the directive) and two key elements of the economy that may be affected by a revision of the directive: employment in tobacco manufacturing and/or sales, and excise duty collection.

In order to estimate the potential changes in terms of employment in tobacco sectors (manufacturing, wholesale of tobacco products and retail sales) due to a revision in the directive, we perform regression analysis. In particular, we use regression analysis to estimate the degree to which changes in prevalence are associated with changes in employment in each sector, and control for other factors that may also influence changes in employment in each sector (manufacturing, wholesale and retail sales). These control factors are taken from the literature (see Appendix B for a full account of the theoretical and empirical underpinnings of our methodology, definitions of variables and data sources) and include:

- firm size;
- labour costs;
- skilled labour;
- technological progress.

In order to estimate the potential relationship between prevalence and employment, it is necessary to use a value of employment that is comparable across countries and takes into

account the size of the labour market in each country. To do this, we use 'employment share', which is the proportion of employees in each tobacco sector (as seen in Table 6.9) to the total number of employed persons in a country.[44]

Table 6.9 shows the share, or proportion, of persons reportedly employed in each tobacco sector across some countries of the EU and Norway.

Table 6.9: Proportion of employed persons in tobacco, by sector, 1996–2007

	Manufacturing*	Wholesale sale of manufactured tobacco**	Retail sale of tobacco***
1996	0.054%	0.018%	0.099%
1997	0.063%	0.007%	0.057%
1998	0.055%	0.017%	0.067%
1999	0.045%	0.014%	0.035%
2000	0.048%	0.011%	0.039%
2001	0.043%	0.019%	0.044%
2002	0.035%	0.011%	0.037%
2003	0.038%	0.023%	0.038%
2004	0.045%	0.037%	0.026%
2005	0.037%	0.024%	0.032%
2006	0.036%	0.023%	0.042%
2007	0.044%	0.033%	0.020%

Source: Author's calculations based on Eurostat (SBS) data

* Depending on the year, countries include Belgium, Germany, Denmark, Spain, Finland, France, Greece, Hungary, Ireland, Italy, Netherlands, Poland, Portugal, UK.

** Depending on the year, countries include Austria, Belgium, Czech Republic, Germany, Denmark, Spain, Finland, France, Greece, Hungary, Ireland, Italy, Lithuania, Netherlands, Norway, Poland, Portugal, Sweden, Slovakia, UK.

*** Depending on the year, countries include Austria, Belgium, Germany, Denmark, Spain, France, Hungary, Italy, Lithuania, Netherlands, Norway, Poland, Portugal, Sweden, Slovakia, UK.

Given potential uncertainties in our model, we offer four forecasts that may provide lower and upper bound estimates of employment shares in tobacco sectors. Table 6.10 describes the distinguishing assumption of each of the forecasts with respect to the prevalence data or values. Essentially, the sensitivity of Forecast A is tested by considering the minimum (Forecast B) and maximum (Forecast C) estimates for the relationship between prevalence and employment shares (still controlling for other factors that may have a relationship with employment shares). We then use another data set that includes a wider variety of countries (as described in Figure 6.2), even those outside Europe, in order to provide a wider range of changes in prevalence and thus takes into account more uncertainty (Forecast D).

[44] The proportions refer to mean values in each year across countries that provided data for all the variables in the analytical model. As such, these proportions may differ from descriptive statistics that do not require data for other variables to be provided also.

Table 6.10: Key assumptions about prevalence in the employment forecasts, Forecasts A–D

	Key assumption	Data
Forecast A	MEAN: We calculate a forecast of employment shares using the mean estimate for the relationship between employment share and prevalence	WHO45 smoking prevalence
Forecast B	MINIMUM: We calculate a forecast of employment shares using the maximum46 estimate for the relationship between employment share and prevalence	WHO smoking prevalence
Forecast C	MAXIMUM: We calculate a forecast of employment shares using the minimum47 estimate for the relationship between employment share and prevalence	WHO smoking prevalence
Forecast D	MEAN: We calculate a forecast of employment shares using the mean estimate for the relationship between employment share and prevalence	OECD48 smoking prevalence

We perform each of these forecasts separately for each sector of the industry:

- manufacturing;
- wholesale manufactured tobacco;
- specialised retail of tobacco products.

We utilise Eurostat data on the factors mentioned earlier (firm size, labour cost, skilled labour and technological progress), which allows us to take into account other influences on employment share in tobacco sectors across countries over time. Such data at the level of each of the tobacco sectors (manufacturing, wholesale sales of tobacco products, and retail sales) are in the section 'Structural business statistics'. These data are available from 1996 to 2007.

6.4.1 Manufacturing

In Figure 6.24, we present employment shares in manufacturing of tobacco over time for each of the forecasts. According to our estimates, the share of employment in the tobacco manufacturing sector may continue to decline until 2027.

[45] Countries include Austria, Belgium, Bulgaria, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, The Netherlands, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden, and United Kingdom..

[46] Using the upper estimate of the confidence interval from the regression analysis.

[47] Using the minimum estimate of the confidence interval from the regression analysis.

[48] Countries include Australia, Austria, Belgium, Canada, Czech Republic, Denmark, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Japan, Korea, Luxembourg, Mexico, The Netherlands, New Zealand, Norway, Poland, Portugal, Slovak Republic, Spain, Sweden, Switzerland, Turkey, United Kingdom, and United States of America.

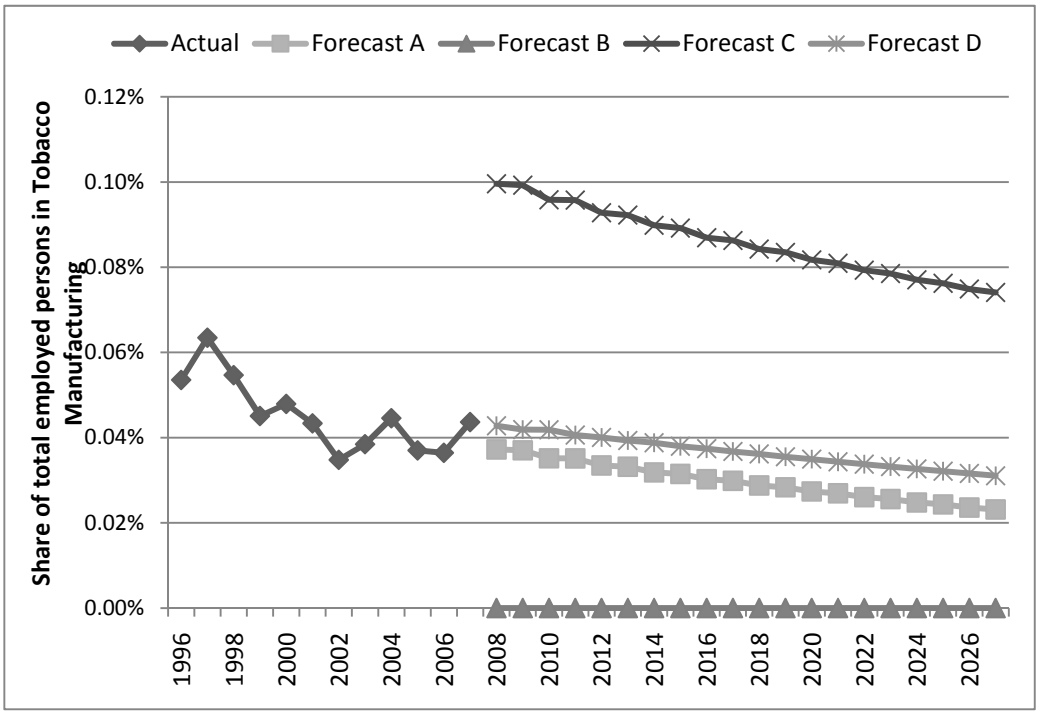


Figure 6.24: Forecast of employment share in manufacturing of tobacco, 1996–2027

6.4.2 Wholesale manufactured tobacco

According to our estimates, the proportion of employed persons that work in the wholesale trading of manufactured tobacco may slightly increase through 2027; this depends on the forecast, however, as Forecast C suggests that the share of employed persons in wholesale manufacture may fall (see Figure 6.25).

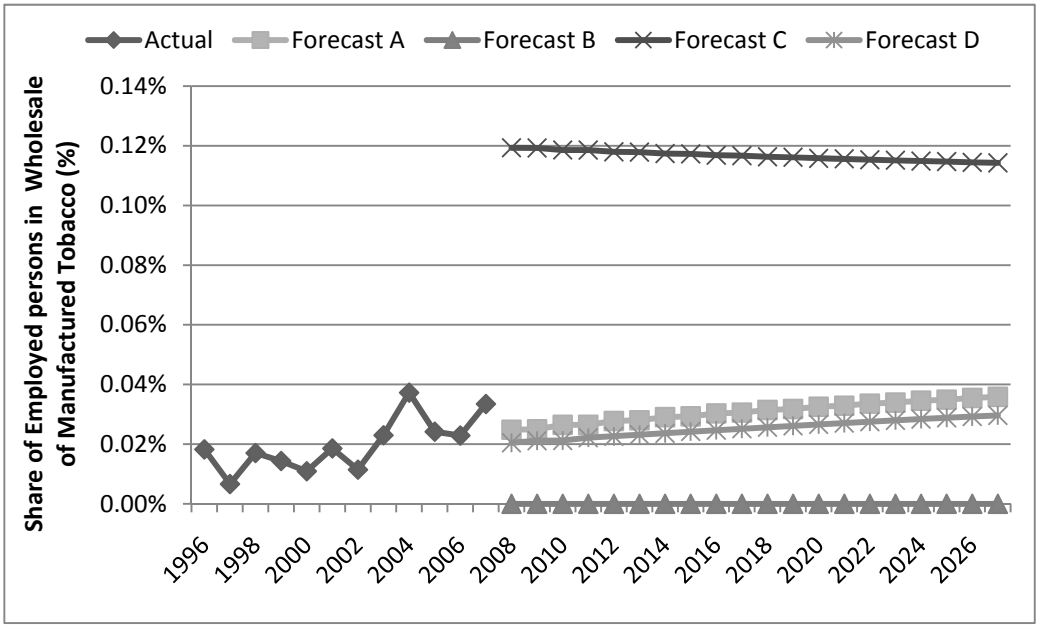


Figure 6.25: Forecast of employment share in wholesale trade in tobacco, 1996–2027

6.4.3 Specialised retail of tobacco

According to our estimates, of those persons employed the proportion in the specialised retailing of tobacco is likely to decline through 2027 (see Figure 6.26).

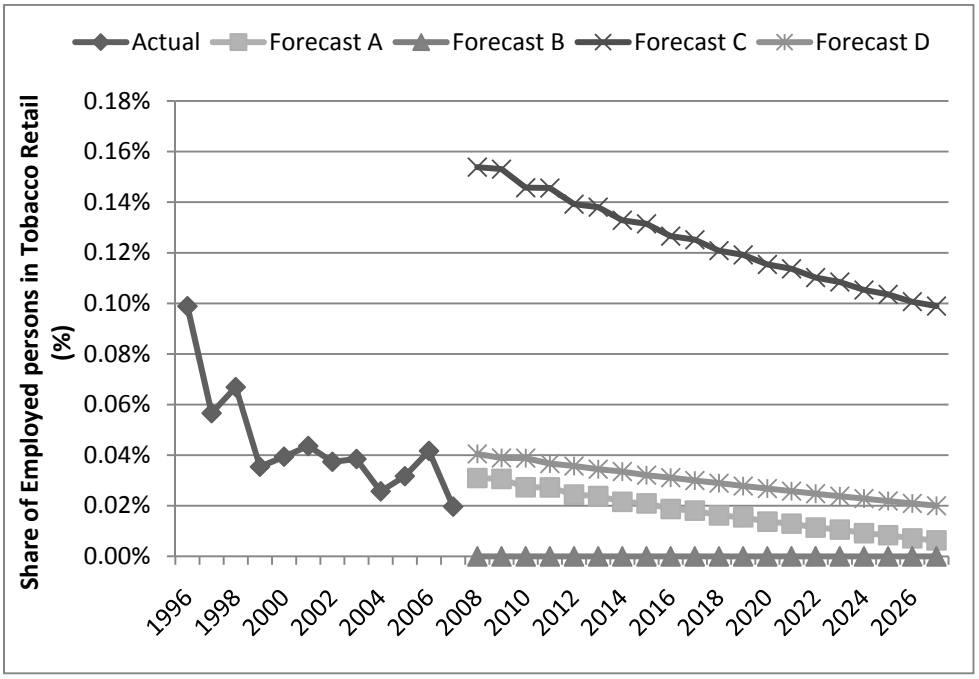


Figure 6.26: Forecast of employment share in retailing of tobacco products, 1996–2027

To summarise this section, forecasts suggest that the share of employment may fall across the tobacco sectors – manufacturing, wholesale of manufactured tobacco and retail sales – although there is some suggestion that there may be increases in the wholesale trading of manufactured tobacco. This is based on the association between smoking prevalence and employment, controlling for other factors.

Table 6.11: Percentage change in employment share for the status quo from 2007 to 2027

Sector	Mean change in employment share*
Manufacturing	–47.0 to –28.8%
Wholesale of manufactured tobacco	–11.4 to 7.1%
Retail sale	–67.8 to 1.9%

* Using both Forecasts A and D on the average potential effect.

6.5 Excise duty collections in the EU

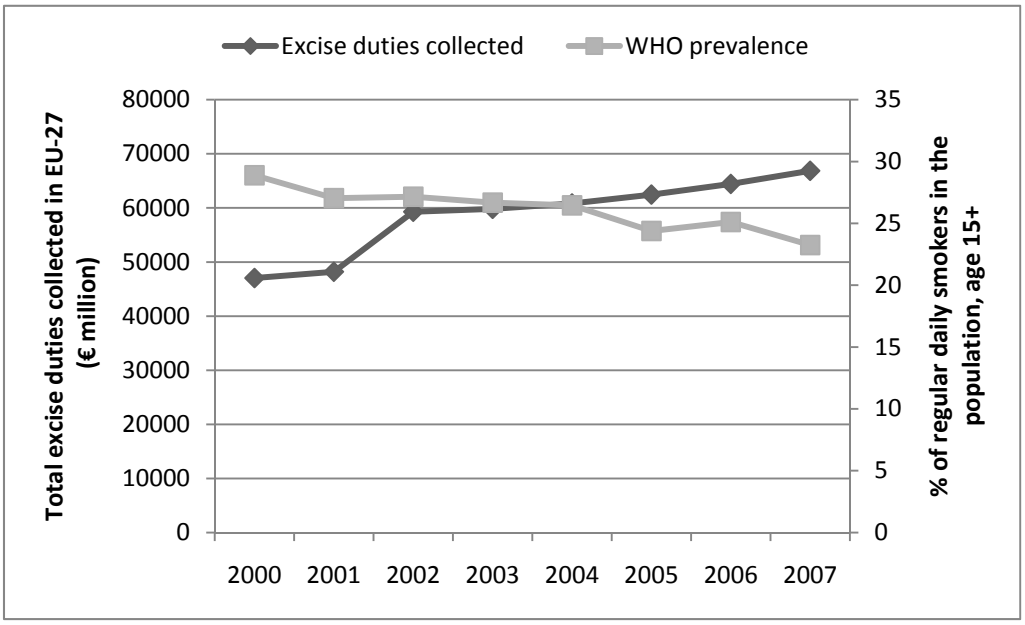
In this section we provide figures for the whole of the EU on how the tax revenues may change over time if there is no revision in the Tobacco Products Directive. In particular, we calculate changes in tobacco tax revenue that may emerge as a result of changes in prevalence.

Given the possibility of a range of outcomes across countries, we provide three forecasts that take into account uncertainty in the future relationship between prevalence and excise duty collected. Table 6.10 describes the characteristics of each of the forecasts. Essentially, the sensitivity of Forecast A is tested by considering forecasted changes in prevalence on excise tax collection and by considering different data.

Table 6.12: Key characteristics of the excise duties collected forecasts, Forecasts A–C

	Elements of the forecast	Data
Forecast A	Median change of excise duties collected from 2000 to 2007 would continue from 2008 to 2027.	Excise duties collected: DG TAXUD, NTL Tables Smoking prevalence: not applicable
Forecast B	Median change of excise duties collected from 2000 to 2007 would continue from 2008 to 2027. Plus an additional change in excise duties collected equal to the change in (forecasted) smoking prevalence.	Excise duties collected: DG TAXUD, NTL Tables Smoking prevalence: WHO smoker prevalence data
Forecast C	Median change of excise duties collected from 2000 to 2007 would continue from 2008 to 2027. Plus an additional change in excise duties collected equal to the change in (forecasted) smoking prevalence.	Excise duties collected: DG TAXUD, NTL Tables Smoking prevalence: OECD smoker prevalence data

All forecasts allow for the collection of excise duties to increase, even with prevalence decreases, by assuming the median annual rate of change in excise duties collected from 2000 to 2007 (2.7 percent) continues into the future. This is an important feature because data suggest (as seen in Figure 6.27) that excise duty collections may increase when prevalence falls.



Source: DG TAXUD, NTL Tables (for excise duties collected) and WHO smoker prevalence data (for prevalence)

Figure 6.27: Excise duty collection and prevalence rates, 2000–07

However, we also consider that this trend may change. That is, changes in excise duty may start to be affected more by prevalence than in the past. In order to introduce this possibility, we assume the previous trend (median change in excise duty collection of 2.7 percent annually) is altered by smoking prevalence. We assume an additional proportional change in excise duty collections to change in prevalence; Forecast B uses WHO prevalence data and Forecast C uses OECD data.

We perform each of the Forecasts A to C for the EU-27.

6.5.1 Forecasts of status quo tax revenues

With decreases in prevalence, the amount of excise duties collected for the consumption of tobacco has been increasing since 2000. The forecasts suggest that the collection of excise duties may remain above €60 billion (2008 prices) into 2027; see Figure 6.28.

In particular, assuming the median annual rate of change in excise duties between 2000 and 2007 is the annual rate of change from 2008 onwards (Forecast A), the total collection of excise duties by 2027 may be €90 billion. On the other hand, the previous trend in excise duty collection (observed in Figure 6.27) may be altered by prevalence more than it has been before. As a lower bound estimate, the total collection of excise duties may range from €62.5 billion to €74.5 billion (2007 prices).

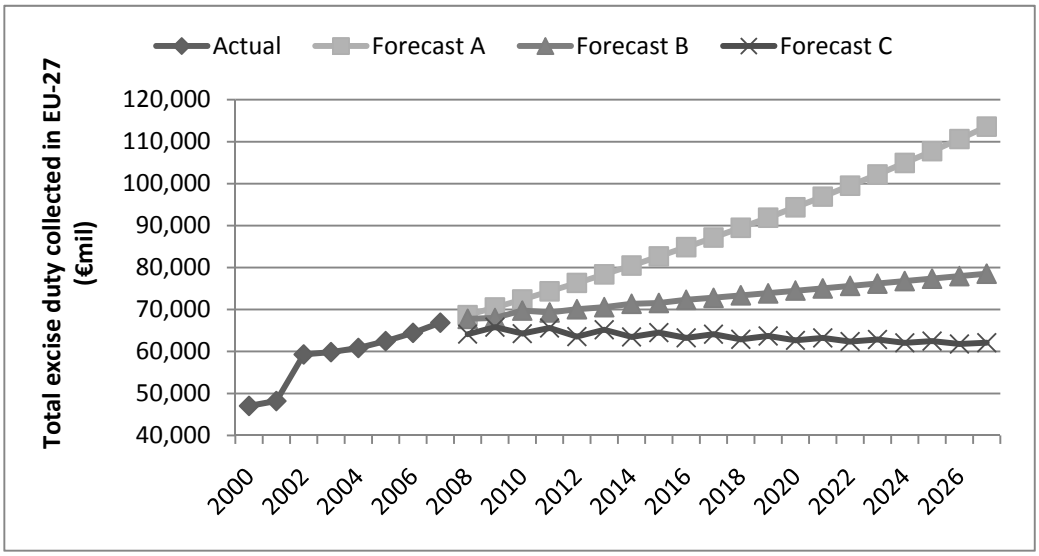


Figure 6.28: Total excise duty collected, EU-27, 2000–27

To summarise the discussion, our forecasts suggest there may be a reduction of approximately 6 percent to an increase of just over 40 percent, from 2007 (the last point at which we have actual data) to 2027 (see Table 6.13).

Table 6.13: Change and level of total tobacco excise duties collected, 2007–27, EU-27

Forecast	Change in excise duties collected from 2007 to 2027 (percent)	Amount of excise duties collected (€ billions, in 2007 prices)
Forecast A	69.9%	€113.6
Forecast B	17.4%	€78.5
Forecast C	–7.1%	€62.1

CHAPTER 7 Scope of regulation

7.1 Introduction

The first area of change this report will address is the scope of the Tobacco Products Directive. Driven by the emergence of new nicotine products and a diversification of tobacco consumption to other forms of tobacco smoking such as water-pipe smoking, DG SANCO is currently considering extending the scope of the directive – that is, the types and products that it covers. An extension of the scope of the directive might be envisaged to include tobacco and nicotine products, non-tobacco/non-nicotine smoking products and paraphernalia. Such a revision would bring the following product groups under the regulation:

1. tobacco products:
    - smoking tobacco products (cigarettes, cigars, RYO),
    - non-combustible tobacco products (*snus*, chewing tobacco, snuff, etc.);
2. unregulated nicotine products (nicotine products that are currently not covered by pharmaceutical, food or cosmetics legislation, such as electronic cigarettes not sold as cessation aids);
3. other (non-tobacco/non-nicotine) smoking products (e.g. herbal cigarettes);
4. paraphernalia (filters, cigarette paper, pipes, water pipes).

There are several ways in which these new products could be regulated. They could be treated in a similar way to manufactured cigarettes, or to other tobacco products (TNCO indications, warnings, etc.). They could be made subject to product authorisation (similar to pharmaceutical products). They could be totally banned as products imitating tobacco or as products dangerous to health.

7.2 Social and health impacts

Extending the scope of the Tobacco Products Directive is primarily driven by the desire to ensure that regulation keeps pace with the increasing diversification of tobacco and nicotine products on the market (DG SANCO, 2007b) by increasing consumer awareness about the harmful character of these products and thus reducing potential negative health effects. An assessment of these impacts will need to consider:

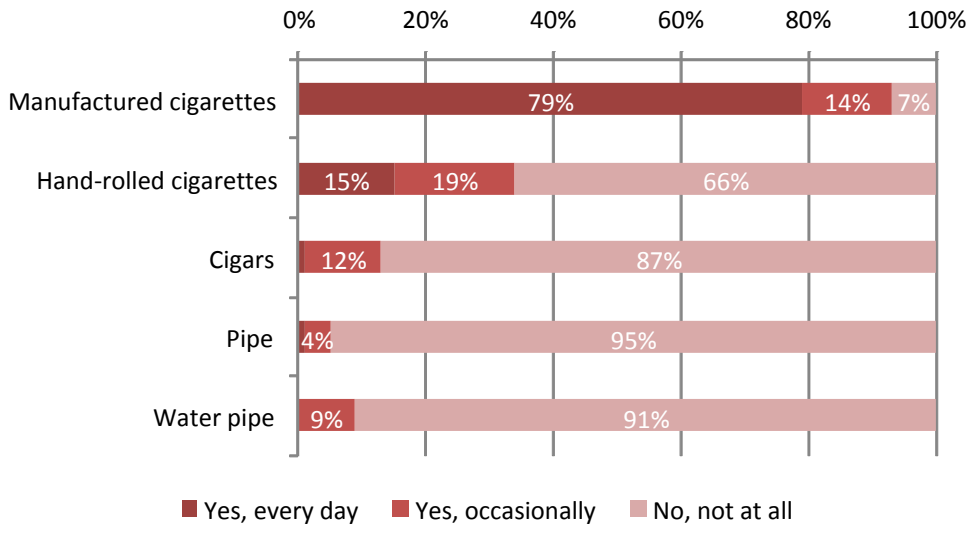
1. the overall prevalence/use of the products to be included;

2. their potential health risks;
3. perceptions about the harm of these products;
4. the current state of consumer information related to these products.

Use of tobacco and other smoking and nicotine products

Unfortunately, time series data on the use of nicotine or smoking products – other than manufactured cigarettes – which would allow for an assessment of trends are currently not available for the EU-27. Two recent Eurobarometer surveys (Eurobarometer, 2009, 2010) provide a snapshot of current patterns of use. Of particular interest are various oral tobacco products, electronic cigarettes, herbal cigarettes and other smoking products which are used in conjunction with or consuming paraphernalia, such as filters, cigarette papers, pipes and water pipes.

Manufactured cigarettes are the dominant category of product used among smokers, followed by hand-rolled cigarettes, cigars, pipes and water pipes. The use of hand-rolled cigarettes is more common in the EU-15 (39 percent of smokers use them at least occasionally) than in the EU-12 (18 percent). Daily use of products other than manufactured and hand-rolled cigarettes is very low (around 1 percent) across the EU, and these products are primarily smoked on an occasional basis (see Figure 7.1).

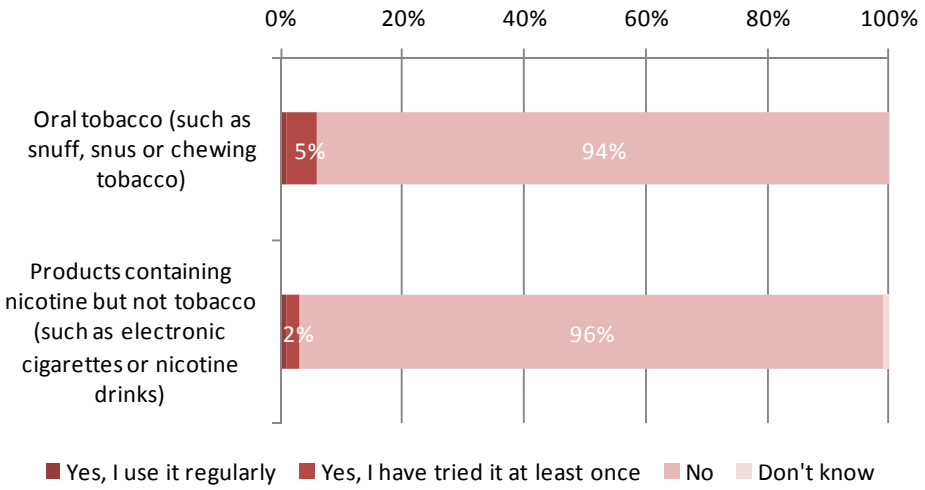


Source: (Eurobarometer, 2010) Question 3a: Do you use the following tobacco products every day, occasionally or not at all? (smokers only)?

Figure 7.1: Smoking of different tobacco products within the EU-27

The use of products that contain nicotine but not tobacco, such as electronic cigarettes or nicotine drinks, is very low. Across Europe only 1 percent of smokers report that they use those products on a regular basis, and 2 percent have tried them at least once (see Figure 7.2) (Eurobarometer, 2010). Use is somewhat different for the Nordic countries (Denark, Finland, Sweden), where 13 percent, 14 percent and 10 percent respectively of the population have used these products (Eurobarometer, 2010). Given the way the Eurobarometer questions were formulated, these figures are, however, likely to include

medical nicotine products sold as cessation aids, making the extent of new products difficult to judge, and they may be lower than the numbers stated here (see Figure 7.2).



Source: (Eurobarometer, 2010) Question: Have you ever tried any of the following products?

Figure 7.2: Use of oral tobacco and products containing nicotine but not tobacco, EU-27

Electronic cigarettes and other ENDS have led to increasing regulatory concern although knowledge about these products in terms of their use, manufacturing and composition remains poor (WHO, 2009a). This is in particular because they appear to exploit a loophole in the regulation of many countries as they do not fall under either tobacco regulation or pharmaceutical regulation as long as they do not make a health claim (see Table 7.1).

Similarly, information about smoking products which do not contain tobacco, such as herbal cigarettes, is underdeveloped. These have, however, not been of major concern to national regulators in Member States. The overall impression is that they are niche products with fairly stable or even stagnating market shares (DG SANCO, 2009b). A summary of the Member States' current legislative frameworks for these products and an assessment of their availability is provided in Table 7.1.

Table 7.1: Legislation and availability of electronic and herbal cigarettes

	Electronic cigarettes		Herbal cigarettes	
	Legislation	**Availability**	**Legislation**	**Availability**
Belgium	With nicotine – pharmaceuticals	0% nicotine – on the market	Not regulated	Not popular
Bulgaria	Not regulated		Not regulated	
Czech Republic	Not regulated	Sold on the market	Not regulated	Sold on the market
Denmark	With nicotine regulated as pharmaceuticals		Not regulated	
Germany	One model with nicotine is classified as a medicinal product requiring a marketing authorisation		Under tobacco legislation from case to case. Normally taxed as tobacco products, but not if they are used only for medical purposes in terms of the German drug law.	Not popular
Estonia	Regulated as pharmaceuticals if with nicotine	0% nicotine – available	Taxed as tobacco products	Not popular
Ireland	Not regulated. Medicines Agency did not agree to regulate as medicinal products.	Some enquiries re placing electronic cigarettes on market. Another product, 'Smokeless' cigarette, sold on Ryanair flights.	Not regulated	Very limited market
Greece	Prohibited under new tobacco legislation	Sold on internet	Not regulated	Nearly not available
Spain	No specific regulation. General Product Safety Directive applies.	Not popular	No specific regulation General Product Safety Directive applies	Not popular
France	If presented as cessation treatment, whatever the nicotine dosage – pharmaceuticals; if not, then: >10 mg nicotine – pharmaceuticals; <10 mg nicotine – General Product Safety Directive. Advertising: should fall under the ban of indirect advertising of tobacco products.	Sold on the internet. Problems with smoke-free environment (SFE) requirements.	Herbal cigarettes fall under tobacco legislation (hence same taxation, same licensing system for sale, same ban on smoking in places of collective use, same ban on advertising)	Problems 6–7 years ago, but almost non-existent since then
Italy	Not regulated	Available on the market and internet	Not regulated	Available in shops selling herbal products
Cyprus	No information			
Latvia	Not regulated, but Ministry of Health has started the discussions for legislation requirement (probably under the law on restrictions regarding the sale, advertising	Available on the market and internet. Distributors would like to sell in airports and on aeroplanes.	Under the law on restrictions regarding sale, advertising and use of tobacco products (amended from 4 March 2010),	Not available officially on the market because the lone merchant does not want to sell herbal cigarettes as a taxable

	and use of tobacco products).		herbal cigarettes are defined as herbal smoking products (products which contain plants or herbal substances, but do not contain tobacco, and are intended for smoking); herbal cigarettes have requirements for labelling (CO, tar yield, attached excise tax stamp); requirements for SFE; prohibition to sell to persons who are under 18 years of age. Taxed as tobacco products (law on excise duties).	product
Lithuania	No specific legislation, but all imitation products are banned. The ban also covers non-nicotine.		Not regulated	
Luxembourg	No information			
Hungary	Not regulated explicitly, but considered as pharmaceutical products by function	Not legally available on the market, only on from foreign websites	Not regulated	Sold in herbal shops and on the internet
Malta	With nicotine, regulated under tobacco act – requirements for labelling, no advertising, no cessation claims and SFE requirements apply	Internet sales	With nicotine, regulated under tobacco act – requirements for labelling, no advertising and SFE requirements apply	Not available
Netherlands	Ban on advertising, product not regulated	Available	Not prohibited	Not popular
Austria	With nicotine, regulated as pharmaceuticals, the apparatus regulated as a medical device		Not regulated	Not popular
Poland	Not regulated	Sold in supermarkets		Not popular
Portugal	With nicotine, pharmaceuticals. With 0% nicotine, not regulated	Sold on internet; not popular	Not regulated	Not popular
Romania	Not regulated	Sold in petrol stations and on internet	Not regulated	Available
Slovenia	Regulated as pharmaceuticals	Available on internet		Advertising not allowed
Slovakia	Regulation of selling and smoking of	In the area of the regulation of selling	Herbal cigarettes are regulated	Available, but not very popular.

	electronic cigarettes by act no. 377/2004 in protecting of non-smokers – total ban on smoking electronic cigarettes in public places such as schools, bus stations, hospitals and cinemas	electronic cigarettes, total ban of selling as well as on selling tobacco products. Sale via the Internet prohibited. Available only in some markets.	similarly to electronic cigarettes because the product is for smoking.	
Finland	Treated as pharmaceutical products, but with problems. Possible ban coming on all nicotine products other than medicine and pesticides.	Very rare	Ban on advertising	Available
Sweden	Regulated as pharmaceuticals, use in smoke-free zones may occur	Sold on internet		Sold in health stores
UK	General product safety requirements apply. Additionally, on 1 February 2010 the Medicines and Healthcare Products Regulatory Authority (MHRA) published a consultation document (see www.mhra.gov.uk) seeking views on whether nicotine-containing products (NCPs) should be considered to be medicinal products and, if so, whether all unlicensed NCPs should be removed from the market.	Available	Covered by domestic smoke-free legislation requirements	Available, not popular
Iceland	Under tobacco act	Sold on internet	Not regulated	Not an issue
Norway	New products with tobacco or nicotine are prohibited	0% nicotine, no information on availability	Not regulated. Taxed as tobacco products.	No information on availability
Turkey		Not an issue		Not an issue

Source: DG SANCO, Summary of the 10th Meeting of the Regulatory Committee, draft table on electronic and herbal cigarettes legislation and availabilityh, responses from Member States not standardised, Apr 2010

Health risks

The health risks of some of the other tobacco products are well established, while the risks of water-pipe smoking have also recently been evaluated and are at least comparable to those of cigarette smoking (see Chapter 2) (BfR, 2009). Herbal cigarettes are less well studied, but there is some evidence that they have similar harmful effects on smokers as conventional cigarettes do, one of the main health risks being considered to be the inhalation of smoke and its toxic constituents (Gan *et al.*, 2009).

The health effects of electronic cigarettes are ambiguous, are currently not well known, and have not been studied in any comprehensive way (WHO, 2009a); in principle, both

positive and negative health effects may be expected from the use of electronic cigarettes and other ENDS.

Most of the harm associated with tobacco use is related to the inhalation of smoke and its toxic constituents; as such ENDS is potentially a safer way of delivering nicotine to smokers, and there is a potential for ENDS to be developed so that they could be used in a similar way to other nicotine products that are regulated under pharmaceutical regulation as part of NRT (ASH, 2009). At the same time there are major health concerns associated with ENDS (WHO, 2009a):

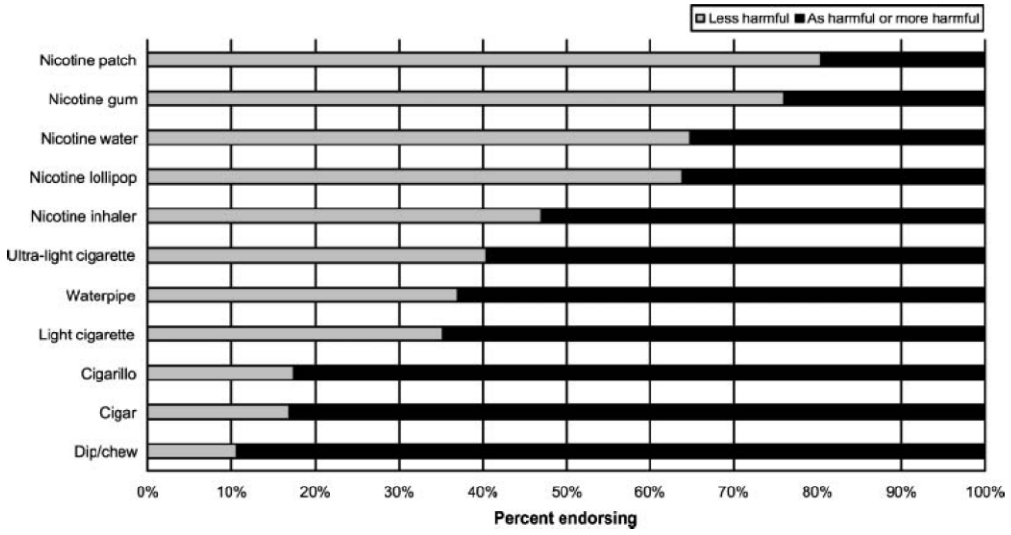
1. Due to the lack of regulation, manufacturers do not currently disclose the ingredients and composition of the ENDS devices marketed. The US Food and Drug Administration analysed the chemicals in 18 varieties of ENDS cartridges marketed in the USA and reported significant variation in content and composition as well as inconsistencies between the actual and declared nicotine levels.
2. The potential for ENDS as part of NRT has not been demonstrated in scientific studies, and overall the evidence has been considered insufficient to conclude that they could be used as smoking cessation aids; thus, more widespread use of ENDS may undermine the smoking cessation policies by creating a new source of nicotine addiction.
3. Direct delivery of nicotine to the lungs may result in stronger toxicological, physiological and addictive effects than those of traditional NRTs.

Consumer awareness of harm

Several studies indicate that consumers perceive other smoking tobacco products to be safer to use than manufactured cigarettes, despite scientific evidence indicating similar levels of harmfulness (Richter *et al.*, 2006).

The ITC survey conducted among 13,000 smokers in the USA, Canada, Australia and the UK found that a quarter of all smokers believed that pipes, cigars and RYO were safer than manufactured cigarettes. This effect was particularly pronounced for the UK, the only European country in the sample. Specifically, this study showed that users of a specific smoking tobacco product are more likely to find that product healthier than other products (O'Connor *et al.*, 2007). Analysing the same survey data, Young *et al.* (2006) focus on the perceptions of RYO users, and also find significant differences in risk perceptions, with RYO smokers being more likely to believe RYO use is less harmful than other forms of tobacco use.

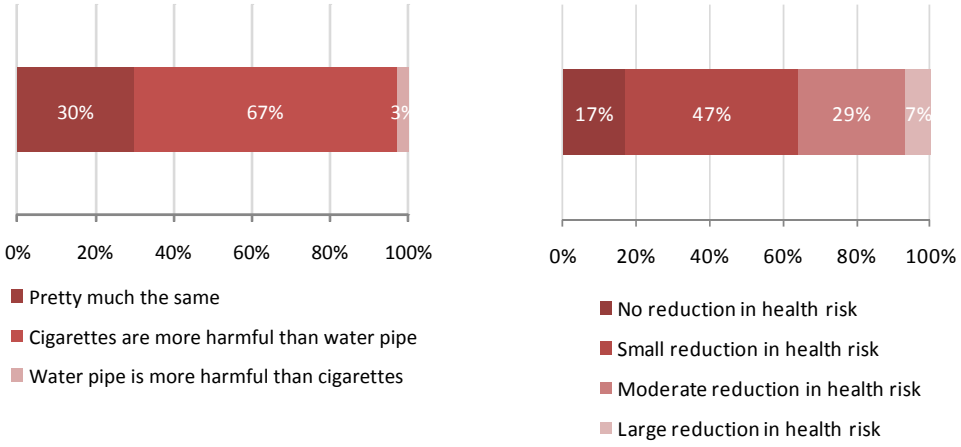
A study conducted using survey data from 411 college freshmen at Johns Hopkins University found substantial differences in the perception of the health risks of other tobacco products compared to manufactured cigarettes. Figure 7.3 shows the perceived harmfulness of different tobacco and nicotine products in comparison to manufactured cigarettes. Among smoking products, ultra-light cigarettes and water-pipe smoking were the most likely to be perceived as being less harmful (Smith *et al.*, 2007).



SOURCE: (Smith *et al.*, 2007)

Figure 7.3: Harm perception of tobacco and nicotine products compared to manufactured cigarettes among a sample of college students (n=411) at Johns Hopkins University

This perception of the lower relative risk of water-pipe smoking has been observed in a number of studies, and it has often been related to the widespread belief that the water through which the smoke flows acts as a filter for dangerous toxicants (Maziak, 2008, Neergaard *et al.*, 2007). A study based on a small convenience sample of 201 water-pipe users by Smith-Simone *et al.* (2008) found, for example, that 67 percent of water-pipe users believed water pipes to be less harmful than cigarettes, and 83 percent believed they could reduce their health risks by switching from cigarettes to water pipes (Figure 7.4).



Perceived harm of water pipe compared to cigarettes

Reduced health risk perception of switching from cigarettes to water pipe

SOURCE: (Smith-Simone *et al.*, 2008)

Figure 7.4: Harm perception of water-pipe use among two convenience samples of US water-pipe users

Similar findings are reported from a study among 937 students of Birmingham University in the UK, with nearly all regular water-pipe smokers perceiving water-pipe smoking to be less harmful than cigarette smoking (Jackson and Aveyard, 2008).

An earlier study conducted in Syria among students and café visitors who regularly smoked water pipes, however, found somewhat different results. Smoking beginners considered water-pipe use to be more harmful than conventional smoking, and only regular users believed in a less harmful effect with water-pipe use (Asfar *et al.*, 2005).

Current level of consumer information

The current level of consumer information mandated by the Tobacco Products Directive differs from that for manufactured cigarettes, which have to carry warning messages and quantitative TNCO labels; and other tobacco products, which have to carry warning messages only.

Currently, four Member States are exceeding these requirements by mandating additional pictorial warnings (UK, Belgium, Romania, Lithuania). However, only the UK has made these mandatory for all tobacco products, not just for manufactured cigarettes.

In many countries, ENDS are controlled under neither tobacco nor pharmaceutical regulation, resulting in very limited information being conveyed to consumers, for example, about the addictive characteristics of nicotine. Herbal cigarettes are also not covered by any regulation other than general product safety regulation and information about their harmful effect does not need to be presented on packs.

Paraphernalia used for RYO, smoking pipes and water pipes is not covered by regulation and does not currently carry any health warning.

7.2.1 Assessment of impact

Summarising this discussion, we may distinguish two phenomena which this measure should address:

1. A lack of consumer understanding of the harmful effects of tobacco products other than manufactured cigarettes, in particular RYO and water pipe, against the background that these other products are used by a considerable share of all smokers.
2. New products on the market that are not regulated, but are potentially harmful to consumers and could undermine smoking cessation policies.

To address the first, the measure suggested is to include paraphernalia under the current regulation, which would allow for the introduction of health warnings about smoking on those products. Such a measure has not been implemented, nor discussed in the relevant literature, so the potential effects on consumer awareness of health risks are uncertain, but it is very likely that more information would lead to better information being given to consumers. In addition, there might be practical difficulties which could limit the impact on any health warnings related to paraphernalia; both for cigarette filters and rolling paper, health warnings could be incorporated into current package designs, although packaging

and surfaces for rolling paper are relatively small.[49] This is likely to make health warnings less effective (see Chapter 8). Secondly, for products that are not consumed during smoking, such as pipes and water pipes, health warnings would be likely to have to be put on the package itself, which is usually discarded after the first use, unless warnings could be put directly on the pipes. Thirdly, there is a strong social component in water-pipe use. Water pipes are often used in cafés or in a group, which means that a user of a water pipe might not necessarily be involved in the preparation of the pipe, and therefore might be aware of a health warning neither on the tobacco pack nor on the pipe itself. Finally, even this extension would not cover the charcoal used for preparing the water pipe, which contributes to the harmful effect of inhaling water-pipe smoke. Against this background, other changes such as revised textual warnings for specific tobacco categories, such as fine cut for RYO or water-pipe tobacco, might address the issue of perceived harmfulness more effectively. Overall, the option might contribute to an increased understanding of the risks of smoking products other than manufactured cigarettes. However, we would expect the contribution to be relatively small, and there is currently not sufficient evidence available for a detailed assessment of the impact.

In terms of ENDS, there is a lack of consistent regulation ensuring that its health impacts can be assessed and controlled. Currently, most Member States which have taken regulatory action assess ENDS under the umbrella of pharmaceutical regulation, treating it in a similar way to other NRTs. Greece and Malta currently ban it under the respective tobacco acts, and in Malta it is also included in the smoke-free regulation – which makes it less interesting as a substitute for smoking. Including ENDS in the directive could mean subjecting it to ingredients reporting and labelling requirements, which would increase consumer awareness of the potential risks of these products. In its third report on the scientific basis of tobacco regulation, WHO however recommends that 'ENDS products should be regulated as combination drugs and medical devices and not as tobacco products' (WHO, 2009a). A regulation classifying it as a pharmaceutical product, in line with other nicotine products, would subject ENDS to the same requirements of testing as other nicotine products, ensuring that the necessary trials were performed to substantiate any health claims. Bringing ENDS under tobacco regulation would be an immediate step towards improving consumer awareness of the related risks, but ultimately they might be better regulated under the pharmaceutical frameworks.

7.2.2 Summary of health impacts

Measure	Health and social impact	Effect
Scope of the directive will be extended to include non-regulated nicotine products, non-tobacco/non-nicotine smoking products, paraphernalia and the tobacco leaf	– Could improve consumer understanding of the risks of tobacco products that are frequently used but which consumers wrongly consider less harmful – Inclusion of alternative nicotine products under tobacco regulation would increase regulators' knowledge and consumers' awareness of the risks of these products	+

[49] Information provided by the European Rolling Paper Association suggests that the standard package size is 7 x 2cm only.

7.3 Economic impacts

Extending the scope of the current regulation may have a number of economic impacts. Of particular importance will be the following economic impacts:

1. Compliance cost and administrative burden for previously unregulated products.
2. Price of tobacco and nicotine products.

We discuss these impacts further below.

7.3.1 Compliance cost and administrative burden for manufacturers

Extending the current requirements to previously less regulated products will create administrative burden and compliance costs for the producers of paraphernalia and electronic cigarettes.

For paraphernalia sold in packages or pouches (such as papers or cigarette filters), this measure would require a change of the product label similar to the changes required for manufactured cigarettes. The evidence available, however, does not allow us at this stage to quantify these costs. For products that are more durable and are not sold in standard packages, introducing new requirements would potentially demand new packaging solution, which would need to be found at the expense of the manufacturer. Again the evidence available does not allow for a quantification of such an effect.

Putting labels on both cigarette paper and pipes is understood in line with the current directive and the suggested policy options – that is, labels would contain a textual, and possibly a pictorial, health warning.

By implication, these two measures would inflict a one-off administrative burden on tobacco manufacturers as they would have to familiarise themselves with the regulation, interpret the regulation, adjust their production processes (e.g. readjusting machinery, staff time) and potentially change the design of their products. Depending on the exact details of how the legislation is drafted and how it is interpreted by manufacturers, it is possible that significant ongoing costs would arise; for example, in the form of material costs (e.g. paper and ink for the label) or decreased factory-level productivity (e.g. longer per output unit production time).

Little is currently known about the producers of and the production process for electronic cigarettes, and it is currently understood that most electronic cigarettes are manufactured in and imported from China (WHO, 2009a); therefore any assessment of impact on these producers must remain vague. Subjecting producers of previously unregulated products, including ENDS, to the same regime as tobacco would require them to test their products and report on the ingredients, and to change their package design in line with the rules for other tobacco products.

7.3.2 Impact on the market of tobacco and nicotine products

Bringing additional products under tobacco product regulation is likely to be accompanied by increased compliance cost and administrative burden as discussed above (e.g. for testing and labelling products). These in turn will be (partially) transferred to the price of the product and may therefore have an impact on the consumption patterns of these products. People might consume less of these products if the price increases or might switch to other products (substitution).

Suggested measures are likely to increase the price of products consumption of which relies on the use of paraphernalia:

  - RYO,
  - water pipe,
  - pipes;
- or previously unregulated products:
  - ENDS,
  - herbal cigarettes.

The result may lead to a shift in the relative prices of tobacco products that may be accompanied by increased awareness of the negative health impacts; consumers may shift their purchasing behaviour away from these products. If the costs of incorporating the regulation are passed on to the consumer, the price of these products will increase. Supposing people using these products are as sensitive to a change in price as cigarette users, the price would need to increase by 10 percent to induce a 5 percent reduction in the use of these products; however, people do switch over to other, cheaper products. Given that the other products (namely cigarettes) are not cheaper than the products to be covered by the revision, there may not be the switching effect we see when increasing cigarette prices. That is, research in Germany indicates that a 1 percent increase in the price of cigarettes results in a 1.2 percent increase in consumption of rolling tobacco, but this is because the increase in prices maked an expensive product even more expensive (Hanewinkel *et al.*, 2008). Making the cheaper product more expensive would not have the same effect as increasing the price of a relatively more expensive product. Given the uncertainty of the costs imposed on manufacturers and products this effect cannot, however, be quantified as part of this research.

Finally, the regulation has an impact on the market for nicotine products. Currently NRTs are regulated under medicinal regulation, while ENDS are sometimes only subject to general product safety requirements. Extending the scope of current regulation would, however, still mean that similar products are regulated in different ways, resulting in potentially distorted competition. At the same time, a more stringent regulation on ENDS may benefit the producers of approved NRTs and level the playing field between these sometimes fairly similar products.

7.3.3 Summary of economic impacts

Impact type Measure	Administrative burden		Industry revenues/profits		Other	
Scope of the directive will be extended	Reporting and labelling costs for manufacturer of paraphernalia and electronic cigarettes; not quantified.	(–)	Shift between tobacco products towards manufactured cigarettes and potentially approved NRTs	≈	More equal (but not identical) regulation for all nicotine products	+

CHAPTER 8 Labelling and packaging

8.1 Introduction

The second area of change that we consider is changes to the labelling requirements currently contained in Article 5 of the directive. It currently stipulates that packages of manufactured cigarettes display the results of TNCO yield measurements, and that all tobacco products must carry textual warnings. In addition it allows Member States to go beyond these requirements and introduce pictorial warnings in line with rules laid down by the EC.

Seven changes to the current labelling regulations will be considered in this chapter, most of which relate to the mandatory introduction of pictorial health warnings:

1. Make pictorial warnings mandatory.
2. Update and enlarge warnings to 50 percent of both sides of the package and place them towards the top of the pack.
3. Further increase of the size of warnings to 75 percent of both sides of the package.
4. Further increase the size of the warnings on the back of the pack to 100 percent.
5. Introduce generic packaging.
6. Replace TNCO quantitative labelling with qualitative information on contents, emissions and quit-lines.
7. Introduce inserts with supplementary information (e.g. on the potential risks).

8.2 Social and health impacts

This section presents the evidence found on the health and social impacts of the different measures considered by DG SANCO.

8.2.1 Health impacts of labelling

The impacts of the labelling of tobacco products on consumers may be broken down into the following categories (Australian Government Department of Health and Ageing, 2008):

1. Increase consumer knowledge of the health effects relating to smoking.
2. Encourage the cessation of smoking.
3. Discourage smoking uptake or relapse.

As with all behavioural change processes, there are different stages that may lead to behavioural change in consumers. This is true also of the potential effect of labelling on consumer behaviour. Sambrook International describes these steps as a five-stage process or 'dimensions of effectiveness' (Sambrook Research International, 2009):

1. Attention: this step determines whether or not consumers notice a warning label that appears on a product.
2. Reading/comprehension: this next step determines whether, once the consumers' attention has been directed at the labels, they proceed to read and comprehend the information presented on the labels.
3. Recall: this step determines if consumers are able to remember the information presented to them on the labels.
4. Judgement: this step is about the consumers' perception of how dangerous and hazardous a product really is.
5. Behaviour compliance: this step determines whether consumers decide to change their behaviour in accordance with the safety messages conveyed in the label.

In this section we are particularly interested in the evidence presented in the literature on step 5 above as this is the one step that will have a direct impact on consumers' health by changing their behaviour.

Pictorial warnings

This sub-section looks in more depth at the potential health impacts of pictorial warnings in particular.

Gospodinov and Irvine (2004) aimed to quantify the impact of the use of pictorial warnings on smoking prevalence using data from two waves of Health Canada's Canadian tobacco use monitoring surveys. Although they could not demonstrate a direct impact on smoking prevalence, their findings indicate that these labels have some impact on smoking intensity (Gospodinov and Irvine, 2004). They conclude that if these reductions in smoking intensity engender a higher probability of smokers quitting, then long-term impacts on smoking behaviour could be stronger than anticipated (Gospodinov and Irvine, 2004). Falba *et al.* (2004) looked at the smoking behaviour of older Americans who had reduced their smoking intensity. This was done through a nationally representative survey of older Americans aged 51–61 in 1991, who were then followed up every two years from 1992 to 1998. The results of this study showed that smokers who had previously reduced their cigarette consumption over a period of two years prior to quitting were more likely to quit smoking successfully (i.e. not relapse) than those who had not (Falba *et al.*, 2004).

In a comparable case, the UK Department of Health conducted its own impact assessment on the introduction of pictorial labels in 2007 (UK Department of Health, 2007). This assessment provided some quantitative estimates of the likely impact on smoking rates in the UK. It concluded that the introduction of pictorial warnings on all tobacco packs with rear warning labels taking up at least 40 percent of the back of packs would produce a 0.5 percent reduction in the UK's smoking population[50] and save on average 600 lives a year. This is compared with their assessment that no change in labelling requirements (i.e. text

[50] This estimate is based on the predicted estimate produced for the introduction of written warnings.

warnings remain) would produce a 0.05 percent decrease in UK smokers (UK Department of Health, 2007). In contrast, if pictorial warnings were introduced only on cigarette packs rather than on all tobacco products, the impact would be 75 percent of 0.5 percent[51] (UK Department of Health, 2007). All of these estimates are based on the assumption that pictorial warning would have a sustained impact that could be achieved by changing the picture and text messages on a regular basis to prevent the messages and impacts 'wearing out'. The sources of evidence reviewed do not specify how often warnings should be changed or rotated to obtain optimal impact on consumers and would-be consumers, although many do refer to the 'wear-out' effect produced by having the same labels on tobacco packets for a sustained period of time. However, one study by the ITC Policy Evaluation Project indicates that the occurrence of the wear-out effect will in large part depend on the attributes of the health warnings used (International Tobacco Control Policy Evaluation Project, 2009). Thus labels that are larger and contain more 'vivid' warnings are more likely to have a lasting impact on consumers than less prominent, text-only warnings (International Tobacco Control Policy Evaluation Project, 2009).

Pictorial warnings versus text-only warnings (status quo)

There is considerable evidence regarding the impact of tobacco product labelling that points to the effectiveness of pictorial warnings combined with text warnings rather than the use of text warnings on their own. For example, the UK Department of Health's impact assessment (2007) mentioned above predicted a 0.05 percent decrease in consumption if the status quo (text warnings only) were maintained and a 0.5 percent decrease with the introduction of pictorial warnings (UK Department of Health, 2007).

A study by Sambrook Research International, commissioned by the EC Directorate-General for Health and Consumers (Sambrook Research International, 2009), carried out a review of the scientific evidence on the effects and impacts of tobacco warning labels on consumer awareness and behaviour. It also looked at the determinants of effectiveness of such labels, such as whether combining text and pictorial warnings was more effective than text-only warnings and whether the size of the warnings impacted on their effectiveness. Nevertheless, the report also acknowledges the limitations of the evidence on which these conclusions are based, including the fact that there is at present no reliable estimate available of how many smokers have changed their behaviour as a result of tobacco health warnings (Sambrook Research International, 2009).

Some of the key findings on the health impacts of using *large*, combined pictorial and health warnings include the following (Sambrook Research International, 2009p.45):

- A high impact on educating smokers and non-smokers about the health effects and risks of tobacco usage evidenced by the observation that some smokers and non-smokers were encouraged to think about their health (up to 37 percent) or have discussed the health effects of smoking highlighted in the warnings with friends and family members (up to 63 percent), which is often a precursor to an attempt to quit.

[51] This is based on the knowledge that 25percent of UK smokers use tobacco products other than cigarettes.

- A medium impact on changing smokers' attitude towards tobacco use with self-reported evidence that warnings have influenced significant proportions of smokers (21 percent to 55 percent) to think more about quitting and also have increased their motivation to quit.
- A medium impact on changing smokers' behaviour with some evidence of self-reported findings indicating that warnings have motivated some smokers to change their smoking behaviour by smoking less (8 percent to 28 percent), by smoking less around others (up to 52 percent), attempting to quit smoking (18 percent to 55 percent), using 'quit-lines' (up to 300 percent) and quitting smoking (2 percent to 8 percent).

This review, however, cautions that the effectiveness of warning labels on tobacco products depends to a large extent on the type of warning label used. Thus, warnings combining text and pictures are shown to be more effective than text alone and bigger-sized labels are more effective than smaller ones (Sambrook Research International, 2009). In addition, consumers were shown to react differently to different text messages and images, and it has been found that shocking and disturbing images are generally the most effective (Sambrook Research International, 2009p.40). Much of this evidence is confirmed by the ITC Four Country Survey (ITC-4), a recent cohort survey of about 9,000 adult smokers aged 18 and older in Canada, the UK, Australia and the USA (International Tobacco Control Policy Evaluation Project, 2009). This cohort survey examined the results of changes in health warnings in text and size only compared with the introduction of pictorial warnings in four countries with very different types of labels (i.e. Canada has coloured pictorial warning labels that cover 50 percent of the cigarette pack face whereas the USA has text-only warnings in black and white on the side of cigarette packs) (International Tobacco Control Policy Evaluation Project, 2009). The key findings of the first five waves of this cohort survey, carried out between 2002 and 2006, included evidence that large pictorial warnings, as used in Canada, result in consumers who are more aware and knowledgeable about the health effects of smoking than consumers who only have access to text warnings on one side of the pack; the latter is the case in the USA (International Tobacco Control Policy Evaluation Project, 2009). This research also confirmed that vivid images are more easily noticed and remembered by consumers (*(International Tobacco Control Policy Evaluation Project, 2009)*.

In addition, there is wide-ranging evidence that different consumer groups (i.e. young, female, older consumers, etc.) react differently to different messages and pictures (Elliott & Shanahan Research, 2009). This indicates that the target population should be thoroughly taken into account in order to produce the most effective warnings possible.

Importance of warnings' size

As mentioned above, there is evidence in the literature that the size of the warnings impacts on consumers' awareness and behaviour, with larger warnings being more effective (See for example: Australian Government Department of Health and Ageing, 2008, Hammond *et al.*, 2006, Sambrook Research International, 2009, UK Department of Health, 2007). 'Typical' conclusions made by these studies tend to be very similar to that made following a study carried out by the Australian Government Department of Health and Ageing in its review of the literature. The department concluded that there is evidence that health warning labels which are larger and more uncluttered, include pictorial

representations of the potential health consequences of smoking, make use of contrasting colours displayed prominently on the pack and are rotated regularly to avoid the 'wear-out' effect on consumers are most effective (Australian Government Department of Health and Ageing, 2008).

The effectiveness of larger warnings on tobacco products is often explained with reference to cigarette pack designs. That is to say that many articles argue that larger warnings are necessary to effectively 'compete' with the designs used by tobacco manufacturers to attract consumers to their products. For example, a study by BRC Marketing and Social Research for the New Zealand Ministry of Health observed that larger health warnings are more likely to stand out against the tobacco manufacturer's branding positioned elsewhere on the cigarette packet (BRC Marketing and Social Research, 2004). Therefore a more 'radical' option aimed at making health warnings on tobacco product packs more salient would be the introduction of plain or generic packaging. The evidence base for the introduction of such packaging is discussed below in relation to its potential health impacts.

Plain or generic packaging

Given that no country has implemented plain packaging to date, no *observed* data currently exist on the impact of plain packaging on consumer behaviour (European Network for Smoking Prevention, 2009). However, a number of studies have been conducted in this area by means of focus groups, interviews and surveys, with most of these presenting evidence of a reduction in attractiveness of cigarette packs to consumers (See for example: Germain *et al.*, 2009, Grant *et al.*, 2008, Hammond and Parkinson, 2009). A number of these studies (See for example: European Network for Smoking Prevention, 2009, Sambrook Research International, 2009) have been able to provide some evidence, albeit based on perception data, of the potential impacts of plain packaging, suggesting that it may (Sambrook Research International, 2009):

- reduce the attractiveness and identification of the link between tobacco packaging, brands and consumer attractiveness, especially among young people;
- increase in the effect, message recall and credibility of health warnings;
- reduce the false beliefs relating to health risks.

A critical review of the evidence for the effectiveness of plain packaging was carried out by LEGG on behalf of PMI and published in 2010 (Padilla and Watson, 2010). It reviewed 13 empirical papers and concluded that none of these papers provides evidence that can be used to evaluate the effectiveness of generic packaging on reducing the take-up of smoking by young people (Padilla and Watson, 2010p.4). This conclusion is based on the fact that the methodologies of the research papers reviewed by the authors were judged to be flawed due to the general overreliance on focus groups and surveys. While this methodological critique should be acknowledged and taken into account when reviewing the evidence presented in the literature, it is not entirely valid given that there cannot possibly be empirical evidence of the impact of a given policy unless legislation is implemented in the first place. Hence, in such cases, legislators have to rely on evidence such as that derived from perception data in order to get as good an indication as feasible of the potential impacts of these policies on consumers.

In addition, while we have thought it useful to include the above source of evidence in order to demonstrate that we have indeed taken into account evidence put forward by the tobacco industry and reflected on its validity, it should be noted that any source of evidence linked to the tobacco industry should be carefully considered in the light of this industry's long history of trying to influence tobacco control policy. The interference of the tobacco industry is thoroughly documented in a report by WH(WHO, 2009c).

In spite of this, the review provides a summary of the conclusions produced by the research papers reviewed, which may be a useful starting point from which to try to understand the potential impact of plain packaging on consumer behaviour and consequently on public health (albeit while bearing in mind the methodological limitations of relying on perception data) (Padilla and Watson, 2010). These conclusions are important:

- The colour of the packaging influences smokers' perception of tar content and taste of cigarettes in different packs. So, light and brown packets are perceived to deliver lower amounts of tar, have a smoother taste and, in some cases, be less risky for the health of consumers.
- Young people are attracted by the packaging used by tobacco manufacturers.
- Generic packaging may enhance the recall and recognition of health warnings; the packaging of tobacco products is as important as brand and peer influence for consumers.

In a journal article, Wakefield *et al.* (2002) present evidence from tobacco industry documents on the importance of cigarette pack design for brand image. They stress the importance of pack designs as endorsements of cigarette brands, given that cigarette packs are carried round by consumers all day and are often displayed on tables or elsewhere, thereby being 'witnessed by others, providing a living testimonial endorsement of the user on behalf of that brand and product' (Wakefield, 2002). Some of this evidence is particularly relevant to the potential health impacts of plain packaging on smokers and consumers at large. For example, they stress the influence of the colour used on cigarette packs on consumers' perception of the risk of smoking. They refer to the *sensation transfer phenomenon*, whereby the impression of lower tar cigarettes may be obtained *with the use of lighter colours* (Wakefield, 2002). This finding is particularly relevant since some consumers choose to smoke what they see as 'less risky' cigarettes that have lower tar content rather than attempt to quit smoking. Thus, some of the consumers' perceptions may change with the use of plain packaging and encourage them to attempt to quit smoking.

A similar argument is made about the importance of cigarette pack design in attracting consumers in an article by DiFranza *et al.* (2003), who state that 'designs help to create the perceived product attributed and project a personality image of the user with the intent of fulfilling the psychological needs of the targeted types of smokers' (DiFranza *et al.*, 2003p.97). This study was based on a computer search of all internet websites containing tobacco industry documents and employed various search terms, including: packaging, package design, package study, box design, and so on (DiFranza *et al.*, 2003). The authors further conclude that 'the same marketing research techniques that have been used to

promote tobacco use can be enlisted in the fight against this addiction and the diseases and suffering it causes' (DiFranza *et al.*, 2003p.107).

Another article by Freeman *et al.* (2008) argues that the current packaging of tobacco products is a key marketing tool for the tobacco industry to promote its products to smokers and aspiring smokers. It also makes the point, as evidenced by the body of research on plain packaging, that current package design may distract consumers from the health warnings (Freeman *et al.*, 2008).

In another study, Wakefield *et al.* (2008) observe the impact of plainer cigarette packaging on the attractiveness of cigarettes to consumers. This study made use of an on-line method to expose 813 Australian smokers to a range of randomly selected cigarette packs, which they were then asked to rate for attractiveness (Wakefield, 2008). It concluded that 'plain packs with increasingly fewer brand design elements are perceived increasingly unfavourably in terms of smokers' appraisals of the packs, the smokers who might smoke such packs, and the inferred experience of smoking a cigarette from these packs' (Wakefield, 2008).

Moodie *et al.* (2009) reviewed the evidence from plain packaging research for the UK Department of Health. Their report confirms much of the evidence presented above and particularly stresses the misleading impact of pack designs on consumers' perception of the harm of different tobacco products, depending on the colour of the pack (i.e. lighter packs are associated with smoother or lighter tastes by some consumers). Because pack designs may detract from health warnings, pack designs also negatively impact on consumers' awareness of the health risks of smoking (Moodie *et al.*, 2009). One of their conclusions is that plain packaging would reduce the potential for consumers being confused or misguided about the harm of different tobacco products (Moodie *et al.*, 2009).

Another study of plain packaging, by the International Union Against Tuberculosis and Lung Disease (2009) similarly concluded that plain packaging would eliminate misleading labelling, increase the salience of health warnings and also thwart the tobacco industry's efforts to 'manipulate package design to more effectively promote tobacco products, particularly to young people' (International Union Against Tuberculosis and Lung Disease, 2009).

In spite of this evidence, it should be noted that some governments have been reluctant to consider seriously the introduction of plain packaging owing to concerns about intellectual property rights and trade issues that have been brought to the fore by the tobacco industry. (For a summary of the arguments and state-of-play, see: Physicians for Smoke-Free Canada, 2008) Nevertheless, 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 (see, e.g., (Gordon, 2010) and (Davison, 2010). In addition, the Australian government has recently announced that the plain packaging of tobacco products will become mandatory from July 2012 (ASH, 2010), and other governments, such as that of the UK, are currently reconsidering the introduction of plain packaging (Rouse, 2010).

While there is still some debate about the feasibility of implementing this measure and about the evidence base for the impact on tobacco consumption, the types of studies

presented in this section provide evidence of the role and importance of cigarette packaging design in attracting consumers (both current smokers and 'aspiring' smokers) to tobacco products. Thus, given the importance of product attractiveness in product purchasing decisions and evidence that such packaging detracts from the health warning currently placed on such products, it is apparent that plain packaging would have some deterrent impact (albeit difficult to quantify) on the consumption of tobacco products. It might also be envisaged that this impact could be greater in deterring consumers who are non-smokers and therefore not yet addicted to nicotine from taking up smoking. Also, given the evidence on cigarette design attractiveness to different target populations, the impact of plain packaging could also have a particularly positive effect on these groups, encouraging them to reduce their cigarette consumption and uptake.

Replace TNCO quantitative labelling with qualitative information on contents and emissions and quit-lines

TNCO quantitative versus qualitative labelling information

There is evidence showing that quantitative information on cigarette packs is misleading for consumers because they may think that lower TNCO yields indicated on packs mean that a tobacco product is less risky to their health; some of them may even decide to smoke lower TNCO yields cigarettes in preference to quitting (Commonwealth Department of Health and Aged Care, 2001p.17). In addition, the method used to measure TNCO yields in manufactured cigarettes (i.e. the ISO standard method) has increasingly been called into question. In particular, the 'ISO measurement of yields is based on smoking simulated by a machine' and 'new evidence has shown that smokers adjust inhalation with the yield' (DG SANCO, 2005). This process of adjusting inhalation is called 'compensation' and raises the issue that, despite lower nominal yields from cigarettes, there is little evidence that these lower yields reduce the 'toxic burden on smokers' (DG SANCO, 2005). In addition, cigarette design has evolved greatly since tests were first put in place, and cigarette manufacturers have employed various designs that have 'reduced the validity of the machine test as a measure of human smoke exposure' (examples of such designs include increasing the length of filters and employing ventilation holes) (WHO, 2000). Owing to these issues, the information on TNCO yields has the potential to mislead consumers into believing that 'low yield products are less harmful and consequently they smoke more of these' (DG SANCO, 2005p.4). It therefore appears that replacing such information with qualitative information could contribute to informing consumers better about the health risks of smoking and that it might encourage some to quit smoking altogether (i.e. those that chose to smoke lower yield cigarettes instead of attempting to quit because of their belief/misunderstanding that lower yield cigarettes are less risky to their health).

Quantitative information on TNCO yields on cigarette packs have already been banned in Australia, Brazil, Venezuela and Thailand (Tobacco Labelling Resource Centre Website, Accessed February 2010). However, evidence of the impact of qualitative versus quantitative information of TNCO yields is scarce. In addition, most sources that we have identified in this area conclude that quantitative information on TNCO yields is misleading for consumers and that new ways of informing them more effectively should be found (See for example: Commonwealth Department of Health and Aged Care, 2001, O'Connor *et al.*, 2006). A study by O'Connor *et al.* (2006) examined whether smokers in four different countries could recall the tar yield of their brand of cigarettes, using data

from the third wave of the ITC Four Country Survey. It found that 'constituent labelling policies can affect whether smokers report a tar yield for their cigarette brand' and concluded that 'there is an urgent need to develop more effective ways to communicate the toxic constituents of cigarette smoke to smokers in a way that is more meaningful than the current FTC/ISO yields (O'Connor *et al.*, 2006p.324 and 328).

Quit-lines information on packs

A study of graphic health warnings was carried out by the Australian Government Department of Health and Ageing in 2008. It was based on a literature review of research studies on graphic health warnings, a number of semi-structured interviews (28), group discussions (24) and a nationwide telephone survey of 1,304 randomly selected Australians (Australian Government Department of Health and Ageing, 2008). This study examined the impact of Quitline phone numbers and the Quitnow address on tobacco and cigarette packs (Australian Government Department of Health and Ageing, 2008p.14-15) and found that 'the inclusion of the Quitline phone number and reference to the Quitnow address on tobacco cigarette packs has resulted in an increase in intended usage of both the Quitline and website, particularly among those contemplating quitting and among "light" smokers' (Australian Government Department of Health and Ageing, 2008p.15).

There is more evidence from Australia that including quit-line information on cigarette packs along with graphic health warnings is effective in encouraging smokers to call such help lines. For example, data collected by Quit Victoria in 2007 showed that the number of callers stating they had obtained the quit-line number from their cigarette pack rose from 6 percent before the inclusion of graphic health warnings to 33 percent after they had been used for two months (Evidence cited in: Elliott and Shanahan, 2008p.19)

Introduce inserts with supplementary information (e.g. on the potential risks)

There is little information available on the potential health impacts of inserts with supplementary information in tobacco product packs; all we have been able to find is some evidence from the Canadian experience of such inserts. Since 2000 Canadian regulation has required the use of such leaflets 'in the case of any package other than a slide and shell package or a tub' (Canadian Government, 2000). In addition, there is some evidence from Health Canada that 'recall and notice of the insert messages is higher than that for messages carried on the flip/side' and that 'both formats [on side of pack or on inserts/leaflets] were seen, by a majority of smokers, as effective in providing information to smokers' (Evidence from Health Canada research cited in: Commonwealth Department of Health and Aged Care, 2001p.16).

Limitations of the evidence presented

There are limitations to consider when reviewing the evidence for different labelling measures and their potential health impacts. Given that the majority of the studies carried out to assess the impacts of labels on consumers are based on surveys (on-line, paper-based and face-to-face) and focus groups, the bulk of the evidence in this area relies heavily on perception data (i.e. consumers' *intention* to change their behaviour or their *perception* of the impacts of such labels). Thus, one of the main limitations of these studies and the conclusions they come to is that there is little evidence of *observed* change as a result of the use of labels on tobacco products (e.g. some studies are able to quantify the proportion of respondents who say they are willing to quit as a result of labels, but not the proportion of

respondents who have actually quit as a result). In addition, very few studies have been able to produce quantitative estimates of the impact of labels on consumers' smoking behaviour. Nevertheless, some studies have produced some estimates. For example, the World Bank Group made reference to a study in Turkey which estimated that the introduction of text labels caused cigarette consumption to fall by 8 percent over six years (Jha and Chaloupka, 1999p.47) and an impact assessment carried out by the UK Department of Health estimated the addition of text warnings on cigarette packs produced a 0.5 percent reduction in the number of smokers in the long term (UK Department of Health, 2007p.10). In addition, this evidence is useful in considering the potential impacts of labelling and the effectiveness of different messages and pictorial warnings as well as sizes of labels on consumers' awareness levels and eventual behaviour change.

The other main limitation of such studies is that, as with all regulatory measures, it is very difficult – if not impossible – to attribute specific impacts to specific measures. This is obviously relevant to labelling, in particular since the introduction of labels on tobacco products has often been simultaneous with other tobacco control measures such as smoking restrictions in public places, price increases, and so on. In addition, there is a range of external factors that may influence behaviour change, including peer pressure, one's economic situation, health concerns, and so on. This limitation is exemplified by Gospodinov and Irvine (2004), who used micro-data from two waves of Health Canada's Canadian Tobacco Use Monitoring Surveys to investigate the impact of the introduction of warnings on smokers (Gospodinov and Irvine, 2004). This study stressed the importance of a range of factors and regulations in producing changes in smoking behaviour. For example, they found that the introduction of a government policy that drove up prices in 2001 had an impact on consumption, as did a range of other factors including 'a secular decline in smoking during the last two decades in Canada' (Gospodinov and Irvine, 2004). Nevertheless, the evidence reviewed in this chapter is essential to understanding the contribution that labelling requirements can make to reducing smoking consumption and uptake.

8.2.2 **Social impact**

There are some social impacts resulting from the labelling of tobacco products. For example, some sources have argued that the introduction of pictorial warnings on tobacco products will have a positive impact on different social groups because, at present, the most disadvantaged might struggle to understand the text-only warnings. This is particularly relevant for those groups with literacy and learning difficulties (See for example: Elliott and Shanahan, 2008p.22-23, UK Department of Health, 2007p.11). On the other hand, pictorial warnings are difficult to integrate on all tobacco products; this is particularly true for smokeless tobacco, which only contains front of pack warnings under the present EC regulation. It is therefore possible that members of some social or ethnic groups who are more likely to use these products will be at a disadvantage as they will have no direct access to the warnings. As a result, they may even perceive that the tobacco products they use are less risky for their health (UK Department of Health, 2007p.15). In addition, if inserts with additional information are inserted they may not be as accessible to lower socioeconomic groups – particularly consumers who are less literate and less well educated.

However, the impact will depend to a large extent on how this information is conveyed (i.e. if it is conveyed in simple terms with the use of plain language, if it uses pictures, etc.).

There is a body of evidence that suggests that difference types of warnings have different impacts on different target groups (See Elliott and Shanahan, 2008 for a summary of the literature evidence on this topic). For example, females have been found to be more responsive to warnings related to pregnancy and children while younger people have been found to respond better to warnings related to more immediate health risks such as poor fitness or negative social consequences (Elliott and Shanahan, 2008p.8). This evidence therefore suggests that, in order to maximise equally the impact on all target groups of the health warnings on tobacco products, a range of messages and images needs to be conveyed.

A summary of the evidence on the social and health impacts of labelling may be found in Table 8.1.

Table 8.1: Summary of evidence on labelling changes

Measures considered	Summary of the evidence of health impact	Summary of the evidence of social impacts
No change.	Some evidence from the UK that no change in labelling requirements would produce a 0.05% drop in tobacco consumption in the long term.	Lower socioeconomic groups and in particular those consumers who are less literate and less educated may not be able to understand fully the meaning of text warnings.
Make pictorial warnings mandatory.	Some evidence from the UK that the introduction of pictorial labels on all tobacco products would produce a drop of 0.5% in tobacco consumption in the long term or a drop of 75% of 0.5% if the pictorial labels are only applied to cigarette packs (note: because 25% of UK smokers consumer tobacco products other than cigarettes).	Lower socioeconomic groups and in particular those consumers who are less literate and less educated will benefit from the introduction of pictorial warnings.
Update and enlarge warnings to 50% of both sides of the pack and place them towards the top of the pack.	Evidence that larger warnings are better because they are more visible and less likely to be ignored by consumers. Similarly, larger warnings may compete better with cigarette pack designs for the attention of consumers.	All consumers would benefit from updated and enlarged warnings.
Further increase in the size of warnings to 75% of both sides of the pack.	Same as above, although increasing the size of pictorial warnings further is likely to increase the reduction in tobacco consumption produced by smaller warning labels.	All consumers would benefit from updated and enlarged warnings.
Further increase the size of the warnings on the back of the pack to 100%.	Same as above, although increasing size of pictorial warnings further is likely to increase the reduction in tobacco consumption produced by smaller warning labels.	All consumers would benefit from updated and enlarged warnings.
Introduce generic packaging.	Most of the evidence found relates to the importance of cigarette pack design in attracting consumers to buy cigarette packs and to the fact that cigarette pack design may distract consumers from the health warnings presented on packs. The evidence available points to the introduction of generic packaging producing a decrease in cigarette pack attractiveness to consumers and an increase of the prominence of health warnings on packs.	All consumers would benefit from updated and enlarged warnings.
Replace TNCO quantitative labelling with qualitative information on contents and emissions and quit-lines.	Most of the evidence found relates to the misleading information presented by quantitative TNCO yield labelling, for two reasons: 1) because the measurement method used (ISO method) is not accurate; and 2) because some consumers believe that cigarettes with lower TNCO yields are 'less risky' to their health. Qualitative TNCO yield labelling would address some of these issues and contribute to informing consumers better about the dangers of tobacco consumption.	Consumers find TNCO quantitative information confusing, so they will benefit from the introduction of qualitative information although lower socioeconomic groups and those consumers who are less literate might not be able to understand fully the meaning of the qualitative information on TNCO yields. This will to a great extent depend on the way in which this information is conveyed.
Introduce inserts with supplementary information (e.g. on the potential risks).	Very little evidence available on the impact of inserts with supplementary information. Some evidence from Canada that consumers respond well to this information.	Lower socioeconomic groups and in particular those consumers who are less literate and less educated may not be able to understand fully the information presented in the inserts. This will to a great extent depend on the way in which this information is conveyed.

8.2.3 Assessment of impacts

Based on the evidence presented above, we would expect the proposed changes to labelling requirements to have the following impacts.

Pictorial warning

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'. As has been discussed, there are some quantitative estimates of the impacts of text-only warnings on the reduction of tobacco consumption versus pictorial warnings from the UK Department of Health. It appears that the social impact of introducing pictorial warnings would be overwhelmingly positive. In particular, the impact on lower socioeconomic groups would be positive since information about the risks of smoking would be more accessible to less educated and/or literate consumers.

a) Mandatory pictorial warnings

As mentioned above, there is a body of evidence that shows that pictorial warnings are more effective than text-only warnings in informing consumers about the health risks of smoking as well as in triggering behaviour change (i.e. calls to quit-lines, reduction in smoking and increased quit attempts). In line with the UK impact assessment, we therefore consider it feasible that the introduction of mandatory pictorial warnings will lead to a reduction in smoking prevalence, and we follow the UK's impact assessment which quantified such a change as being 0.5 percent. A reduction of smoking prevalence across the EU by 0.5 percent would lead to around 900 fewer tobacco-related deaths and 9,300 fewer cases of lung cancer, aerodigestive cancer and COPD annually in the EU by 2027. In addition, updating the warnings is likely to produce a positive impact on tobacco consumption as it has been shown that consumers experience the 'wear-out' effect if the same warnings are used for prolonged periods of time.

b) Increased size of pictorial warnings (50 percent, 75 percent, 100 percent)

The evidence has also shown that the larger the warnings, the more impact they produce on consumer behaviour. Therefore, increasing the size of the warnings of the back of the pack to 50 percent, 75 percent or 100 percent could reduce prevalence by even more than 0.5 percent. There are, however, no quantifications available of the effect of larger labels on prevalence. We thus assume that these changes will decrease prevalence by at least 0.5 percent, with a higher certainty the bigger the labels are. Again, a reduction of smoking prevalence across the EU by 0.5 percent would lead to around 900 fewer tobacco-related deaths and 9,300 fewer cases of lung cancer, aerodigestive cancer and COPD annually in the EU by 2027.

Plain or generic packaging

The evidence presented on plain packaging indicates that plain or generic packaging is less attractive to consumers. It also enables warning labels to be more prominent and, as a result, to have a greater impact on both consumers' awareness of the health risks of tobacco

smoking and on their attempts to quit smoking or to reduce their tobacco consumption. Given the evidence presented on the attractiveness of cigarette packs to consumers and the fact that these designs may detract from the health warnings present on packs, it appears that plain packaging would supplement the introduction of pictorial warnings and reinforce their effect.

Information on leaflets

The evidence base to support the introduction of leaflets or inserts is much less developed than the evidence supporting the introduction of larger pictorial warnings and plain packaging, although there is some evidence from Canada that consumers respond well to information presented to them in this way. Due to the nature of their packaging, it is not always practical to display warnings on all tobacco products. Given the evidence presented on the introduction of leaflets or inserts, it appears that such information would benefit consumers of tobacco products that cannot practically accommodate health warnings at present by enabling them to access health information.

Qualitative TNCO information

The introduction of qualitative TNCO yield labelling would address the issue of giving misleading information to smokers, resulting from inaccuracies in measurement methods and the erroneous belief that cigarettes with lower TNCO yields are 'less risky' to their health. This form of labelling would thus constitute an important element of consumer information.

8.2.4 Summary of health impacts

Measure	Health and social impact	Effect
Make pictorial warnings mandatory	- A reduction in smoking prevalence across the EU by at least 0.5% would probably lead to around 900 fewer tobacco-related deaths and 9,300 fewer cases of lung cancer, aerodigestive cancer and COPD annually in the EU by 2027. Less literate and less educated smokers are likely to understand health warnings.	+
Update and enlarge warnings to 50% of both sides of the pack and place them towards the top of the pack	- Reduction in smoking prevalence possible and more likely than for smaller pictures. A minimum of a 0.5% reduction of smoking prevalence across the EU would lead to around 900 fewer tobacco-related deaths and 9,300 fewer cases of lung cancer, aerodigestive cancer and COPD annually in the EU by 2027. - Warnings are likely to be more effective, and less literate and less educated smokers are likely to understand health warnings better.	+
Further increase of the size of warnings to 75% of both sides of the pack	- Reduction in smoking prevalence possible and more likely than with smaller pictures. A minimum of a 0.5% reduction of smoking prevalence across the EU, would lead to around 900 fewer tobacco-related deaths and 9,300 fewer cases of lung cancer, aerodigestive cancer and COPD annually in the EU by 2027. Warnings are likely to be more effective, and less literate and less educated smokers are likely to understand better health warnings.	++
Further increase the size of the warnings on the back of the pack to 100%	- Reduction in smoking prevalence possible and more likely than for smaller pictures A minimum of a 0.5% reduction of smoking prevalence across the EU would lead to around 900 fewer tobacco-related deaths and 9,300 fewer cases of lung cancer, aerodigestive cancer and COPD annually in the EU by 2027. - Warnings are likely to be more effective, and less literate and less educated smokers are likely to understand health warnings better.	++
Introduce generic packaging	- Reduction of smoking prevalence through reduced brand and pack attractiveness likely, but effect currently not quantifiable on a population level. - Warning labels would be more visible and consumers would benefit from readability of warnings.	++
Replace TNCO quantitative labelling with qualitative information on contents and emissions and quit-lines	- Consumers would be better informed about the harms of smoking and the unintended misleading effects of quantified TNCO yield labelling.	+
Introduce inserts with supplementary information (e.g. on potential risks)	- Better consumer information on harms of tobacco smoking. - Lower socioeconomic groups and in particular those consumers who are less literate and less educated may not be able to understand fully the information presented in the inserts. This would to a great extent depend on the way this information is conveyed.	(+)

8.3 Economic impacts

The changes suggested to the current labelling requirements are likely to have at least the following economic impacts:

1. Compliance cost and administrative burden for manufacturers of the relevant products.
2. Impact on tobacco market: commoditisation and reduced brand equity.
3. Revenues and profits from the sale of tobacco and nicotine products.
4. Employment in the tobacco industry.
5. Governments' tobacco consumption tax revenues.
6. Healthcare costs.

We address these impacts by considering the following framework: there are two perspectives – the producer and the consumer – when assessing the economic impacts from increased regulations on labelling and packaging. For the producer, if the new labelling and packaging requirements are introduced immediately there will be an increase in costs because of adjusting their operations and equipment to take into account the new regulation (impact 1). When the operation yields less profit (because inputs to produce tobacco products are more expensive), the supply of tobacco may fall (impact 2).

Thus far we have described the short-term effects. In the long run, producers are able to adjust their equipment to take into account the labelling and packaging requirements; with no resources costs unchanged, there are no changes to factors of production (i.e. employment).

For the consumer, the new labels and packages are designed to reduce the attractiveness of smoking (i.e. reduce the proportion of smokers in the population) and demand falls so that at any given price there are fewer people willing to purchase tobacco products (impact 3). Assuming the labelling and packaging requirements will be communicated to producers so that they have time to adjust their equipment, the increased costs producers may still experience will be due to additional material they have to include in packaging. Firms may have to reduce the number of employees (impact 3) in order to remain competitive.

Reduced consumption means reduced revenues are generated from consumption tobacco taxes (impact 5). Lower consumption would also reduce the poor health outcomes associated with tobacco consumption, thereby cutting expenditure on healthcare for those types of outcomes (impact 6).

We discuss these impacts in detail below.

8.3.1 Administrative burden and compliance costs for manufacturers

The changes suggested in this area are concerned with the packaging of tobacco products and will therefore affect tobacco manufacturers primarily, rather than retailers or growers. The reason is that labelling and packaging are done by manufacturers, either by themselves or by outsourcing some of the activities.

These costs are classified primarily as administrative burden – labelling and packaging are means of information provision to consumers and thus fall under the definition of administrative burden.

The measures discussed in this section – such as mandatory pictorial warnings, generic packaging, qualitative labelling and inserts with supplementary information – generally affect the same stages of the production process and impose costs on business in similar ways. For a general discussion see Chapter 5. Here only the specific aspects of each measure are spelled out.

Introduce pictorial warnings of different sizes

As described in Chapter 5, making pictorial warnings mandatory imposes administrative burden on manufacturers as they would have to understand and interpret the regulation, and familiarise themselves with picture formats and pictures available to be put on the pack. They would also have to change printing equipment (e.g. cylinders) in order to be able to print the required pictures on the packs. Furthermore, changes in labelling and packaging regulation may make manufacturers redesign their packs completely. Beyond this one-off administrative burden, ongoing burdens would also arise in terms of ink and other raw materials used for printing. However, ongoing burdens are likely to be offset by the decreasing costs of textual warnings if, for example, a warning picture replaces warning text, or by decreasing costs of labelling the rest of the pack if, for example, the brand pictorials are partially replaced by pictorial warning. It is worth noting that in several Member States pictorial warnings are already implemented, so manufacturers do not have to readjust their production process completely.

There are differences in the implied costs of the legislation depending on a small number of crucial details of this proposed measure. If the size of the pictorial warning equals the current size of the textual warning, the costs are likely to be lower than in the case of larger warnings as pack designs do not have to be changed. Furthermore, the time span within which manufacturers have to comply fully with the regulation has a considerable impact on administrative burden as labels are regularly changed regardless of regulation (e.g. for marketing purposes) and the stock of old labels is used up over time. By implication, if a sufficiently long time is allowed for compliance the administrative burden associated with changing equipment and discarding old packs and labels becomes marginal (EAS, 2004, Muth *et al.*, 2003). Our subsequent estimates are based on a basic scenario of colourful pictorials which are uniform across the EU-27. The ranges of quantitative estimates below reflect the different implementation time spans: from immediate implementation to implementation time equal to pack change period in the absence of regulation.[52] Here we report cost estimates for different sizes of pictorial warning:

1. Pictorial warning is the same size as the existing textual warning (currently ranging from 30 percent to 50 percent of the pack's surface).
2. Pictorial warning is 50 percent of both sides of the pack and placed towards the top of the pack.

[52] Cigarette and cigar industries reported varying time frames for regular pack and labelling changes. That is, cigarette manufacturers typically change their pack designs more frequently than cigar manufacturers do.

3. Pictorial warning is 75 percent of both sides of the pack.
4. Pictorial warning is further increased to 100 percent of the back of the pack.

According to the responses of the one cigarette producer in Europe that provided quantitative estimates, the initial administrative burden of introducing mandatory pictorial warnings on all cigarette packs would amount to between 32.5 and 125.4 million euros in the EU-27 for the whole cigarette manufacturing industry (Table 8.5). The company disclosed that the initial administrative burden would be approximately 40 to 45 million euros for the company if considerable time were not allowed for compliance. This translates into 18,100–20,400 euros per SKU. The numbers are solely based on one company's estimates which, in addition, did not provide any further detail on the make-up of the overall cost (e.g. quantitative estimate of labour costs).

In order to put the above estimates in perspective, a close comparator of tobacco pack labelling is chosen: food labelling. Estimates from previous research suggest a range of total costs of changing a label to be 2,000–4,000 euros per SKU (see Table 8.2, column 2). This suggests that our cost estimates for replacing cigarette textual warnings with pictorial warnings may be excessively high.

Table 8.2: Estimates of total costs for changing a label per SKU, food labelling

	Small change	Extensive redesign
Cost range	€2,000–4,000	€7,000–9,000

Source: EAS (2004)

The cost range of initial administrative burden for the whole EU was reached on the basis of the only available company-level estimate, scaling it up based on sales volume and considering a longer time period for compliance as the lower bound estimate. By allowing for a longer time period for compliancem (i.e. approximately two years, which is the lifespan of a typical cigarette label), the time variant elements of administrative burden become marginal. These elements are buying new machines, adjusting the production process and discarding old labels. As there were no estimates available for these cost elements from the responding cigarette manufacturer, RAND Europe approximated the cost break-down by the cost structure of cigar manufacturers. Based on this approximation, 74 percent of total initial administrative burden is time variant – that is, 74 percent of total initial administrative burden may be eliminated if sufficient compliance time is allowed for.

According to the responses of the cigar producers of Europe that provided quantitative estimates, the initial costs of introducing mandatory pictorial warnings on all cigar packs would amount to between 1.4 and 5.5 million euros in the EU-27 for the whole cigar manufacturing industry (Table 8.5). According to these responses, per company costs would range from 0.7 to 0.8 million euros for cigar manufacturers if considerable time were not allowed for compliance. This range translates into a per SKU cost ranging

between 240 and 1,450 euros. These administrative burden estimates are considerably smaller than that of the cigarette industry and the cost estimates of Table 8.2.

The responding companies disclosed overall administrative burden estimates, except for one company which provided a detailed breakdown. According to this company, the structure of administrative burden associated with the mandatory introduction of pictorial warnings is described in Table 8.3 (cost category 1.2 is not applicable to this measure as a pictorial warning of the same size as the textual warning would not require a redesigned pack).

The cost range of initial administrative burden for the whole EU was reached on the basis of the available company-level estimates, scaling them up on the basis of sales volumes, and considering a longer time period for compliance as the lower bound estimate. By allowing for a longer time period for compliance (i.e. approximately five to seven years, which is the lifespan of a typical cigar label), the time variant elements of administrative burden become marginal. As there were no available estimates for the cost elements from all cigar manufacturers, RAND Europe approximated their cost break-down by the one disclosed cost structure. Based on this approximation, 74 percent of total administrative burden is time variant.

No quantitative cost estimate could be obtained for producers of other tobacco products such as pipe tobacco.

It is important to note that whereas total costs accruing to cigarette manufacturers are much larger than those accruing to cigar manufacturers, the relative burden of compliance (e.g. costs per revenue) is much higher for cigar manufacturers as cigar manufacturers' brands are typically of much smaller quantities. Costs therefore fall on a much smaller number of units sold.

Table 8.3: The break-down of the potential initial administrative burden associated with pictorial warnings, typical cigar producer, 2009

#	Cost category	Cost (thousand euros)
1	time invariant costs:	525
1.1	development of pictorial health warnings	25
1.2	redesigning the pack/box	350
1.3	project team labour costs	150
2	time variant costs:	500
2.1	discarding old labels	375
2.2	readjusting machinery	125
3	total administrative burden	1025

Based on our estimates the total initial administrative burden of introducing mandatory pictorial warnings amounts to 33.9–130.9 million euros in the EU-27 for cigarette and cigar manufacturers (see also Section 2.5 and Chapter 5).

There are ongoing administrative burdens due to this potential regulation: changing textual warning into pictorial warning is likely to cause additional administrative burden only in terms of ink because colourful pictorials require more expensive ink than black and

white warning texts. As pictorial warning would take the place of textual warnings, additional administrative burden would be partially offset by falling production costs (i.e. administrative burden associated with textual warnings).

According to the response of the one cigarette producer of Europe that provided quantitative estimates, the ongoing additional administrative burden of introducing mandatory pictorial warnings on all cigarette packs would amount to between 53.1 and 70.8 million euros per annum in the EU-27 for the whole cigarette manufacturing industry. The company disclosed that the ongoing administrative burden would be for them approximately 18 to 24 million euros per annum. This translates into 8,100–10,900 euros per SKU a year. These numbers are solely based on one company's estimates which we could not directly triangulate with any other data source, therefore they must be handled with care.

The per SKU additional administrative burden of pictorial warnings (8,100–10,900 euros per SKU a year) constitutes an approximately 200 percent printing cost increase compared to the reported costs of the black and white textual warnings of the same company (4670 euros per SKU a year). This is strikingly different from the data of (EAS, 2004), which report that a five-colour label is 15 percent more expensive than its three-colour version.

According to the responses of the two cigar producers of Europe that provided quantitative estimates, the ongoing additional administrative burden of introducing mandatory pictorial warnings on all cigarette packs would amount to between 4 and 5 million euros per annum in the EU-27 for the whole cigar manufacturing industry. This is based on a per company additional administrative burden ranging from 0.5 and 0.7 million euros per annum. It translates into 180–400 euros per SKU a year, which constitutes a percentprinting cost increase of approximately 13–20 percent compared to the reported costs of black and white textual warnings of the same companies (160–330 euros per SKU a year). This is in line with the data of (EAS, 2004).

The above reported additional ongoing administrative burden is solely due to the higher cost of coloured inks than black and white ink.

Our estimates of initial administrative burden are higher than those based on the only other directly comparable international evidence. That is the impact assessment commissioned by the UK Department of Health in 2007 (UK Department of Health, 2007), which found that introducing pictorial warnings would cost British cigarette manufacturers 4.5 million euros (£3,050,000).[53] On scaling up the British figure to the whole EU-27 the resulting cost figure is 31.6 million euros (Table 8.5).[54] The Department of Health impact assessment considered ongoing costs to be marginal. The lower figure of the UK Department of Health may be due to the more detailed approach, which might have improved precision, in particular lowering the potential room for overreporting by industry.

The estimates of additional ongoing administrative burden are discarded from any further analysis for three main reasons:

[53] Exchange rate on 1 August 2007: 1 euro = £0.674.

[54] The GDP weight of the UK compared to EU-27 GDP was used to scale up the data.

1. Estimates are based on one company's data in the case of cigarette manufacturers and two companies in the case of cigar producers.
2. The only directly comparable impact assessment available considers these administrative burdens to be zero.
3. The only available cost estimate of ink colour change suggests a considerable overestimation of additional ongoing administrative burdens.

RAND Europe also examined the administrative burden due to potential measures which would make pictorial warnings larger on both sides of the pack. The potential variations of this measure – that is, the size of increase of pictorial warnings (50 percent–75 percent–100 percent) – bear little cost difference in terms of initial administrative burden for manufacturers. The reason is that by introducing either version of the enlarged pictorial warnings approximately the same types and amounts of costs arise. As noted above, first, they require businesses to familiarise themselves with the new regulation and its implications, which is comparable across all the variants. Secondly, they also make businesses readjust their production processes, the costs of which are relatively similar as any size of the enlarged pictorial warning makes it necessary to readjust the machinery completely (e.g. change all the cylinders used for printing).[55] Thirdly, any versions of enlarged pictorial warnings necessitate the redesign of the whole pack, which implies approximately the same costs across the suggested size variations.

For estimating the administrative burden associated with larger pictorial warnings, the same company responses were used and the same analytical steps taken. The only factor that drives the differences between the administrative burden associated with pictorial warnings of the same size as the current textual warnings and the administrative burden due to larger pictorial warnings is package redesign costs. RAND Europe concluded, based on company responses and the literature, that packs would have to be redesigned if larger pictorial warnings became mandatory. Based on the available break-down of administrative burden (Table 8.3), design costs were added (i.e. based on relative proportion of design costs to overall costs).

For the cigarette manufacture industry, introducing any version of the suggested enlarged pictorial warnings would imply a one-off administrative burden of 97.5–190.4 million euros for the whole EU. The corresponding administrative burden estimate for the cigar industry is 4.3–8.4 million euros (Table 8.5). Thus, the overall initial administrative burden associated with enlarged pictorial warnings is 101.8–198.8 million euros for the EU-27 cigarette and cigar industries (see Section 2.5 and Chapter 5).

No ongoing additional administrative burden is considered in this case for the above reasons.

[55] A similar line of reasoning is found in the case of food labelling (Golan *et al.*, 2000; Muth *et al.*, Golan, E.H., F. Kuchler and L. Mitchell, *Economics of Food Labeling*, Washington, D.C.: U.S. Dept. of Agriculture, Economic Research Service, 2000, Muth, M.K., E.C. Gledhill and S.A. Karns, *Fda Labeling Cost Model. Final Report*, Research Triangle Park, NC: RTI International, 2003.

Introduce plain or generic packaging

Introducing generic packaging would impose administrative burden on manufacturers of tobacco products in the form of information collection about the regulation and one-time adjustment of the production process. Additional ongoing administrative burden is probably negative as the production costs of a plain package are lower than ongoing production costs currently accrued by manufacturers (e.g. fewer colours are used). However, a significant burden falling on manufacturers would be the loss of their brand values, which is considered to be much higher than production costs.

Implementation of the generic packaging regulation for cigar and other non-cigarette products appears to be much less straightforward than for cigarette products as packaging is much less standardised.

According to the responses of the one cigarette producer of Europe that provided quantitative estimates, the initial administrative burden of introducing mandatory generic packaging would amount to between 32.5 and 125.4 million euros (Table 8.5). The company disclosed that the initial administrative burden would be approximately 40 to 45 million euros for the company if considerable time were not allowed for compliance. This translates into 18,100–20,400 euros per SKU.

These numbers are identical to the administrative burden estimates of mandatory pictorial warning of the same size as the textual warning. We used the same figures because cost elements are close to identical in both cases and no design costs arise. As the same data were used, the same reservations regarding data quality apply. On comparing our estimates with the likely costs of an extensive redesign (Table 8.2) it is apparent that our administrative burden figures may be overstatements.

Once again, the range of estimates for the EU-27 reflects the different time horizons of implementation. No quantitative estimate could be obtained for cigar and other non-cigarette tobacco producers.

Replace TNCO quantitative labelling with qualitative information on contents and emissions and quit-lines

A further potential change to the regulatory environment is replacing TNCO quantitative labelling with qualitative information on contents and emissions and quit-lines. Most probably, in order to comply with such a regulation, manufacturers would have to familiarise themselves with the regulation, collect information to be put on the pack and change the printing equipment to reflect the new text. Crucial aspects of such measures are length of the text, its style, its placement, its content and the frequency of the change of wording. Overall, compared to the previous measures, we consider this measure to constitute only a small labelling change which does not result in substantial initial administrative burden. Indeed, this measure may even result in a reduction in the ongoing administrative burden of manufacturers as quantitative TNCO yield information would not need to be adjusted any more to reflect changes in the product over time. The baseline administrative burden of this change is estimated to be 4.8–9.8 million euros a year for the whole EU. Detailed discussion of the baseline administrative burden of quantitative labelling may be found in Chapter 5.

Overall, we associate this measure to be with little to no cost for producers.

Introduce inserts with supplementary information (e.g. on the potential risks)

The last potential measure regarding labelling requirements which causes administrative burden for manufacturers of tobacco products is introducing mandatory inserts with supplementary information (e.g. on the potential risks). This measure would result in initial as well as ongoing administrative costs for manufacturers. Based on reports by the industry, beyond the initial cost of gathering and interpreting information on the new legislation, the largest portion of initial cost would be due to necessary changes to the printing machinery. As currently no cigarette or cigar manufacturer has machinery capable of printing inserts, companies would have to invest in new or enhanced machinery. In addition, staff would have to learn how to run these new printing machines. Smaller producers, typically cigar manufacturers, suggested that compliance would be achieved by adding the inserts manually by employees, which entails lower initial but higher ongoing costs. In either case, ongoing costs would arise in the form of reduced factory efficiency (i.e. higher production cost per unit of output) and the material costs of the insert itself (i.e. paper and printing ink).

Aspects of the potential regulation which have important cost implications are the frequency of change of the text of the insert, the complexity of collecting all the information put on the insert and the question of black and white or colourful text. For the quantitative estimates below, it is assumed that the text of the insert would be printed in black and white and it would change only occasionally.

Based on self-reported data from one large cigarette producer in Europe, the initial costs of introducing mandatory inserts to all cigarette packs would amount to approximately 47.2 million euros in the EU-27 for the whole cigarette manufacturing industry (scaling up based on sales volume). This company disclosed that its initial administrative burden would be about 16 million euros, which translates into 7,240 euros per SKU. This per SKU cost appears to be high compared to a complete labelling change ascertained by (EAS, 2004) (see Table 8.2). Moreover, the industry claimed that they would have to buy completely new machinery to comply with the regulation, which is unreasonable given the fact that supplementary inserts are regularly attached to cigarette packs for marketing reasons.

We could not obtain estimates of the initial administrative burden for the cigar industry and for producers of other tobacco products such as rolling or pipe tobacco.

Again, based on self-reported data from cigarette producers, the ongoing administrative burden for the EU-27's cigarette manufacturers would be between approximately 40.9 and 60.8 million euros a year and for cigar manufacturers it would be 1.3–11.5 million euros a year. One of the two cigarette manufacturers that disclosed quantitative estimates reported that the ongoing administrative burden would be approximately 15 million euros a year in terms of raw materials and about 7 million euros a year in terms of lower factory productivity. The other cigarette manufacturer reported a lower cost figure: 9 million euros a year as overall additional administrative burden. One of the reasons for this discrepancy was that one company believed that declining factory productivity could be offset by investing in additional machinery. Nevertheless, the full comprehension of cost differentials between the two companies was not possible on the basis of the evidence available. These per company overall administrative burdens translate into 6,100–11,300

euros per SKU. The cigar producers reported 0.8–2.3 million euros a year per company additional ongoing administrative burden; that is 40–840 euros per SKU a year. The cost ranges for cigarette and cigar manufacturers are explained at least in part by the different technological solutions (i.e. manual or machine based).

No quantitative cost estimate could be obtained for producers of other tobacco products.

Adding up the administrative burden of cigarette and cigar manufacturers, the total one-off administrative cost would amount to approximately 47.2 million euros and the total ongoing administrative burden would be likely to be between 42.2 and 75.5 million euros a year in the EU-27.

Summary

Looking at the measures discussed above in a comparative way, it is apparent that ongoing costs are generally much lower than one-off costs; in many cases, such as generic packaging, they may be close to zero (Table 8.5 and Table 8.6). The only measure with quantifiable and considerable ongoing costs is the introduction of supplementary inserts. The most costly measure in terms of one-off administrative burden is the introduction of enlarged pictorial warnings, both for cigarette and cigar manufacturers.

If we compare the combined profits of the four largest cigarette manufacturers (Table 8.4) with the combined maximum administrative burdens they face due to any of the potential measures (Table 8.5 and Table 8.6), even the most expensive measure would decrease combined profits only by 2–3 percent.

Table 8.4: Corporate summaries, European business statistics, 2008

	British American Tobacco	Philip Morris International*	Imperial Tobacco	Japan Tobacco International*
Net revenue	€6,043	€20,822	€4,011	€11,012
Profit	€1,542	€3,221	€1,930	€367
Cigarette volumes	260 bn	243.5 bn	124.6 bn	114.8 bn
Share of its business in Europe (in terms of operating income)	31%	46%	73%	.

Source: 2009 annual reports for BAT, PM, JTI and ITGI

*Profits refer to operating income.

Notes: PMI and JTI figures converted from dollars to euros using average 2008 conversion of £1=$1.46. Information for PMI refers to the EU. Information for JTI includes 'Western Europe (including Switzerland, France, and Germany)'.

While cigar manufacturers would face lower administrative burden than cigarette manufacturers, for each measure the burden of complying with regulation would fall more heavily on them. The reason is that cigar manufacturers are much smaller enterprises and each of their products (i.e. SKUs) is typically of smaller quantity.

The administrative burden estimations presented in this chapter must be used with caution. While specific issues are highlighted in the discussion of each measure, there are overarching data problems, as follows:

- Many estimations are based on a small number of company responses to the business questionnaire; in some cases only one company provided a quantitative estimate.
- The potential additional administrative burden associated with different measures is estimated on the basis of hypothetical scenarios and no historical data are available.
- Several estimations are based on overall cost estimations of the industry in which no detailed cost break-down was disclosed, which decreases the precision and reliability of the estimations.
- Several per company estimates showed large discrepancies across companies, which we could not substantiate owing to lack of detailed cost break-down.
- The manufacturing industry is motivated to disclose cost figures that are higher than they actually are in order to reduce the probability of additional regulation being enacted.
- The tobacco manufacturers' self-reported data were higher than those of direct comparators available (e.g. food labelling), which strengthens the suspicion that some of the administrative burden data are overstated.

Table 8.5: Summary of initial administrative burden of potential regulatory measures for tobacco manufacturers in the EU-27, million euros

	RAND Europe estimates based on industry responses		RAND Europe estimates based on UK DH (2007)[56]
	Cigarette	Cigar	Cigarette
Make pictorial warnings mandatory (no size change)	32.5–125.4	1.4–5.5	31.6
Update and enlarge warnings to **50%** of both sides of the pack and place them towards the top of the pack	97.5–190.4	4.3–8.4	Not available
Further increase of the size of warnings to **75%** of both sides of the pack	97.5–190.4	4.3–8.4	Not available
Further increase of the size of warnings to **100%** of the back of the pack	97.5–190.4	4.3–8.4	Not available
Introduce **generic packaging**	32.5–125.4	Not available	Not available
Replace TNCO quantitative labelling with **qualitative information** on contents and emissions and quit-lines	Marginal	Not applicable	Not available
Introduce **inserts** with supplementary information (e.g. on the potential risks)	47.2	Not available	Not available

[56] UK Department of Health, "The Introduction of Picture Warnings on Tobacco Packs - Final Regulatory Impact Assessment," 2007.

Table 8.6: Summary of ongoing administrative burden of potential regulatory measures for tobacco manufacturers in the EU-27, million euros

	RAND Europe estimates based on industry responses		RAND Europe estimates based on UK DH (2007)[57]
	Cigarette	Cigar	Cigarette
Make **pictorial warnings** mandatory (no size change)	Not available	Not available	0
Update and enlarge warnings to **50%** of both sides of the pack and place them towards the top of the pack	Not available	Not available	Not available
Further increase of the size of warnings to **75%** of both sides of the pack	Not available	Not available	Not available
Further increase of the size of warnings to **100%** of the back of the pack	Not available	Not available	Not available
Introduce **generic packaging**	Negative	Negative	Not available
Replace TNCO quantitative labelling with **qualitative information** on contents and emissions and quit-lines	(–4.8)–(–9.8)	Not applicable	Not available
Introduce **inserts** with supplementary information (e.g. on the potential risks)	40.9–60.8	1.3–11.5	Not available

8.3.2 Impact on tobacco market: commoditisation and reduced brand equity

The introduction of further labelling measures, ranging from large pictorial warnings to plain packaging, would lead to an (intended) substantially different appearance for cigarette packs and tobacco products. This could have impacts on the functioning of the tobacco market and its key players. Two interrelated effects could be expected, a loss in brand value and a commoditisation (Morgan Stanley, 2008). Currently tobacco packaging gives one of the very few remaining possibilities for tobacco manufacturers to advertise their products. With possibly less or no space on the pack to display brand logos and recognisable graphical features, it will become difficult for tobacco companies to sustain their brands and sell their products at a premium rate, and that would negatively affect the value of the current brands. Some of the tobacco brands – for example, Marlboro, a brand used by PMI – have considerable value. Marlboro has been repeatedly ranked one of the top 20 global brands since 2001, and has recently been assessed as the number 17 top brand in the world at a total brand value of $19 billion (Interbrand, 2010).

Currently, highly branded cigarettes are sold with considerably higher margins than unbranded cigarettes. If the brand attraction cannot be maintained, the tobacco market may become more commoditised, and profit margins (but also prices) would drop, having varied impacts on tobacco manufacturers. Those with a larger portfolio of high-margin brands are likely to incur higher costs by implementing the suggested measures (Morgan Stanley, 2008).

[57] UK Department of Health, 2007.

8.3.3 Revenues/profitability

The measures may affect revenues and costs (thus profits) of firms in the tobacco industry. Revenues and profits may be affected in the following two ways:

- **Reduced demand.** This would reduce the scale of production, which increases the marginal cost of producing another unit of tobacco (thereby reducing profitability).
- **Increased costs of production.** For no change in price, the labelling and packaging revision is likely to increase the marginal cost of producing another unit of tobacco (see previous section), thereby leading to smaller profit margins.

A change in costs and demand may reduce firms' revenues, as we show in Table 8.7. Assuming the change in prevalence and change in costs leads to proportionate changes in revenues, the outcome would be the equivalent of reducing revenues of the five major firms from the self-reported €41.888 billion (2008) to €41.679 billion, or even increasing to €41.889 billion in the first year following the introduction of the measure.

A change in the cost of production may alter profits. Assuming the change in prevalence and change in costs leads to proportionate changes in profits (self-reported value of approximately €7.06 billion in 2008), the profits may be from €7.025 billion to no change (still €7.060 billion).

Table 8.7: Potential change in revenues and profits of four major tobacco businesses operating in Europe

	Potential change in prevalence	Potential revenues (€ billions)	Potential profits (€ billions)
Make pictorial warnings mandatory (no size change)	–0.5000%	41.679	7.025
Update and enlarge warnings to 50% of both sides of the pack and place them towards the top of the pack	–0.5000%	41.679	7.025
Further increase in the size of warnings to 75% of both sides of the pack	–0.5000%	41.679	7.025
Further increase of the size of warnings to 100% of the back of the pack	–0.5000%	41.679	7.025
Introduce generic packaging	–0.5000%	41.679	7.025
Replace TNCO quantitative labelling with qualitative information on contents and emissions and quit-lines	0.0018%	41.889	7.060
Introduce inserts with supplementary information (e.g. on the potential risks)	–0.0159%	41.881	7.059

8.3.4 Employment changes

A change in demand for tobacco products and increase in costs may lead to a change in the share of people employed in tobacco sectors. We first assume that the administrative burdens of each measure are fully passed on to consumers and the sensitivity of consumers to price changes is –0.5 (or –0.5 percent reduction in prevalence for a 1 percent price increase). We then consider the change in attractiveness as determined in the literature (estimated to be a –0.5 percent reduction in prevalence). Lastly, we add these figures to consider the upper bound on the change in prevalence that these measures could have. Our estimates suggest that this could alter employment shares in tobacco by less than 1 percent to upwards of 24 percent.

Table 8.8: Percentage difference in employment share relative to status quo in 2027, by measure of labelling and packaging

	Manufacturing	Wholesale of manufactured tobacco	Retail
Make pictorial warnings mandatory (no size change)	–0.45% to –0.44%	–1.45% to 0.36%	–2.86% to –1.26%
Update and enlarge warnings to 50% of both sides of the pack and place them towards the top of the pack	–0.45% to –0.44%	–1.45% to 0.36%	–2.86% to –1.26%
Further increase of the size of warnings to 75% of both sides of the pack	–0.45% to –0.44%	–1.45% to 0.36%	–2.86% to –1.26%
Further increase of the size of warnings to 100% of the back of the pack	–0.45% to –0.44%	–1.45% to 0.36%	–2.86% to –1.26%
Introduce generic packaging	–0.45% to –0.44%	–1.45% to 0.36%	–2.86% to –1.26%
Replace TNCO quantitative labelling with qualitative information on contents and emissions and quit-lines	–0.44%	–1.45% to 0.36%	–2.85% to –1.19%
Introduce inserts with supplementary information (e.g. on the potential risks)	–0.46%	–1.44% to 0.37%	–2.95% to –1.23%

Using both Forecasts A and D on the average potential effect.

8.3.5 Tax revenues

When people demand fewer tobacco products because cigarettes are less attractive, tobacco tax revenue falls. At the same time as people shift from purchasing tobacco to purchasing other goods and services or saving their money, governments' revenues increase again. We consider the direct effect the proposed policy changes are likely to have on demand and thus on governments' tobacco tax revenue.

Assuming the revision in labelling and packaging reduces the demand for tobacco products (through increase in costs and passing those through to price), the excise duty collected may fall. As seen in Table 8.9, our estimates suggest that the proposed measures for revising the directive in labelling and packaging could change revenues from tobacco consumption taxation in 2027 by approximately –0.5 percent to 2 percent.

Table 8.9: Potential change in total excise duty collection due to labelling and packaging measures, in billions of euros and percentage difference

		Potential total excise duty collection (€ millions)	Difference between status quo and measure in 2007 (percent)
	Status quo	62,088–78,527	
Labelling and packaging measures	Make pictorial warnings mandatory (no size change)	63,208–78,143	–0.49% to 1.80%
	Update and enlarge warnings to 50% of both sides of the pack and place them towards the top of the pack	63,208–78,143	–0.49% to 1.80%
	Further increase of the size of warnings to 75% of both sides of the pack	63,208–78,143	–0.49% to 1.80%
	Further increase of the size of warnings to 100% of the back of the pack	63,208–78,143	–0.49% to 1.80%
	Introduce generic packaging	63,208–78,143	–0.49% to 1.80%
	Replace TNCO quantitative labelling with qualitative information on contents and emissions and quit-lines	63,540–78,528	0.00% to 2.34%
	Introduce inserts with supplementary information (e.g. on the potential risks)	63,529–78,514	–0.02% to 2.32%

These estimates are only for the change in tobacco excise duty collection, not overall government excise duty collection. The overall change in excise duty collection will be dependent on whether consumers spend the same amount on tobacco or make savings from fewer purchases of tobacco products.

8.3.6 Direct and indirect costs of healthcare and ill health

When people stop or reduce smoking, there will be an improvement in their health. Thus there will be fewer doctor's visits, surgeries, treatments and/or pharmaceuticals related to smoking. The healthcare system is likely to save costs. We therefore consider how changes to smoking-related illnesses (due to the reduction in demand) may influence healthcare costs.

To assess how the 2027 predicted estimates of mortality and costs (Chapter 6) would change as the result of changes in the prevalence of smoking in 2010 (which in turn would change as the result of change in tobacco regulation), we adopted a conservative approach, assuming that only half of the percentage change in prevalence would translate into a change in mortality and costs in 2027.

Figure 3.15 and Figure 3.16 show how any reductions in prevalence (in 2010) under those assumptions would lead to corresponding reductions in mortality and direct and indirect costs in 2027.

Specifically, the reduction in prevalence of 0.5 percent corresponds to healthcare cost savings near €91 million in direct costs and €108 million in indirect costs.

8.3.7 Summary of economic impacts

Impact type Measure	Administrative burden		Industry revenues/profits		Employment		Tax revenues		Direct and indirect costs of healthcare and ill health		Other	
Make pictorial warnings mandatory (no size change)	Admin burden through label change One-off costs 33.9–130.9m euros	–	Reduced prevalence and increased cost, decrease in revenues by 200m and profits reduced by 35m euros p.a.	–	Reduced sales, change of employment share by –0.5% for manufacturers, –1.5 to 0.4 for wholesale, –2.9% to –1.3% for retailers	–	Change in tax revenue: €1,120 to –€384 million in 2027 (2007 prices)	–/+	Reduction in prevalence of 0.5% corresponds to healthcare cost savings near €91 million in direct costs and €108 million in indirect costs	++	None	≈
Update and enlarge warnings to 50% of both sides of the pack and place them towards the top of the pack	Admin burden through label change One-off costs 101.8–198.8m euros	–	Reduced prevalence and increased cost, decrease in revenues by 200m and profits reduced by 35m euros p.a.	–	Reduced sales, change of employment share by –0.5% for manufacturers, –1.5 to 0.4 for wholesale, –2.9% to –1.3% for retailers	–	Change in tax revenue: €1,120 to –€384m in 2027 (2007 prices)	–/+	Reduction in prevalence of 0.5% corresponds to healthcare cost savings near €91m in direct costs and €108m in indirect costs	++	None	≈
Further increase of the size of warnings to 75% of both sides of the pack	Admin burden through label change One-off costs 101.8–198.8m euros	–	Reduced prevalence and increased cost, decrease in revenues by 200m and profits reduced by 35m euros p.a.	–	Reduced sales, change of employment share by –0.5% for manufacturers, –1.5 – 0.4 for wholesale, –2.9% to –1.3% for retailers	–	Change in tax revenue: €1,120 to –€384m in 2027 (2007 prices)	–/+	Reduction in prevalence of 0.5% corresponds to healthcare cost savings near €91m in direct costs and €108m in indirect costs	++	Impact on brand equity for branded producers	(–)
Further increase of the size of warnings to 100% of the back of the pack	Admin burden through label change One-off costs 101.8–198.8m euros	–	Reduced prevalence and increased cost, decrease in revenues by 200m and profits reduced by 35m euros p.a.	–	Reduced sales, change of employment share by –0.5% for manufacturers, –1.5 to 0.4 for wholesale, –2.9% to –1.3% for retailers	–	Change in tax revenue: €1,120 to – €384m in 2027 (2007 prices)	–/+	Reduction in prevalence of 0.5% corresponds to healthcare cost savings near €91m in direct costs and €108m in indirect costs.	++	Impact on brand equity for branded producers; commoditisation of tobacco products	(–)

Introduce generic packaging	Admin burden through label change One-off costs 32.5–125.4m euros	– –	Reduced prevalence and increased cost, decrease in revenues by 200m and profits reduced by 35m euros p.a.	–	Reduced sales, change of employment share by –0.5% for manufacturers, –1.5 to 0.4 for wholesale, –2.9% to –1.3% for retailers	–	Change in tax revenue: €1,120 to –€384m in 2020 (2007 prices)	–/+	Reduction in prevalence of 0.5% corresponds to healthcare cost savings near €91m in direct costs and €108m in indirect costs	++	Strong impact on brand equity for branded producers; commoditisation of tobacco products	-
Replace TNCO quantitative labelling with qualitative information on contents and emissions and quit-lines	One-off admin burden through label change, minor costs Ongoing admin burden saving, 4.8–9.8m euros/year	+	Reduced prevalence and increased cost, increase in revenues by 1m euros p.a. and no change to profits	+	Reduced sales, change of employment share by –0.4% for manufacturers, –1.5 to 0.4 for wholesale, –2.9% to –1.2% for retailers	–	Change in tax revenue: €1,452 to €0m in 2020 (2007 prices)	–/+	No substantial impact expected	≈	None	≈
Introduce inserts with supplementary information (e.g. on the potential risks)	Admin burden through changes in production process One-off costs of 47.2m euros for cigarette manufacturers and 40.9–60.8m euros/year ongoing costs	+ +	Reduced prevalence and increased cost, decrease in revenues by 7m and profits reduced by 1m euros p.a.	–	Reduced sales, change of employment share by –0.4% for manufacturers, –1.5 to 0.4 for wholesale, –3% to –1.2% for retailers	–	Change in tax revenue: €1,441 to –€13m in 2020 (2007 prices)	–/+	No substantial impact expected	≈	None	≈

CHAPTER 9 Registration and market control fees

9.1 Introduction

In this chapter we analyse the potential impact of changes to the current regulation and of new measures in the area of registration, reporting and market control fees. The following measures have been suggested by DG SANCO in this area of change:

1. Make reporting formats for product ingredients compulsory.
2. Introduce fixed yearly registration fees in order to finance ingredients work; only registered products may be marketed.
3. Introduce fines for industry in the case of non-delivery of ingredients data.
4. Introduce market control fees proportionate to the number of outlets the product is sold in.
5. Integrate the health costs of smoking into the calculation of the fees.
6. Based on the polluter pays principle, internalise the external health costs of smoking by requiring full liability and payment of the health costs of smoking by the tobacco industry to national health systems.

These measures may be divided into two groups. Measures 1 to 4 are aimed at improving the currently unsatisfactory situation of ingredient reporting, as stated in the directive's first and second application reports (DG SANCO, 2005, 2007b) and to develop a basis for financing ingredient work; options 5 to 6 are motivated by the desire to internalise the external cost of smoking.

9.2 Social and health impacts

9.2.1 Improving ingredient reporting and the use of ingredient information

In May 2007 the EC issued a practical guide on reporting product ingredients, introducing a (non-mandatory) format for submitting ingredient information, ideally electronically (DG SANCO, 2007a). The motivation for the development of the practical guidance was problems documented with industry reporting of ingredients (i.e. incomplete and too sparse or too detailed data) and with different formats that produced non-comparable information (DG SANCO, 2005). This diversity of formats and reporting mechanisms (electronic, paper) made ingredient information difficult to process for Member States, and as a result only a few have submitted ingredient information so far (eight Member States reported ingredient information to the EC in 2009). The practical guidance developed by

the EC has improved this situation and the large cigarette manufacturers are now using the recommended format; however, some Member State regulations require manufacturers to derogate from the guidance to meet national standards, smaller producers seem to struggle to provide information and manufacturers have general concerns about their trade secrets.

To increase the harmonisation and reduce the varying levels of detail, the EMTOC programme had been developed since 2007 on the basis of the practical guidance and will be rolled out to Member States willing to participate in 2010 (DG SANCO, 2009a). As of 2010, 11 Member States are participating in EMTOC, although only Austria has made the use of EMTOC mandatory.[58] At this stage the ingredient data submitted by industry are not systematically analysed at European level; however, work is ongoing to establish a systematic analysis of data.

In terms of transmitting non-confidential ingredients to the general public, only Germany has made ingredient data available to the general public so far, in the form of a searchable on-line database.[59] Thus, the degree and comprehensiveness of consumer information about the ingredients in tobacco products is still low. To summarise, the last years have seen a move towards harmonised electronic data submission which could form the basis for systematic analysis of ingredient information.

Making reporting formats compulsory, as suggested in **measure 1**, ideally combined with the electronic submission of data, would support the ongoing process of improving data on ingredient use in tobacco products and on the establishment of a common list of ingredients.

Measure 2 aims to address two additional shortcomings of the current ingredient reporting regime. By introducing fees for the scientific analysis of tobacco ingredients, it will be ensured that the necessary analysis can be performed in the future. Ensuring that only registered products, for which manufacturers have provided ingredient information, are marketed would be a way of incentivising compliance with the reporting requirements, increasing the comprehensiveness of any data that could be analysed later on and partially disclosed to consumers. However, we understand that ingredient information is already submitted by the large manufacturers, which cover a very substantial share of the tobacco market. Therefore, additional measures would primarily relate to importers and small outlets.

Measure 3 is designed to address the same issue of non-compliance with the delivery of data on ingredients, and again aims to improve data delivery – however, imposing fines for the non-delivery of data. In order to assess the overall effectiveness of both these measures to deliver on their intended objectives, there are two key observations worth discussing. First, the reasons for non-compliance in providing ingredient information must be understood. If this is primarily an issue of capacity and expertise in small businesses, as suggested by some of the consultation responses, then introducing fines and registration

[58] See http://www.bmg.gv.at/cms/site/attachments/3/0/7/CH0756/CMS1157719354616/tabakerzeugnis-inhaltsstoffe-erhebungsverordnung_-_tiev__bgbl__ii_nr__16_2010.pdf

[59] See http://service.ble.de/tabakerzeugnisse/index2.php?site_key=153&site_key=153 accessed 17 February 2010.

requirements may not necessarily lead to rapid improvements in compliance. However, there is very little evidence available to assess the reasons for non-delivery of some businesses. Secondly, the scientific analysis of ingredients does not depend on having the most comprehensive data set in terms of covering all businesses; rather it depends on data quality – that is, having data in a meaningful format that can be analysed – and coverage of all products on the market is not a precondition for scientific analysis. If ingredient information is, for example, already delivered for 75 percent of products in a good comparable format, this might be a sufficient foundation for any analysis of ingredient data and cover almost all ingredients available, unless it excludes very specific small products which have a particular composition and related health risks.

Measure 4, finally, aims at putting the financing of the ingredient work on a better financial basis by levying a fee on tobacco manufacturers. In contrast to measure 2, these fees are intended to be calculated according to the number of outlets the product is sold in. As such, the fees would to a certain extent be proportionate to the size of the business. As discussed in more detail in Section 11.3, such a measure might, however, be difficult to implement due to the requirement to be able to asses in how many outlets a specific product is sold.

Based on this discussion, we may conclude that the measures suggested do not have immediate, direct health or social impacts, but may indirectly contribute to health impacts if ingredients are systematically analysed and the use of the most harmful ones is restricted in the future, as well as if information about ingredients is effectively communicated.

9.2.2 Transferring the direct and indirect costs of smoking to tobacco manufacturers

Measures 5 to 6, which propose an integration of healthcare costs of smoking into fees and industry payment of healthcare costs, are designed to internalise the external costs of tobacco use. Measure 5 specifically proposes to integrate the costs that Member States' healthcare systems incur into a fee to be paid by tobacco manufacturers and importers. Under measure 6, tobacco manufacturers would be made liable for health problems deemed to be associated with tobacco use, which would ultimately result in some kind of compensation payment by tobacco manufactures to health systems at a similar level.[60]

Both of these measures increase the cost of delivering tobacco products and are therefore likely to lead to an increase in the price of tobacco products, resulting in prevalence changes and further likely reduction in smoking-related mortality and morbidity (see Section 9.3 for details). If we assume total direct healthcare costs of €100 billion per annum added to the price of tobacco products, we would expect a resulting change of smoking prevalence of around 25 percent, resulting in substantial changes in tobacco-related mortality by 2027 with an estimated 45,000 smoking-related deaths avoided and 465,000 fewer cases of lung cancer, aerodigestive cancer and COPD annually in the EU.

[60] For a detailed discussion of liability, see GHK, *A Study on Liability and the Health Costs of Smoking. Final Report. Study Commissioned by Dg Sanco*, London: GHK, 2010..

9.2.3 Summary of health impacts

Measure	Health and social impact	Effect
Make reporting formats for product ingredients compulsory	Improved usefulness of ingredient information could lead to better protection from harmful ingredients in the future and better consumer information	≈
Introduce fixed yearly registration fees in order to finance ingredients work; only registered products may be marketed	Improved compliance with reporting requirements and usefulness of ingredient information could lead to better protection from harmful ingredients in the future and better consumer information Analysis of ingredients could lead to a ban on particularly harmful ingredients in the future.	≈
Introduce fines for industry in case of non-delivery of ingredients data	Improved compliance with reporting requirements and usefulness of ingredient information could lead to better protection from harmful ingredients in the future and better consumer information	≈
Introduce market control fees proportionate to the number of outlets the product is sold in	Improved compliance with reporting requirements and usefulness of ingredient information could lead to better protection from harmful ingredients in the future and better consumer information Analysis of ingredients could lead to overall less harmful cigarette consumption in the future.	≈
Integrate the health costs of smoking into the calculation of the fees	Integration of healthcare costs would lead to a substantial increase in price of tobacco products. A possible 25% reduction in prevalence could prevent 45,000 smoking-related deaths and 465,000 fewer cases of lung cancer, aerodigestive cancer and COPD annually by 2027.	++
Based on the polluter pays principle, internalise the external health costs of smoking by requiring full liability and payment of the health costs of smoking by the tobacco industry to national health systems	Integration of healthcare costs likely to lead to a substantial increase in price of tobacco products. A possible 25% reduction in prevalence as a consequence of price increases could prevent 45,000 smoking-related deaths and 465,000 fewer cases of lung cancer, aerodigestive cancer and COPD annually by 2027.	++

9.3 Economic impacts

Revising and extending current reporting requirements and introducing new market control fees, as foreseen under these measures, could result in the following economic impacts:

1. Compliance cost and administrative burden for manufacturers of the relevant products.
2. Revenues and profitability from the sale of products incurring the costs.
3. Employment in the tobacco industry.
4. Governments' revenues from fees and taxation.
5. Healthcare costs.

The economic impact of introducing fees, fines and internalisation of health costs has impacts on both the producers and the consumers of tobacco products.

For the producers, there is an increase in costs, implying a reduction in supply because it costs more to produce the same amount as before the introduction of fines and fees. For the consumers, if they continue to spend the same amount on tobacco, they will need to reduce the amount of tobacco they consume.

However, this depends on the elasticity of demand and the responsiveness of consumers to price. That is, some consumers exhibit inelastic demand (i.e. addictive behaviour) and will continue to consume the same amount of tobacco despite the higher prices; this is possible by spending less money on other goods, such as food, travel, and so on. Those consumers more responsive to price changes (i.e. the marginal tobacco consumers) will reduce their consumption of tobacco and producers will need to find ways to start cutting their costs (i.e. reduce the number of full-time workers) if they want to maintain their previous profits (impacts 2 and 3).

Where market control fees are added on top of the current prices, this will affect the amount of revenue governments receive (impact 4). As the higher prices affect consumption, the costs incurred by health systems may change (impact 5).

9.3.1 Administrative burden and compliance costs for manufacturers

Making reporting formats compulsory for manufacturers would impose administrative burden on them as they would have to change the way in which information on their products is provided to national authorities. Introducing fines for industry in the case of non-delivery of ingredients data and the various versions of imposing fees on the industry would translate into only marginal administrative burden or compliance costs as they mainly imply direct financial costs (for discussion of these direct financial impacts see the rest of this section).

The administrative burden of making reporting formats for product ingredients compulsory would mean that manufacturers would have to adjust their own data collection systems and change the way they report the collected data to the EU. Initial costs of compliance with this potential measure cover familiarising themselves with the compulsory formats and reporting standards, purchasing the necessary equipment – mainly IT

infrastructure (software as well as hardware) – and retraining staff. Complying with the regulation would imply ongoing administrative burden which would, however, be offset by the ongoing costs of the existing fragmented reporting system.

The practical guide issued by the EC (DG SANCO, 2007a) provides a framework for reporting product ingredients defining the exact content of this measure. Respondents to RAND Europe's tobacco manufacturer questionnaire (see Appendix C) referred to this guide in their answers. As the EC's guide suggests that ideally submission happens in electronic format, the costs of setting up and running the EMTOC system were also explored.

As two of the tobacco manufacturers had already adopted the reporting formats defined in the EC's guidelines, quantitative estimates could be obtained of actual costs incurred by companies. This implies that making the reporting formats mandatory would impose costs only on those companies that had not yet adopted a system compliant with the guidelines. However, precise measurement is hampered by that fact that it is unclear which proportion of companies do voluntarily comply already, particularly in the case of cigar manufacturers. The range of estimates below reflect this uncertainty.

Two out of the four major cigarette manufacturers of Europe already voluntarily comply with the EC's guidelines on reporting formats and it is unclear whether the two others do so too. For these companies the initial (self-reported) administrative burden ranged from 50,000 to 950,000 euros per company, and there were no ongoing costs reported. On the basis of the data available, it is unclear whether making reporting formats mandatory would impose any additional administrative burden on cigarette manufacturers. Reflecting this uncertainty and taking the least-cost way of compliance yields an initial additional administrative burden for the cigarette manufacturing industry of the EU-27 of between 0 and 67,000 euros. This range reflects the fact that it is possible that all cigarette manufacturers already voluntarily comply with the regulation (thus the zero additional administrative burden). Moreover, it also assumes that if the two other large companies do not comply voluntarily, then their administrative burden would be proportionate to their size.

For cigar manufacturers that provided quantitative estimates, the costs ranged from 14,000 to 125,000 euros per company. Assuming that 20 percent of cigar manufacturers already comply with the regulation – which is the compliance rate according to our responses from the industry – the whole cigar manufacturing industry would face initial administrative burden due to this measure of 96,000 to 471,000 euros. No additional ongoing administrative burden would arise.

On the basis of the cigarette industry's responses, introducing and running the EMTOC system is more costly. Initial administrative burden amounts to 1.5 million euros per company and ongoing administrative burden is 1.3 million euros a year per company. For cigar manufacturers, initial set-up costs amount to 56,000 euros per company and there was no ongoing administrative burden reported. For more discussion on EMTOC see Section 5.1.4.

Table 9.1: Summary of administrative burden of potential regulatory measures for tobacco manufacturers, million euros

	One-off		Ongoing	
	Cigarette	Cigar	Cigarette	Cigar
Making reporting formats compulsory	0–0.07	0–0.5	0	0

In addition, the measure foresees fees to finance the EC's ingredients work. At this stage the costs for such work are, however, unclear and the analysis of ingredients has not yet started on the European level. It is therefore not possible to assess the overall costs. If this work is done in a centralised laboratory for all 27 Member States, these costs can be expected to be relatively small.

Measure 4 would aim to roll market control costs over to manufacturers depending on the size of the retail outlets a product is sold in. This measure will have a negative cost impact on tobacco producers; however, it is currently not possible to estimate the size of the effect. First, manufacturers usually do not sell directly to retailers; secondly, data on the number of retail outlets a product is sold in may be very scattered; thirdly, data collection costs would fall either on manufacturers or public authorities. While larger cigarette manufacturers may already have this information at hand, it may be difficult for small companies to compile it and even more difficult for regulators to verify it. However, in other sectors, such as pharmaceuticals, systems whereby distributors keep a record of their clients are in place and every distributor reports on the number of their customers to the manufacturer or importer. Fourthly, Member States will find it difficult to calculate the costs of market control as these may be incurred by bodies at different levels of government and at sub-regional level. Enforcing age-restricted sales is, for example, often done by local authorities and often in conjunction with other regulatory work. So while this measure will create administrative burden and compliance costs, it is currently impossible to establish at what level.

9.3.2 Prices and reduction of demand

Transferring costs for healthcare as foreseen in measures 5 and 6 may have effects on the price and consumption of tobacco products, as described in this and the subsequent sections.

We begin with a Member State (Germany) with complete information (Neubauer *et al.*, 2006). Table 9.2 shows the average healthcare cost per cigarette that may be transferred to a Member State based on the data for Germany. As Table 9.2 indicates, healthcare costs attributed to smoking in Germany were approximately €21 billion in 2003. Taking into account the number of cigarettes smoked in 1980,[61] this is an average healthcare cost per cigarette of €0.15, or €3.00 per pack (of 20 cigarettes) in the most popular price category (MPPC).

[61] We use the number of cigarettes consumed in 2000 reported by WHO and apply the change of prevalence from 2000 to 1980 as reported by WHO.

Table 9.2: Healthcare costs per cigarette (Germany)

Healthcare costs (€, Germany 2003)	Total number of cigarettes (1980)	Average healthcare cost per cigarette (€)	Additional cost per pack of 20 cigarettes
20,678,000,000	141,485,702,614	0.146	3.00

Considering the average retail price of a pack of 20 MPPC in Germany in 2009 as €4.71 (see Table 4.5), and adding the healthcare cost of €3.00 to the pack, this would result in a 62 percent increase in the price per pack of cigarettes.

Taking into account responsiveness to price, the addition of healthcare costs to a pack of cigarettes could lead to an 18–31 percent reduction in the consumption of cigarettes. However, this only considers altering cigarette prices. With literature from Germany indicating switching to rolling tobacco, the 62 percent price increase in cigarette pack prices might be accompanied by a 75 percent increase in rolling tobacco consumption.

Table 9.3: Number of cigarettes that would have been consumed if revision in 1980 is based on German data

Number of cigarettes consumed (billions, 1980)	Change in number of cigarettes consumed (percent)	New number of cigarettes consumed (billions)
141.5	–31.0 to –18.6	97.6 to 115.1

We need to make a series of assumptions in order to apply this to the wider EU Member States. Assuming the healthcare costs in each country are proportional to the number of cigarettes consumed relative to Germany, we arrive at the following relative consumption and cost levels across countries, as demonstrated in Table 9.4. For example, the number of cigarettes consumed in Austria was reportedly 10 percent of the number in Germany; with the assumption that costs were relative to level of consumption, the healthcare costs attributable to cigarette consumption in Austria were approximately €2.1 billion (or 10 percent of the German costs).

Table 9.4: Health costs in 2003 by country (in euros), assuming costs are proportional to cigarette consumption in Germany

	Cigarette consumption relative to Germany (1980)	Potential health cost (in euros, 2003)
Austria	0.10	2,129,770,077
Belgium	0.13	2,656,796,567
Bulgaria	0.11	2,228,997,090
Cyprus	n/a	n/a
Czech Republic	n/a	n/a
Denmark	0.05	1,069,431,829
Estonia	n/a	n/a
Finland	0.04	821,498,027
France	0.61	12,521,459,354
Germany	1.00	20,678,000,000
Greece	0.14	2,928,935,341
Hungary	0.18	3,799,244,500
Ireland	0.04	912,968,750
Italy	0.67	13,789,345,207
Latvia	n/a	n/a
Lithuania	n/a	n/a
Luxembourg	n/a	n/a
Malta	0.00	98,692,096
Netherlands	0.19	3,979,912,550
Poland	0.61	12,685,411,263
Portugal	0.08	1,745,566,295
Romania	n/a	n/a
Slovakia	n/a	n/a
Slovenia	n/a	n/a
Spain	n/a	n/a
Sweden	0.08	1,739,281,026
United Kingdom	0.76	15,705,014,952
TOTAL	-	99,490,324,926

Now we assume the revision increases the cost of the cigarettes to be consumed by €0.17;[62] this varies from the previous amount of €0.15 per cigarette because that referred to the number of cigarettes consumed in 1980, which we assume is more likely to have generated healthcare costs in 2003 than the cigarettes consumed in the same year. We now attribute healthcare costs in current years to cigarettes currently consumed.

Table 9.5 shows that the average retail price of a pack of cigarettes (with 20 pieces) in the MPPC increases from €3.55 to €6.47 (a 93.2 percent increase). Assuming the general

[62] Total healthcare costs in 2003 divided by the number of cigarettes in 2009. The number of cigarettes in 2009 is assumed to be equal to the total number of cigarettes in 2000 adjusted by the change in prevalence from 2000 to 2009.

responsiveness of consumers to price described in the literature,[63] this could lead to a 23 percent to 38 percent reduction in cigarette consumption and a potential rise in consumption of rolling tobacco (according to German data) by 112 percent.

Table 9.5: Potential healthcare cost and consumption impact due to internalisation of healthcare costs

Potential total healthcare costs (in 2003)	Potential total number of cigarettes (millions, in 2009)	Increased cost per cigarette (€)	Increase in the average retail price	New number of cigarettes (millions)
99,490,324,926	601.7	0.17	93.2%	370.9 to 463.2

9.3.3 Revenues/profitability

Calculations thus far suggest the measures for internalising healthcare costs may affect the competitiveness of firms involved in the manufacture and sale of tobacco products. That is, the measures to internalise the full costs associated with tobacco consumption may generally affect businesses in one or both of the following two ways:

- Reduce demand. The measures may reduce the scale of production, which may increase the marginal cost of producing another unit of tobacco (thereby reducing profitability).
- Increase costs of production. For no change in price, the measures may increase the marginal cost of producing another unit of tobacco (thereby leading to smaller profit margins).

Regarding changes in revenues, we can see in Table 9.6 the short-term changes in revenues and profits for each measure. The assumption is that the reduction in prevalence (25 percent reduction) leads to a proportionate decrease in revenues and would be the equivalent of reducing self-reported revenues of the five major firms from €41,888 million (2008 prices) to €31,416 million.

Regarding profits, the self-reported increases in the cost of production may reduce profits margins for the manufacture and sale of tobacco products. By examining the self-reported profits of the major cigarette firms (approximately €7,060 million in 2008) and the revenue–profit ratio, it appears that the annual profits may fall to €5,295 million.

Table 9.6: Potential short-term change in revenues/profits for top businesses in tobacco, by measure of registration and market control fees

	Potential change in prevalence	Potential revenues (€ millions)	Potential profits (€ millions)
Internalisation of healthcare costs	–25.00%	31,416	5,295
Make reporting formats for product ingredients compulsory	–0.000%	41,888	7,025

[63] We assume a price elasticity of demand of –0.5 or a 10percent increase in price leads to a 5percent reduction in demand, where demand is represented by prevalence rates.

9.3.4 Employment changes

In this section we calculate the change in employment share across tobacco sectors (manufacturing, wholesale of manufactured tobacco products, and retail sale) associated with the measures to internalise the healthcare costs into the price of tobacco products. An overall reduction in demand for cigarettes and increase in costs may lead to a smaller share of employment in the tobacco industry.

We present our estimates of the potential impacts of the measures to internalise healthcare costs in Table 9.7. Our estimates suggest that the proposed measure to internalise healthcare costs may reduce the employment share in retail sale by 50 percent to 70 percent and potentially increase the share of employment in wholesale of manufactured tobacco. This may be due to overseas markets and the incentives to sell outside the EU. It is consistent with falling employment in the other sectors.

Table 9.7: Potential short-term change* in employment share due to registration and market control fees measure

	Manufacturing	Wholesale of manufactured tobacco	Retail
Internalisation of healthcare costs	–22.31% to 21.98%	10.03% to18.01%	–10% to to 50%
Make reporting formats for product ingredients compulsory	0.0%	0.0%	0.0%

*Using both Forecasts A and D on the average potential effect.

9.3.5 Tax revenues

Assuming the measures to internalise healthcare costs are implemented, there may be a reduction in the demand for tobacco products. This may have the effect of altering tobacco tax revenues generated from the consumption of tobacco. As seen in Table 9.8, the potential change in revenues ranges from approximately 24 percent reduction to an increase of approximately 2 percent.

Table 9.8: Potential change in total excise duty collection due to registration and market control fees, in billions of euros and percentage difference

		Potential total excise duty collection (€ millions)	Difference between status quo and measure in 2007 (percent)
Status quo		62,088–78,527	
Registration and market control	Internalisation of healthcare costs	46,979–59,387	–24.33% to –24.37%
	Make reporting formats for product ingredients compulsory	63,539–78,527	0.00% to 2.34%

9.3.6 Direct and indirect costs of healthcare and ill health

As in the previous chapter, in order to assess how the 2027 predicted estimates on mortality and costs (Chapter 6) would change as a result of changes in the prevalence of smoking in 2010 (which in turn would change as the result of change in tobacco regulation), we adopted a conservative approach, assuming that only half of the percentage change in prevalence would translate into a change in mortality and costs in 2027.

Figure 3.15 and Figure 3.16 show how any reductions in prevalence (in 2010) under those assumptions would lead to corresponding reductions in mortality and in direct and indirect costs in 2027.

With a linear system presented, a 25 percent reduction in prevalence corresponds to multiplying the savings at 5 percent reduction in prevalence by 5. Thus, the reduction in prevalence of 25 percent corresponds to potential healthcare cost savings of almost €4.5 billion in direct costs and €5–€6 billion in indirect costs.

9.3.7 Summary of economic impacts

Impact type / Measure	Admininstrative burden Compliance cost		Industry revenues/profits		Employment		Tax revenues		Direct and indirect costs of healthcare and ill health		Other	
Make reporting formats for product ingredients compulsory.	Additional one-off admin burden for tobacco manufacturers: 0.1–0.5m euros	-	No substantial impact expected	≈	No substantial impact expected	≈	No substantial impact expected	≈	No substantial impact expected	≈	Potential savings through standardised and electronic reporting	(+)
Introduce fixed yearly registration fees in order to finance ingredients work; only registered products may be marketed.	Industry must pay fee, but overall expected to be low	(–)	No substantial impact expected	≈	No substantial impact expected	≈	No substantial impact expected	≈	No substantial impact expected	≈	None	≈
Introduce fines for industry in case of non-delivery of ingredients data.	No substantial impact expected and can be avoided by business	(≈)	No substantial impact expected	≈	No substantial impact expected	≈	No substantial impact expected	≈	No substantial impact expected	≈	None	≈
Introduce market control fees proportionate to the number of outlets the product is sold in.	Costs for maintaining and delivering register of retailers	(–)	n/a	()	n/a	()	n/a	()	n/a	()	Industry must pay market control fees	(–)
Integrate the health costs of smoking into the calculation of the fees.	No substantial impact	≈	Reduction in revenues by €10,472m, and profits of €1,765m	–	Change in employment share, manufacture: –22.3% to 22%, wholesale: 10% to18%, retail: –10% to –50%	–	Reduction of tax revenues by €15,109m to €19,140m	–	Reduction of healthcare costs in 2027 near €4.5bn in direct costs and €5bn to –€6bn indirect costs	++	Cost for healthcare (€100bn) transferred to industry	--
Based on the polluter pays principle, internalise the external health costs of smoking by requiring full liability and payment of the health costs of smoking by	No substantial impact	≈	Reduction in revenues by €10,472m, and profits of €1,765m	–	Change in employment share, manufacture: –22.3% to 22%, wholesale: 10% to 18%, retail: –10% to –50%	–	Reduction of tax revenues by €15,109 to €19,140m	+	Reduction of healthcare costs in 2027 near €4.5bn in direct costs and €5bn to €6bn indirect costs	++	Cost for healthcare (€100bn) transferred to industry	--

Measure	Impact type	Admininstrative burden Compliance cost	Industry revenues/profits	Employment	Tax revenues	Direct and indirect costs of healthcare and ill health	Other
the tobacco industry to national health systems.							

CHAPTER 10 Ingredients

10.1 Introduction

Under the heading of **Ingredients** this chapter discusses measures that would address changes to the regulation of the ingredients of tobacco products and the measurement of tobacco yields. In detail, these measures are to achieve the following:

1. Ban additives that are carcinogenic, mutagenic or toxic for reproduction (CMRs) or that form CMRs during pyrolysis in order to establish a common list of ingredients.
2. Introduce an additional measurement method for TNCO (the modified ISO method) and set maximum limits accordingly.
3. Introduce maximum limits for other yields and ingredients.
4. Continuously decrease the maximum limits for TNCO and other yields and ingredients.
5. Refine the definition of ingredients to include the tobacco leaf.
6. Set up an EC laboratory for the evaluation of tobacco and smoking products.

10.2 Social and health impacts

The health impacts of the measures subsumed in this area of change are aimed at reducing the harm related to the consumption of a specific tobacco product – in other words to make tobacco use less harmful, even when prevalence rates remain stable.

The evidence presented in this section relies for the most part on qualitative information provided in the literature on this topic. During our evidence review, we have not been able to identify any quantitative information or data on the impact of different ingredients on tobacco consumption or the health of consumers more generally. In addition, some of the authors of journal articles on the subject of tobacco ingredients have direct links with the tobacco industry, and in particular with PMI, which poses some challenges in identifying unbiased sources of evidence (See for example: Lemus *et al.*, 2007, Roemer *et al.*, 2002, Rustemeier *et al.*, 2002). Thus, most of the evidence we have been able to identify on the impact of different ingredients relates to their likely effect on the palatability and attractiveness of tobacco products.

On the other hand, a large body of evidence exists on measuring TNCO yields according to ISO standards. Regarding the social impacts of this measure, we have not been able to identify any sources that address this aspect, so we have had to deduct the potential social impacts from the evidence presented on the health impacts of these measures. The findings of this evidence review are presented in this section.

10.2.1 Ban additives that are CMRs or that form CMRs during pyrolysis in order to establish a common list of ingredients

Additives classified as CMRs have been identified as harmful to health. Therefore, it follows that a ban on such ingredients could have some positive impacts on the health of consumers, including passive smokers. This is, nevertheless, hard to quantify not only because there is a lack of evidence on which ingredients fit within that category in the literature, but also because of the complex interactions between different additives and ingredients during the cigarette or tobacco burning process. Indeed, throughout our review of the evidence we have been unable to find any evidence that some countries have successfully banned such ingredients or that these ingredients have been clearly identified. This issue is clearly compounded by the fact that hundreds of ingredients and additives are currently used in tobacco products. Bates *et al.* counted over 600 additives present in tobacco products throughout the EU in 1999 (Bates *et al.*, 1999). In addition, there is a general lack of research and knowledge available regarding the health effects of individual ingredients and additives used in tobacco products (Danish Cancer Society, 2008p.9). As a result, we have had to rely on qualitative sources of evidence that describe the various effects that ingredients added to tobacco products may have on consumer health and smoking behaviour. It should be noted that even this body of qualitative evidence is hard to come by and that we have to base our assessment on very few sources. (Our evidence has had to rely heavily on the following sources of evidence: ASPECT Consortium, 2004, Bates *et al.*, 1999, Danish Cancer Society, 2008, WHO, 2002b, 2003b)

The ingredients added to tobacco products serve a multitude of purposes including the following (Danish Cancer Society, 2008):

- Contributing to the specific flavour and taste of individual cigarette brands: **aromatic purposes**.
- Altering the way in and rate at which the burning process takes place so that the cigarette burning rate is controlled: **combustion-regulating purposes**.
- Preventing the tobacco from drying out during the time lapse between the harvest, production and consumption: **moisturising purposes**.
- Preventing the tobacco from decomposing: **preservative purposes**.
- Distributing other additives evenly throughout the whole cigarette through the use of solvents: **dissolving purposes**.

In addition, given these purposes, it is clear that ingredients contribute to making tobacco products more palatable to consumers and therefore may increase the addictiveness of these products.

As stated in a review of the literature on tobacco ingredients carried out by the Danish Cancer Society, these ingredients and additives have both direct and indirect negative

effects; some additives used are toxic to humans (direct effect) and some additives have a large range of side effects that are much more difficult to identify because of the complex chemical processes taking place when a cigarette is burning (indirect effects) (Danish Cancer Society, 2008). The indirect effects include enhancing the damaging effects of tobacco products by contributing to the formation of additional harmful compounds during pyrolysis and increasing tobacco addiction through an increase in the absorption of other compounds that are already present in the smoke (ASPECT Consortium, 2004, Danish Cancer Society, 2008).

Since a large number of ingredients is being used in tobacco products, it would not be feasible to include all the evidence available on their individual health impacts in this report. Nonetheless, we have chosen to present the case of menthol, an ingredient that is widely used in cigarettes, as an illustration of the type of impacts that ingredients added to tobacco products may have on the health of consumers. Ingredients such as menthol are added to ease the uptake of cigarette smoke and this particular ingredient may act as a local anaesthetic when its concentration is high, as well as giving the smoker a refreshing feeling while the smoke is inhaled (Danish Cancer Society, 2008). Both of these effects are worrying as they may contribute to masking the early symptoms of respiratory illnesses linked to tobacco consumption, such as coughing and breathing difficulty, which could signal the onset of COPD and cancer (Danish Cancer Society, 2008). Other additives such as liquorice and propylene glycol are also used to sweeten and reduce the harshness of tobacco smoke (Danish Cancer Society, 2008).

The ASPECT Consortium makes the important point that it is not the toxicity of the ingredients *per se* that is most detrimental to health but rather the way in which the ingredients act together during pyrolysis (ASPECT Consortium, 2004). In addition, it appears that many of the ingredients and additives used in tobacco products are not essential to their manufacture and storage and that 'few ingredients were used in cigarettes before 1970' (ASPECT Consortium, 2004). What is more, some types/brands of cigarettes currently claim to be additive free and cigarettes sold in Canada contain only a sparing amount of additives (ASPECT Consortium, 2004).

The Scientific Advisory Committee on Tobacco Product Regulation (SACTob) of WHO also stresses the danger of consumers' exposure to tobacco ingredients when it states that 'exposure to nicotine in itself is believed not to be responsible for more than a minor portion of tobacco-related disease' and that 'harmful gases and particulates, which can be thought of as contaminants of the cigarette as a nicotine delivery device, cause the great majority of smoking-related diseases and their specific role in the reinforcing effects of smoking is not well understood' (WHO, 2002a).

In addition, the use of ingredients for aromatic purposes also raises the issue that they may make tobacco products more attractive to young people and children in particular. Fowles *et al.*, in a study of the chemical factors influencing the addictiveness and attractiveness of cigarettes in New Zealand, examined the use of flavourings such as fruit extracts and sweeteners in cigarettes and argue that 'since children are well known to seek out sweet tasting foods it is not unreasonable to assume that any added sweetness in tobacco smoke would be received favourably by the child experimenting with smoking' (Fowles *et al.*, 2001).

We have not been able to find any sources of evidence that point to quantifiable estimates of the impact of individual tobacco ingredients on the health of consumers, and there is only a limited number of sources that have been able to estimate qualitatively the potential impacts of different tobacco ingredients and flavourings on smokers' health. Nevertheless, it is still possible to envisage that banning ingredients that have been classified as CMRs would have a positive impact, albeit currently unquantifiable, on the health of smokers and passive smokers alike, given that the nature of these ingredients itself is harmful to health.

In addition, we have not been able to identify a list of ingredients classified as CMRs for tobacco products. This means that more research in this area is needed not only to identify potential CMR ingredients but also to evaluate their likely impact on consumers' health. This additional research is pressing, given that some of the ingredients and additives have already been shown to be toxic and that others have been shown to have an impact on tobacco attractiveness and addictiveness for consumers, including youth and children. However, as stated in WHO's second report on the scientific basis of tobacco product regulation, there is currently no scientific evidence to show that individual ingredients or additives are responsible for specific disease risks:

> *Science has not established that reduction of any individual toxicant in machine-measured cigarette smoke* [including those proposed in this report]*, will reduce actual human exposure or disease risk. Mandating lower levels and removing some brands with higher levels from the market do not constitute a statement that the remaining brands are safe or less hazardous than the brands removed, nor does it represent government approval of the safety of the products that remain on the market* (WHO, 2008c)

This is an argument that was also put forward in 2003 in another WHO document giving recommendations on tobacco product ingredients and emissions, which stated that 'the development of ingredient and emissions regulation should aim to reduce health risks, although there is no expressed or implied measure of disease reduction' (WHO, 2003b).

It is clear that research in this area will be fraught with difficulty, given that tobacco ingredients and additives act in complex ways. This is not least because of the sheer number of them and their interactions with each other, but also because they react differently during combustion and pyrolysis. In spite of this, carrying out this research is a required step if the ingredients and additives that are most damaging to consumers' health are to be identified and removed from tobacco products.

10.2.2 Introduce an additional measurement method for TNCO (the modified ISO method) and set maximum limits accordingly

The arguments relevant to this option are the same as those presented in Section 8.2.1 on the health impacts of replacing quantitative TNCO labelling with qualitative information on contents and emissions. As such, they relate to two main findings:

- TNCO measurement methods are inappropriate and misleading at best because they are produced using measurements from a machine that does not accurately mimic smokers' smoking behaviour and does not take into account the fact that smokers compensate for cigarettes with lower yields by adjusting their inhalation (i.e. if the yield is lower, smokers will inhale more deeply in order to get the amount of nicotine they need). In addition, cigarette designs have evolved since

the TNCO measurement methods were first developed, and cigarette manufacturers have employed various designs that have the ability to reduce the validity of these tests even further (i.e. by producing artificially low readings due to different length of filter and ventilation holes).

- Consumers find this information confusing and may rely on it as an indicator of toxicity (i.e. the lower the content, the less toxic they think the product is and vice versa).

It therefore appears that while introducing additional measurement methods may provide consumers with more information in terms of volume, it may also confuse them further and reinforce some consumers' belief that these readings are an indicator of toxicity when, in fact, there is no evidence to show that lower yield cigarettes are less dangerous. This is even more relevant since there is evidence to show that 'reductions in machine smoked tar yields can be achieved relatively easily by changing the design of the cigarette, and together with compensatory changes in smoking behaviour, these do not result in differences in exposure to the smoker' (ASPECT Consortium, 2004p.173).

What is more, such a measure could produce some social impacts since TNCO yield measurements cannot be readily included on all types of tobacco product. For example, it is not feasible to produce such measurements for rolling tobacco, given that each cigarette is made by the consumer and may contain more or less tobacco. There are, however, voluntary schemes giving readings for different diameters of hand-rolled cigarettes – for example, in The Netherlands. Hence, it can be envisaged that such a measure would create different impacts on consumers, depending on which tobacco products they are using.

From this evidence it would appear that while introducing an additional measurement method for TNCO would produce more information for regulators and consumers, it could also contribute to misleading them further into believing that tobacco products that present lower TNCO readings are less risky than those with higher readings. This is especially important since it has been shown that some consumers choose to smoke cigarettes that display lower TNCO yields rather than attempt to quit smoking altogether.

10.2.3 Introduce maximum limits for other yields and ingredients

We have found very limited evidence regarding the health impacts of introducing maximum limits for other yields and ingredients. In addition, we have found no evidence of such a measure having been implemented in any country. However, SACTob stated that 'given that tobacco product emissions are known to vary greatly and can consist of thousands of toxicants, there is no alternative but to establish upper limits for selected constituents, based on toxicity profiles, as a means of progressive toxicant reduction in order to begin progress towards reduce toxicity and addictiveness' (WHO, 2003b). At the same time, the report made it clear that the health impacts of such a measure were uncertain when it stressed that 'standards for upper limits of ingredients or emissions will not necessarily result in decreased health risks even though that is the intent' and that 'these recommendations must not form the basis for the development of product descriptors and claims that would imply health benefits or claims about the health effects of the products' (WHO, 2003b).

Thus, while it may be helpful to put in place maximum limits for other yields and ingredients in order to reduce the toxicity of tobacco products progressively as far as possible, there is currently no evidence that this would produce a less harmful product, and further health benefits for consumers are currently unknown.

10.2.4 Continuously decrease the maximum limits for TNCO and other yields and ingredients

The evidence for this measure has been presented in Sections 10.2.2 and 10.2.3 above. The conclusion from these sections is that there is a strong evidence base showing that the current measurement methods for TNCO yields are misleading consumers. Neither are they accurate, given that tobacco manufacturers make use of cigarette design techniques to obtain lower TNCO readings for their products.

Given the measurement methods currently used, therefore, there is at present no strong evidence to recommend decreasing the maximum limits for TNCO in tobacco products. Regarding other yields and ingredients, there is some evidence that decreasing their amounts in tobacco products could be beneficial but there is at present no evidence that such a measure would produce less harmful tobacco products.

10.2.5 Refine the definition of ingredients to include the tobacco leaf

We have found no evidence of this measure currently being applied in any country. All the evidence we have been able to gather on this subject relates to the components of the tobacco leaf and their likely impact on consumers. On this matter, the ASPECT report indicates that the tobacco leaf naturally contains ammonia, which is also sometimes used in the growing process in the form of ammonium salt and which is thought by some experts to increase the addictiveness of tobacco (ASPECT Consortium, 2004p.178). A report from Bates *et al.* (1999) based on a review of evidence from the tobacco industry's internal documents stated that 'ammonia emerges as the primary chemical tool used to enhance nicotine effects'. However, this argument is made in relation to the ammonia that is added to the cigarette by the tobacco manufacturers rather than in relation to the ammonia naturally occurring in tobacco. Nevertheless, information on the ingredients of tobacco products should be made clear to consumers and the present state of play, where the definition is rather restrictive, should be amended to encompass all ingredients included in the final tobacco product. This argument is put forward by the ASPECT Consortium when it states the following:

> *The EU Directive 2001/37/EC reflected the state of regulatory awareness at that time, essentially limiting ingredients to substances which were added during the manufacturing process alone. Since then, it has emerged that some substances may enter the product during earlier phases, such as through agricultural practices. These substances are excluded from the definition, and, therefore, from regulation despite the fact that they are present in the final product, and ingested by the smoker. One example of an ingredient of this kind is ammonia, a substance known to alter the form of nicotine and hypothesised to increase the addictiveness of nicotine. Ammonia is present in the tobacco leaf itself and ammonium salt may be added to the growing process* (ASPECT Consortium, 2004p.178).

As discussed above, there is evidence to show that a more comprehensive definition of ingredients that includes the tobacco leaf would be beneficial to consumers by enabling

tighter regulation of these ingredients and contributing to informing them better about the tobacco products they are using. We may envisage that this would be particularly beneficial if information to consumers were accompanied by some information on the likely health impacts of the different ingredients used in tobacco products.

10.2.6 Set up an EC laboratory for evaluation of tobacco and smoking products

We have not been able to find any sources of evidence on the health or social impacts that the creation of an EC-wide laboratory might have. Given the lack of evidence in this area, all we are able to say is that there would be a positive impact on consumers' and regulators' knowledge. As became evident in the review of evidence on the harmfulness of ingredients, there are still substantial knowledge gaps regarding the types of ingredient used in tobacco products, and the potential effects on health that these ingredients have on their own as well as in combination.

Based on improved reporting arrangements (see discussion in Chapter 5) which should increase the availability of ingredient information, the suggested laboratory could begin the analysis of currently collected data, substantially improve the understanding of ingredients' health impacts and contribute to regulatory decisions in the future for banning specific ingredients and additives that are deemed specifically harmful. Thus an adequately funded laboratory would contribute indirectly to long-term positive health impacts.

10.2.7 Assessment of impacts

The evidence presented in this section has showed that there are currently hundreds of ingredients being used in tobacco products and that there is little evidence of the potential health impacts that could result from banning individual ingredients. Nonetheless, ingredients that have been classified as CMRs are known to be detrimental to health by their very nature. It may therefore be envisaged that banning such ingredients would have positive health impacts on both smokers and passive smokers, albeit these are currently unquantifiable. However, there is at present little research available on the feasibility and health impact of banning such additives and ingredients from tobacco products. Nonetheless, there is some qualitative evidence that a number of the additives and ingredients currently used in tobacco products contribute to increasing both their addictiveness and attractiveness to consumers.

There is currently no documented evidence on the health impact of introducing maximum limits for other yields and ingredients although SACTob advises the introduction of such limits to reduce progressively the toxicant levels of tobacco product ingredients (WHO, 2008c).

The evidence for continuously decreasing the maximum limits for TNCO and other yields and ingredients in tobacco products is mixed. There is no strong evidence at present that justifies decreasing the maximum limits for TNCO in tobacco products, given the measurement methods currently used. Regarding other yields and ingredients, there is some evidence that decreasing their amounts in tobacco products could be beneficial, but there is at present no evidence that such a measure would impact upon the harmfulness of tobacco products. Based on this evidence, more research is needed in order to understand better the impacts of reducing the limits of TNCO, other yields and ingredients in tobacco

products. There is no current evidence to show that such limits would have a tangible health impact on consumers.

The evidence presented does show that a more comprehensive definition of ingredients, including the tobacco leaf, would be beneficial to consumers as it would enable tighter regulation of those ingredients and contribute to better informing consumers about the tobacco products they are using. This would be particularly beneficial if information to consumers were accompanied by some information on the likely health impacts of the different ingredients used in tobacco products. Based on this evidence, it appears that the current definition of ingredients should be amended to include the tobacco leaf. In addition, it would be beneficial to make ingredient information available to consumers. This should be qualitative and explain in simple terms the impacts of the different ingredients.

There is limited evidence on the health impacts of setting up an EU-wide laboratory. Nevertheless, it may be envisaged that such a measure would have a positive impact on consumers as it would mean that all EU consumers would benefit equally from this measure. Additionally, it would represent a strengthening of regulation in this area where currently the onus for the provision of toxicological data is put on the manufacturers or importers of tobacco products. While the health impacts of such a laboratory are uncertain, it might enable greater control of the ingredients included in tobacco products and contribute to the creation of a more even state of play for consumers of tobacco products throughout the EU. In addition, novel tobacco products would be reliably tested before being made available to consumers.

Tighter regulation and control of tobacco additives and ingredients to limit their use to what is necessary for the manufacture and storage of tobacco products might be beneficial to consumers and would have some positive social impacts. For example, the limitations or banning of some ingredients used for flavourings might reduce the attractiveness to and uptake of smoking for young people, including children. Measures related to the limitations of TNCO yields as well as other yields and ingredients might have a small negative impact if these were only practically applicable to some tobacco products, not all of them. This would create a situation in which some consumers were better protected than others, according to the types of tobacco product they were using. There appears to be no negative social impact from the creation of an EU laboratory. On the contrary, such a laboratory would contribute to informing and protecting all EU consumers equally.

10.2.8 Summary of social and economic impacts

Measure	Health and social impact	Estimate of effect
Ban additives that are CMRs or that form CMRs during pyrolysis in order to establish a common list of ingredients	Ingredients that are classified as CMRs are known to be detrimental to health by their very nature. Banning them is therefore likely to engender some positive impact, albeit currently unquantifiable, on the health of both smokers and passive smokers. There is some general evidence, albeit qualitative, that some ingredients currently contained in tobacco products may increase addictiveness, make tobacco products more palatable and contribute to attracting young people to smoking (e.g. through flavours added to tobacco products, such as bubble gum).	(+)
Introduce an additional measurement method for TNCO (the modified ISO method) and set maximum limits accordingly	A large body of evidence points to the misleading character of TNCO measurement methods for two main reasons:1) the measuring methods (ISO) for these yields are inherently flawed as they are based on machine readings and not on the way humans smoke; and 2) there is ample evidence that consumers assume that tobacco products with lower TNCO yield readings are less risky to their health, which is not the case. Hence, no matter what the limits on these yields are, this is not an effective measure to reduce the health impacts of smoking.	≈
Introduce maximum limits for other yields and ingredients	See evidence presented above.	≈
Continuously decrease the maximum limits for TNCO and other yields and ingredients	See evidence presented above.	≈
Refine the definition of ingredients to include the tobacco leaf	We have not been able to find evidence that the tobacco leaf is included in any country's definition of tobacco ingredients. However, there is evidence that the tobacco leaf contains ammonia, which is a substance that has been found to increase the addictiveness of tobacco (ASPECT Consortium, 2004p.3). Ammonia is found naturally in the tobacco plant and is also added in the growing process. Thus, including the tobacco leaf in a definition of ingredients would contribute to informing consumers better about the content of the products they are consuming.	≈
Set up an EC laboratory for evaluation of tobacco and smoking products	An EC laboratory could improve the knowledge base for regulating tobacco products, and thus have indirect health effects in the future.	(+)

10.3 Economic impacts

Further regulations in the area of ingredients and the set-up of an EC laboratory might have the following economic impacts:

1. Compliance cost and administrative burden for manufacturers of the relevant products.
2. Compliance cost to the EU to fund the setting up of an EU laboratory.
3. Employment in the tobacco industry.
4. Governments' revenues from tobacco consumption taxation.
5. Healthcare costs.

The economic impact for producers of adjusting ingredient regulations takes the form of increased costs (impact 1). In order to set up an EC laboratory, funding would need to be generated from revenues acquired (impact 2).

The intention of the measure is to affect consumers' desire to consume tobacco. This will affect demand and supply of tobacco products, which may alter the employment (impact 3) and tax revenues generated from them (impact 4). With changes in the demand for tobacco, the health outcomes related to tobacco consumption will be affected (impact 5).

We discuss each of these in further detail below.

10.3.1 Compliance cost and administrative burden

The measures included in this area of change would result in a number of compliance costs and administrative burdens for tobacco manufacturers, which, however, cannot easily be quantified.

Banning additives that are CMRs or that form CMRs during pyrolysis in order to establish a common list of ingredients (impact 1), introducing maximum limits for other yields and ingredients (impact 3) and continuously decreasing the maximum limits for TNCO and other yields and ingredients (impact 4) would require the reformulation of products and adjustments in production processes, creating one-off compliance costs and potentially increasing ongoing production costs.

Introducing an additional measurement method for TNCO (the modified ISO method), and setting maximum limits accordingly, would require tobacco manufacturers to run a second testing system at an additional cost. If we assume that the administrative burden of the new system would be comparable to the cost related to the current TNCO testing, industry would have to face an additional ongoing administrative burden of between 1.1 and 10.2 million euros a year. These figures are, however, likely to overestimate the testing costs as synergies between the testing methods may be expected. The cost impact of maximum TNCO yields defined according to the new method could not be ascertained as it is unclear how this would impact on products and production. It is possible that some products would have to be repositioned in the market due to lower TNCO yield and that the production processes of these products would have to be altered.

Including the tobacco leaf in the definition of ingredients would also pose administrative burden to tobacco manufacturers, in terms of familiarising themselves with the regulation, adjusting their IT systems to report about tobacco leaf content and adjusting their own measurement processes to obtain reliable information. No quantitative estimate could be obtained from either cigarette producers or cigar producers. Nevertheless, it is suggested that the administrative cost of this measure would be in line with introducing compulsory reporting formats for product ingredients and that overall costs could be decreased if the two regulations were harmonised.

The measure of setting up an EC laboratory for the evaluation of tobacco and smoking products might impose additional administrative burden on the tobacco industry if the costs were transferred to manufacturers through market control fees. Otherwise, Member States or the EC would need to finance this institution. At this stage it is not possible to define the costs of setting up such a laboratory.

10.3.2 **Employment in the tobacco industry**

With no costs identified for administering the measurement of ingredients and no change in prevalence identified, we cannot calculate changes in employment.

10.3.3 **Tax revenues**

With no costs identified for administering the measurement of ingredients and no change in prevalence identified, we cannot calculate changes in excise duty collections.

10.3.4 **Direct and indirect costs of healthcare and ill health**

With no change in prevalence and no quantifiable health benefits associated with different ingredients identified, no change in healthcare costs may be estimated.

10.3.5 Summary of economic impacts

Measure \ Impact type	Administrative burden Compliance cost		Industry revenues/profits		Employment		Tax revenues		Direct and indirect costs of healthcare and ill health		Other	
Ban additives that are CMRs or that form CMRs during pyrolysis in order to establish a common list of ingredients	Product reformulation and adjustment costs for industry	(–)	No substantial impact expected	≈	No substantial impact expected		No substantial impact expected	≈	No substantial impact expected	≈	None	
Introduce an additional measurement method for TNCO (the modified ISO method) and set maximum limits accordingly	€1.1m–€10.2m for running second measurement method One-off compliance cost from production process adjustment and product repositioning in the market	–	No substantial impact expected	≈	No substantial impact expected	≈	No substantial impact expected	≈	No substantial impact expected	≈	None	≈
Introduce maximum limits for other yields and ingredients	One-off compliance cost from production process adjustment and product repositioning in the market	(–)	No substantial impact expected	≈	No substantial impact expected	≈	No substantial impact expected	≈	No substantial impact expected	≈	None	≈
Continuously decrease the maximum limits for TNCO and other yields and ingredients	One-off compliance cost from production process adjustment and product repositioning in the market	(–)	No substantial impact expected	≈	No substantial impact expected	≈	No substantial impact expected	≈	No substantial impact expected	≈	None	≈
Refine the definition of ingredients to include the tobacco leaf	Costs for new reporting and testing processes and for ensuring characteristics of tobacco used	(+)	No substantial impact expected	≈	No substantial impact expected	≈	No substantial impact expected	≈	No substantial impact expected	≈	None	≈

Measure	Impact type	Administrative burden Compliance cost		Industry revenues/profits		Employment		Tax revenues		Direct and indirect costs of healthcare and ill health		Other	
Set up an EC laboratory for evaluation of tobacco and smoking products		Fees for business if costs are transferred	(–)	No substantial impact expected	≈	No substantial impact expected	≈	No substantial impact expected	≈	No substantial impact expected	≈	Costs for Member States or EC to finance laboratory, unless charged to industry	(–)

CHAPTER 11 Sales arrangements

11.1 Introduction

In this chapter we assess different measures relating to the sale of tobacco products. The suggested measures may be grouped in four main categories:

1. Measures regulating the use of vending machines:
    1. Make vending machines inaccessible to minors.
    2. Ban vending machines.
2. Regulation of promotions and displays of tobacco products in retail stores:
    3. Ban promotion (sheers, billboards, big packets, discount banners, etc.) at retail outlets.
    4. Restrict the display of products at retail outlets.
    5. Ban the display of products at points of sale.
3. Measures regulating the size of packages:
    6. Introduce minimum package size.
    7. Introduce a standard package size.
4. And finally two other measures intended to reinforce current regulation:
    8. Harmonise legal buying age of 18 in order to avoid sales to minors.
    9. Ban cross-border internet sales including the free distribution of product samples.

11.2 Social and health impacts

Before assessing sales arrangements, it is important to review current Member State regulation in this area. Table 11.1 provides an overview of current Member State regulation of the sale of tobacco products, based on WHO (WHO, 2007b) information, updated by the research team using further published and unpublished sources.

Table 11.1: Overview of Member State regulation of tobacco sales

	Age restriction	Vending machines	Mail order and internet	Single or unpacked cigarettes	Sales in packages with less than 19 cigarettes	Free samples	Point of sale advertising
Austria	16	Restriction	Ban	Ban	Ban	Ban	Restriction
Belgium	16	Ban	Restriction	Ban	Ban	Ban	Restriction
Bulgaria	18	Ban	Restriction	Ban	Ban	Ban	Restriction
Cyprus	18	Ban	None	Ban	n/a	Ban	n/a
Czech Republic	18	Restriction	Ban	Ban	None	Ban	None
Denmark	18	None	Restriction	Ban	None	Ban	Restriction
Estonia	18	Ban	None	Ban	Ban	Ban	Ban
Finland	18	Restriction	None	Ban	None	Ban	Ban
France	18	Ban	Ban	Ban	Ban	Ban	Restriction
Germany	18	Restriction	None	Ban	Ban	Ban	None
Greece	18	Ban	n/a	Ban	None	Ban	None
Hungary	18	Ban	Ban	Ban	Ban	Ban	Restriction
Ireland	18	Restriction	None	Ban	Ban	Ban	Ban
Italy	16	Restriction	Ban	Ban	Ban	Ban	Ban
Latvia	18	Ban	Ban	Ban	None	Ban	Restriction
Lithuania	18	Ban	Ban	Ban	Ban	Ban	Ban
Luxembourg	16	Restriction	Ban	Ban	None	Ban	Ban
Malta	18	None	Restriction	Ban	None	Ban	None
Netherlands	16	Restriction	None	Ban	Ban	Ban	Restriction
Poland	18	Ban	None	Ban	Ban	Restriction	Ban
Portugal	18	Restriction	None	Ban	Ban	Restriction	Ban
Romania	18	Ban	Ban	Ban	Ban	Ban	Restriction
Slovakia	18	Ban	Ban	Ban	None	Ban	Ban
Slovenia	18	Ban	Restriction	Ban	None	Ban	None
Spain	18	Restriction	Ban	Ban	Ban	Ban	Ban
Sweden	18	Restriction	Ban	Ban	Ban	Ban	Ban
United Kingdom	18	Restriction	Ban	Ban	None	Ban	Restriction

Source: (WHO, 2007b), updated using new country reports, consultation responses and exchange with EC officials

Note: 'Ban' refers to a complete prohibition of the activity, 'Restriction' refers to the activity being regulated and partly restricted, 'None' refers to the activity currently being not restricted or regulated.

11.2.1 **Vending machines**

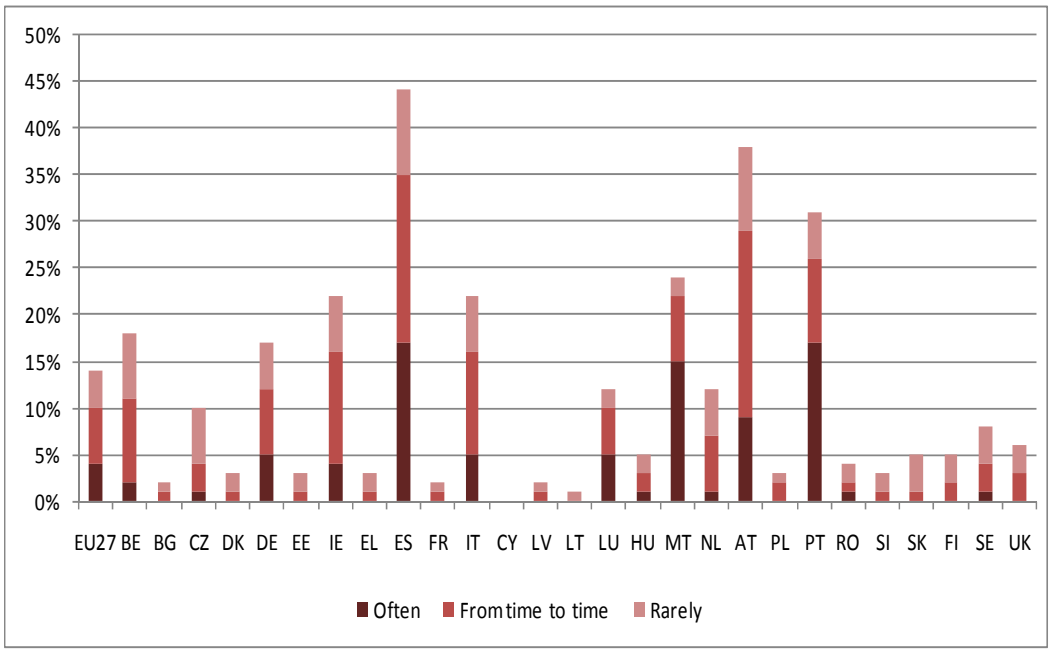
As shown in Table 11.1 above, only 2 of the 27 EU Member States (Denmark and Malta) have no restriction or ban in place on vending machines, whereas 13 Member States have banned vending machines completely and 12 have put restrictions in place to limit underage consumers' uncontrolled access to tobacco products.

The sale of tobacco products through vending machines presents a risk for young people because vending machines do not sufficiently restrict their access to tobacco products (See for example: DiFranza *et al.*, 1996, Forster *et al.*, 1992, UK Department of Health, 2008a). This is particularly the case in instances where vending machines present no age restriction devices or other measures that could prevent the sale of tobacco products to underage consumers. Thus, DG SANCO is considering two possible measures to strengthen tobacco control in this area:

1. Make vending machines inaccessible to minors.
2. Ban vending machines.

According to an impact assessment carried out by the UK Department of Health on mandatory age restriction technology or prohibition for tobacco vending machines, governments have a duty to intervene in order to prevent easy access to tobacco products by young people (UK Department of Health, 2008a). Data used in this impact assessment show that 17 percent of 11- to 15-year-old regular smokers in the UK use vending machines as their regular source of cigarettes, compared with the 78 percent who buy cigarettes from shops and the 49 percent who obtain cigarettes from friends (UK Department of Health, 2008a). This is despite the fact that the UK has some restrictions in place to limit young people's access to tobacco products through vending machines. This takes the form of 'a voluntary agreement between cigarette vending machine manufacturers and the managers of sites where vending machines are located' in order to ensure that machines are 'sited in places where children cannot access them and should be in full view of staff' (Smoke Free Action, 2009). Thus, while purchasing cigarettes from vending machines is by no means the only or primary way in which young people access tobacco products in the UK, it is nonetheless a non-negligible source for this group in that particular country, in spite of the restrictions that are in place.

Figure 11.1 below shows that a very small proportion of EU consumers regularly purchase tobacco products from vending machines overall. When asked the question 'In the past 12 months, have you bought tobacco products through vending machines?', 4 percent responded 'often', compared with 85 percent stating that they had never done so (Eurobarometer, 2010).



Source: (Eurobarometer, 2010p.5) Question 17.2 In the past 12 months, have you bought tobacco products through vending machines?

Figure 11.1: Purchasing of tobacco through vending machines

In addition, it should be noted that consumers who occasionally or often purchase tobacco products from vending machines would typically purchase such products from other sources too, so it cannot be assumed that bans or restrictions on tobacco vending machines would result in a decrease in tobacco consumption proportional to the percentage of consumers purchasing tobacco products from that source. We have not been able to identify any quantitative estimates of the impact on tobacco consumption of restrictions on the use of vending machines for minors or of blanket bans of vending machines. However, it may be assumed that, given the small proportion of EU consumers who often use these to purchase tobacco products, the quantitative impact would be quite small.

Restrictions on vending machines in order to make them less accessible to youths could take many forms such as electronic age verification, ID coin mechanism and remote control (UK Department of Health, 2008a). There is some evidence in the literature – mainly from the USA, where some states have applied locks on vending machines to limit youth access – showing that even when there are restrictions in place on vending machines, a large proportion of youths can still purchase tobacco products from these sources (See for example: DiFranza *et al.*, 1996, Forster *et al.*, 1992). The study by DiFranza *et al.* (1996), using 12 young people to make 480 attempts at purchasing tobacco from vending machines with locks in Massachusetts, found that young people have consistently been more successful in purchasing cigarettes from vending machines than over the counter (DiFranza *et al.*, 1996). Also, it should be noted that vending machine restrictions do not make tobacco products totally inaccessible to youths. This is because enforcement of the law is still required to check that restrictions have been properly implemented and are enforced by retailers. Furthermore, there is a financial dimension for regulatory authorities in checking all vending machines in a given area and ensuring that restrictions are properly enforced (Forster *et al.*, 1992). In other words, such restrictions are not foolproof.

Work by Schneider *et al.* looks at the implementation of electronic locking devices (in this case the need to insert some form of electronic identification into the machine in order to purchase tobacco) on electronic vending machines in Germany, the Member State which has the highest number of vending machines (Schneider *et al.*, 2009). This study made use of interviews with young people aged 12 to 15 in Cologne. It also recorded and mapped the number of commercial tobacco sources in two districts of the city in order to study the changes in the number of tobacco vending machines before and after the introduction of these new controlling measures (Schneider *et al.*, 2009). The study found that in addition to being an easy source of tobacco for youths, vending machines in public areas normalised the perception of cigarettes and also increased their acceptance. Its conclusion was that electronic locking devices on vending machines were not an effective means of limiting youths' access to tobacco products. The authors concluded by saying that they supported the calls of international experts for a complete ban of cigarette vending machines and this despite the fact that they acknowledged that youths often found ways to circumvent age control restrictions placed on the machines by getting their tobacco from other sources (Schneider *et al.*, 2009).

In addition, as with all efforts to reduce youth access to tobacco products, it is often possible for youths to identify shops that continue to sell to minors and/or to find an older or older-looking friend to purchase tobacco on their behalf, so these measures are never totally foolproof in themselves (Asma *et al.*, 2009). In fact, WHO recommended the banning of vending machines altogether as one of the measures needed to limit access to tobacco products by youths in its European Strategy for Tobacco Control report (WHO, 2002a). Its rationale for recommending these measures was explained as follows:

> *International experience shows that age restrictions on the sale of tobacco products are difficult to enforce unless they are supplemented by very strict regulation of retailers through licensing and by eliminating all impersonal and promotional modes of sales and distribution* (WHO, 2002a).

Given the evidence presented above, it appears that merely restricting youth access to vending machines is not sufficient to limit the access of young people to tobacco products. This is because youths are often able to circumvent restrictions, either because these measures are not applied strictly by retailers (e.g. no systematic check of proof of age is made when a purchase is made or there is complete failure to implement restrictions such as installing locks on the machines) or because youths can find other people to purchase tobacco products from vending machines for them. While it might be argued that youths would be able to access tobacco products from other sources, such as by using friends or family members, even if vending machines were banned, it still appears that a complete ban of vending machines would be the most effective means of limiting youth access to tobacco products. This would be particularly true if this ban were applied along with other tobacco control measures.

The social impacts of measures either to ban or restrict vending machines are likely to be limited as these measures would apply to the whole population equally. However, as is noted in the UK Department of Health's impact assessment on vending machines, restrictions or bans of vending machines would have a different impact on youths from that on adults because, while adults would still be able to purchase tobacco products from

a range of other sources, youths would not be legally able to do so (UK Department of Health, 2008ap.17-18).

11.2.2 Promotions and displays of tobacco products in retail stores

Currently, a total of four countries globally have adopted laws to prohibit the visible display of tobacco products at the PoS. They are Iceland in 2001, Thailand in 2005, Ireland in 2009 and Norway (Smoke Free Action, 2009?, The Telegraph, 2010). In addition, 12 out of 13 Canadian provinces have enforced a ban from 2005 onwards, as well as some Australian states and territories (due to come into effect in 2011) (Smoke Free Action, 2009?). 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 (UK Department of Health, 2009). As shown in Table 11.1, 21 out of 27 EU Member States have already taken steps to limit promotions and displays at the PoS by restricting or banning some forms of advertising, although none has yet implemented complete bans on promotions and displays at retail stores.

Promotions and displays of tobacco products in retail stores are an important means through which consumers become aware of their ability to purchase tobacco products in a given location. These are particularly key to the tobacco industry's marketing strategy, which is – according to WHO – for the most part aimed at 'circumventing prohibitions on advertising, promotion and sponsorship that are designed to curb tobacco use' (WHO, 2008d). In addition, these promotions and displays are located behind or near shop counters, exactly where purchasing decisions are made, in order to maximise the impact on consumers' purchasing decisions (Liljenwall, 2004). It has also been shown that 'unplanned purchases were more likely when displays were located near the cash register, or at the end of shopping aisles, than in the middle of an aisle (Wakefield *et al.*, 2007). Thus, the main purpose of promotions and displays of tobacco products in retail stores is to trigger the purchase of tobacco products by consumers. This is an assumption that is often disputed by tobacco companies when arguing against restrictions or bans of such measures because they argue that 'its advertising and promotion efforts are not intended to expand sales or attract new users, but simply to reallocate market share among existing users' (WHO, 2008dp.36). However, the evidence in the literature reviewed shows that promotions and displays of tobacco products do play a key role in triggering tobacco product purchases by underage consumers in particular – as well as by regular smokers, smokers attempting to cut down or quit altogether, and non-smokers. It should be noted here that an overwhelming majority of the research identified and reviewed on this topic concentrated on the impact of displays and promotions at retail stores on youth smoking, and that there is currently very little research available on their impact on adult smokers' tobacco consumption behaviour (Slater *et al.*, 2007).

It follows that the rationale for restricting or banning promotions and displays in retail stores is principally twofold: to prevent the uptake of smoking in youths in particular and to remove cues that could trigger the desire to smoke in consumers trying to quit, stay quit or cut down on their tobacco consumption. Following on from this rationale, the main health benefit derived from restrictions or bans of promotions and displays at retail stores is to achieve a reduction in smoking-related morbidity and mortality rates through reductions in tobacco use.

According to the UK Department of Health, restricting or banning promotions and displays of tobacco products in retail stores is a tobacco-control measure that could reduce smoking prevalence in under-18s in particular because 'a significant body of research demonstrates a correlation between the advertising and promotion, including through retail display, of tobacco products and initiation into tobacco use, and also suggests that retail displays can trigger those trying to quit to continue their habit' (UK Department of Health, 2008b).

The majority of the evidence in the literature reviewed with regard to the impact of promotions and displays of tobacco products in retail stores shows that there is a correlation between tobacco promotion and people taking up smoking or continuing to smoke. This evidence is particularly strong with respect to young people who are thought to be more susceptible to such promotions and displays as well as not 'fully capable of understanding the risks' of smoking (Henriksen *et al.*, 2004, Paynter and Edwards, 2009, The Centre for Tobacco Control Research, 2008, UK Department of Health, 2008bp.1 and see also:).

A review of the literature available on the impact of tobacco advertisements on purchasing behaviour and tobacco consumption, as well as the possible impact of a display ban conducted by researchers at the Norwegian Institute for Alcohol and Drug Research (SIRUS), concludes that restrictions and a ban on tobacco advertisement reduces tobacco consumption, and that the literature on these effects may be transferred to displays of tobacco products as one type of advertising (Lund and Rise, 2008).

Promotions and point-of-sale displays may also have an impact on regular smokers and the general public at large by 'reinforcing the acceptability and normalcy of the purchase' (The Centre for Tobacco Control Research, 2008) by 'depicting it [tobacco] as being no different from any other consumer product' (DiFranza *et al.*, 2006, WHO, 2008dp.36, see also:) and therefore undermining other efforts to curb tobacco consumption such as health warnings and making it more difficult for people to understand fully the health risks of tobacco consumption (Loomis *et al.*, 2006).

A study of reported cigarette purchasing behaviour by Wakefield *et al.* based on a telephone-administered population survey of 2,996 adults including 526 smokers of manufactured cigarettes and 67 recent quitters in Victoria, Australia, found that 25.2 percent of smokers impulse purchased cigarettes as a result of seeing cigarette displays in retail shops while '38 percent of smokers who had tried to quit in the past 12 months and 33.9 percent of recent quitters experienced an urge to buy cigarettes as a result of seeing the retail cigarette display' (Wakefield *et al.*, 2007p.322). Another study carried out by Henriksen *et al.* through a survey of 2,125 middle-school students in the state of California found that visits to retail stores were associated with 'a 50 percent increase in the odds of ever smoking, even after control for social influences to smoke' (Henriksen *et al.*, 2004).

Paynter and Edwards (2009) recently published a systematic review of evidence on the impact of PoS advertising on smoking-related behaviours and beliefs based on 12 peer-reviewed studies, of which 10 focused on children (Paynter and Edwards, 2009). The conclusions of their review included the following: '7 of 8 observational studies found significant associations between exposure to tobacco promotion at the PoS and smoking initiation or susceptibility to smoking'; '2 experimental studies of children found

statistically significant associations between exposure to PoS tobacco promotions and beliefs about ease of getting tobacco and smoking prevalence among their peers' and 'a cross-sectional study found that 25 percent of adult smokers reported impulse purchasing and a third of recent ex-smokers reported urges to start smoking after seeing tobacco displayed' (Paynter and Edwards, 2009p.1).

It is clear that the results of such studies should be carefully considered along with the limitations associated with their methodology. Most of these rely on self-reported behaviour rather than observed behaviour, typically include relatively small samples of the population at large and are also subject to context-specific conditions (i.e. the display and promotions used in Australia may vary from those used in different EU Member States). However, the results of these studies still indicate that displays and promotions may influence smoking behaviour and increase the likelihood of tobacco product purchases at retail stores (See for example: DiFranza *et al.*, 2006, Henriksen *et al.*, 2004, Loomis *et al.*, 2006, Paynter and Edwards, 2009). In addition, while these studies rely on self-reported behaviour, it is clear that obtaining robust empirical evidence on the impact of such measures is fraught with difficulties. For example, it would neither be feasible nor ethical to carry out randomised controlled trials to gauge the impact of displays and promotion on smoking behaviour and uptake (Willemsen, 2000?). In addition, as with all such measures, quantifying the impact of banning or restricting promotions and display of tobacco products at retail stores presents some important challenges, not least because such measures are never implemented in isolation. It is therefore difficult, if not impossible, to attribute impact to specific tobacco control measures.

A report funded by PMI reviewed the effectiveness of display bans in the case of Iceland, a country that implemented a display ban in 2001, in order to provide a quantitative estimate of the impact of this measure on tobacco consumption (Padilla, 2009). This report, based on an econometric analysis of smoking prevalence data, made use of multiple regression analysis and came to the conclusion that 'the experience in Iceland does *not* suggest that a display ban would reduce smoking prevalence, and instead shows that other measures may be more effective in controlling tobacco consumption' (Padilla, 2009p.22). However, the methodology applied makes use of time series data which present particular statistical limitations, but potential bias of findings resulting from this approach has not been acknowledged in that paper. In addition, one section of this report compares Iceland to Norway and Sweden to assess differences in tobacco consumption trends, the two last-named countries not having introduced a display ban. The report claims that 'the evolution of smoking rates in those countries without display bans provides a good benchmark to assess the effect of tobacco display restrictions on smoking prevalence' and that 'finding that the display bans did not have an impact on the evolution of smoking prevalence in Iceland in comparison to smoking rates in Norway and Sweden, after controlling for other factors that influence smoking rates, is therefore a good indication that the display bans are not an effective tobacco control measure' (Padilla, 2009p.29). However, there are obvious shortcomings and limitations, which are not made explicitly in this paper, when benchmarking different countries' trends and drawing conclusions from these trends, even when these countries 'appear' to have similar characteristics. Therefore, it seems that the conclusions of this paper should be read with these limitations in mind. Interestingly though, this paper does acknowledge that other tobacco control measures are

effective. For example, it states that 'other tobacco control measures, like bans on smoking in public areas and health warnings on cigarette packs were effective tobacco control measures, as they had a negative and statistically significant effect on smoking prevalence' (Padilla, 2009p.22). In addition, as previously mentioned in Section 8.2.1, any evidence from researchers funded by the tobacco industry should be carefully considered given the industry's history of interfering with tobacco control policy and of funding research to counter independent research on the health impacts of tobacco (WHO, 2009c).

The evidence presented above has shown that several studies have reported a positive correlation between displays and promotions at retail stores and tobacco consumption as well as tobacco initiation. Given this evidence, it would appear that restricting or banning such displays and promotions would produce positive health impacts on youths and adults alike. The options available to DG SANCO according to its proposal with regard to such restrictions or bans are as follows:

1. Ban promotion (sheers, billboards, big packets, discount banners, etc.) at retail outlets.
2. Restrict the display of products at PoS
3. Ban the display of products at PoS.

While it is not possible to quantify the likely health impact of each of these measures, it follows from the evidence that the stricter the ban or restrictions, the stronger the positive health impact on consumers is likely to be. In particular this should be seen against the observation that the tobacco industry reinforces promotions and displays to maximise their effectiveness when restrictions on advertising are in place elsewhere. As WHO states in its report on the global tobacco epidemic, 'even when enforced, partial bans have limited impact, because tobacco companies simply reallocate spending to other marketing channels' (Asma *et al.*, 2009p.1293, WHO, 2008dp.52, see also:).

It follows from this evidence that promotions and displays at retail stores influence purchasing decisions and may have an impact on smoking uptake by youths. Therefore, it may be envisaged that the strongest of the three measures presented above, namely banning the display of products at the PoS, would have the strongest positive impact on both youths and adult by removing cues to purchase tobacco products.

Regarding the social impacts of this measure, it may be envisaged that these will be limited, given that this measure will apply equally to the whole population. However, given the evidence presented above on the particular impact of displays and promotions on youth smoking, the impact of these measures might be stronger on this group and might also benefit 'adults and smokers of all ages who are trying to quit' (UK Department of Health, 2008bp.22).

11.2.3 **Size of packages**

DG SANCO considers two options with regard to package size: the introduction of a minimum package size and the introduction of a standard package size.

Currently, no EU Member State allows the sale of individual cigarettes or unpacked cigarettes and, in fact, 'most governments dictate the smaller pack size that can be sold (and legislate against selling cigarettes individually) and it is the choice of the

manufacturers with regard to what pack size varieties to offer (influenced, in part, by tradition and excise duty)' (Farrell *et al.*, 2003p.1-2). Yet, despite the fact that package size is regulated in a number of countries worldwide, there appears to be very limited evidence with regard to the impact of cigarette pack size on tobacco consumption. The evidence also appears to be mixed with, for example, the British Medical Association's Scottish Council calling on a ban on smaller (10) packs of cigarettes because these packs are 'more appealing to young people because they are cheaper to buy' (BBC News Website, 2007) and Professor Luke Clancy, Chairman of Action on Smoking and Health Ireland, making a similar argument by stating that 'young people are price sensitive and it is expected that the requirement to purchase 20 cigarettes as opposed to 10 will be a barrier to some people experimenting with tobacco' (Action on Smoking and Health (ASH) Ireland, 2007). On the other hand, some research conducted for the most part in the USA, Canada and Australia has shown that there is a strong association between pack sizes and daily cigarette intake, with higher numbers of cigarettes per pack linked to higher consumption (Hill *et al.*, 1998, Kozlowski *et al.*, 1989). For example, research undertaken by Farrel *et al.* into the impact of packet size on tobacco consumption, using a statistical model, concluded that 'smokers regulate their consumption in accordance with the size of packets that are available' (Farrell *et al.*, 2003p.32-33).

Following on from this, it appears that the evidence linking package size and tobacco consumption is mixed. While on one hand some argue that larger, and therefore more expensive, packs would limit youth smoking, others argue that larger packs would contribute to an increase in regular consumption. Therefore it is difficult to estimate the likely impacts of the introduction of a standard package size and, indeed, what the ideal size would be in order to limit youth smoking and tobacco consumption as a whole. Regarding the introduction of a minimum package size, it may be envisaged that this option would have limited health impacts given that most EU countries have already implemented such a measure. It is also difficult to assess what the ideal minimum package size would be if this measure were to be implemented equally across all 27 EU Member States, given that currently some EU Member States have banned cigarette packs of fewer than 19 cigarettes while others still allow packs of 10 (Table 11.1).

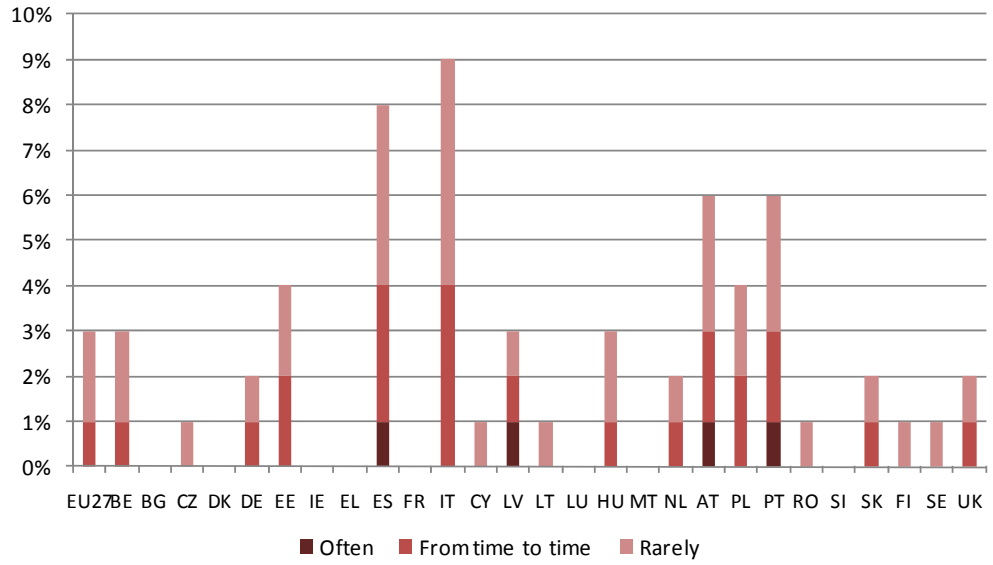
Given that the evidence presented above on the impact of pack size on tobacco consumption is mixed, we envisage that the social impacts of enforcing minimum package size and standard package size will also be mixed. For example, if the smaller package size was banned, some would argue that this would have a positive impact on youths while other would argue that it could contribute to adult smokers increasing the consumption of tobacco.

11.2.4 Cross-border internet sales of tobacco products

The sale of tobacco products via the internet potentially undermines national tobacco control efforts, in particular enforcement of the minimum purchasing age as well as collection of tax revenues (Goolsbee *et al.*, 2010, Leverett *et al.*, 2002). Using data on cigarette tax rates, taxable cigarette sales and individual smoking rates of US states from 1980 to 2005 merged with data on internet penetration, Goolsbee *et al.* (Goolsbee *et al.*), for example, demonstrate how internet sales reduced the ability of US states to enforce higher levels of taxation and safeguard revenues from tobacco taxation.

Member States thus expressed concern about cross-border sales of tobacco products (DG SANCO, 2009c). Currently there is little information available on the extent of cross-border sales of tobacco product via the internet. In the latest Eurobarometer data, only 3 percent of smokers were reported to have purchased tobacco products on the internet within the previous 12 months – and occasionally or rarely. In some Member States internet purchasing seems, however, to be more common – notably in Italy, Spain, Portugal and Austria, despite some of those countries having banned the internet sale of tobacco products (see Figure 11.2) (Eurobarometer, 2010).

From the data available we cannot infer what the share of cross-border purchases is. However, given that internet sales are banned in some of the countries (e.g. Italy, Spain and Austria), and price differentials between countries make the form of purchase particularly attractive, a substantial share will be cross-border. For the UK, a study based on the ITC survey showed that internet sales constituted only a small part of tobacco purchasing in 2002 (Hyland *et al.*, 2006), also demonstrating that duty-free and traditional cross-border purchasing were the most important source of reduced price tobacco. This is confirmed by recent Eurostat data, which shows that around a quarter of smokers purchased tobacco in other (EU) countries on at least a few occasions a year, as compared to the 3 percent who have bought tobacco on-line (Eurobarometer, 2010).



SOURCE: (Eurobarometer, 2010) Question 17.1 In the past 12 months, have you bought tobacco products over the internet?

Figure 11.2: On-line purchasing of tobacco products

Distance sale of tobacco products is already regulated in about half of the Member States; it is either banned or restricted to ensure compliance with relevant, in particular purchasing age, regulation. As reported in (DG SANCO, 2009c), Member States use a variety of approaches – including advertising regulation, tax law and licensing regulation – to regulate internet sales. Enforcement appears, however, to be a particular problem in relation to internet sales, in terms of policing an actual ban on internet sales as well as of

enforcing other tobacco regulation – such as access to minors and tax regulation when on-line sales are not prohibited.

The proposed measure of banning cross-border internet sales is likely to have indirect health and social impacts by allowing Member States to maintain stringent tobacco control measures, such as high tobacco taxes and purchasing age restrictions, without the threat of cross-border trade undermining this regulation. This said, any measure will only be effective if sufficiently enforced, which is notoriously difficult with internet purchasing.

11.2.5 Harmonising minimum legal purchasing age

Introducing a minimum purchasing age for tobacco products is a common element of tobacco control and youth protection policies across the world. The primary rationale behind this measure is that minors should be protected from the inherent dangers of tobacco consumption as they may not be able to assess appropriately the risks of becoming addicted to nicotine and of the exposure to harmful smoke (Asma *et al.*, 2009). Over the last ten years minimum legal purchasing age regulations have been adopted or tightened by all Member States. A legal minimum purchasing age of 18 is now effective in 22 Member States, and 5 Member States regulate a minimum age of 16 (see Table 11.2).

Table 11.2 Tobacco minimum legal purchasing age

Minimum purchasing age	Number of countries	Countries
18 years	22	Bulgaria, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Ireland, Latvia, Lithuania, Malta, Poland, Portugal, Romania, Slovenia, Slovakia, Spain, Sweden, United Kingdom
16 years	5	Austria, Belgium, Italy, Luxembourg, Netherlands

Source: (WHO, 2007b), updated by RAND Europe based on Member State reports and comments received during consultation.

The evidence of the effectiveness of youth access laws in reducing youth smoking prevalence has been described as mixed, which is in particular due to the difficulties in enforcing underage sales regulation, as well as to shifts of the supply of tobacco to other sources (Asma *et al.*, 2009, Chaloupka and Warner, 2000, Levy *et al.*, 2004).

A systematic review of the effectiveness of age control laws (Stead and Lancaster, 2005) concludes that legislation alone is not sufficient to prevent tobacco sales to minors. Even if a high level of enforcement and community policies were to lead to good compliance of retailers, this might not sufficiently restrict access. Minors would use other routes outside the scope of access laws to obtain tobacco. Thus it is not surprising that only a few studies so far have found a positive correlation between age restriction and youth smoking prevalence among adolescents (Stead and Lancaster, 2005).

Looking at the impact of different tobacco policy measures across the EU 27, Schnohr *et al.* (2008), for example, could not establish a positive correlation between age restriction and daily youth smoking. On the contrary, they found a negative correlation, which may be explained by an exceptionally high adolescent smoking rate triggering action to introduce age restrictions.

A study from Finland which examines the effects of the country's ban on tobacco sales to minors between 1977 and 2003 found, however, that the sales ban appears to have

decreased tobacco purchase and may have contributed to a recent decrease in smoking (Rimpela and Rainio, 2004). The study, however, observed a shift from commercial to social sources – for example, friends or family – to obtain tobacco. According to the study, social sources of tobacco beyond the legislative control were more important than expected; only 2–3 percent of the underage daily smokers obtained all their tobacco from commercial sources (Rimpela and Rainio, 2004).

A recent study (Verdonk-Kleinjan *et al.*, 2008) from The Netherlands showed the effectiveness of the minimum age (16 years in The Netherlands) in reducing purchase of tobacco products by 13- to 15-year-olds, but is cautious in attributing observed reduction in smoking prevalence among adolescents to this measure.

In sum, existing evidence indicates that while minimum age laws may reduce tobacco consumption by minors, the size of the effect is influenced both by the extent to which minors turn to non-commercial sources of cigarettes and by the extent to which the laws and regulation are enforced effectively.

Against the evidence presented above, the health impacts of introducing a harmonised legal purchasing age of 18 years across all Member States are likely to be very small. First, already more than 80 percent of the European population is subject to the age limit of 18, and in the remaining countries an age limit of 16 is in force. Only 20 percent of the population would be affected by a tightening of existing regulation by two years. Secondly, this measure does not cover issues of enforcement and compliance, which appear to be of high importance in this context – in particular as enforcement is often done by local authorities with few extra resources to be shifted to new tasks. Thirdly, tobacco sold in official outlets constitutes only one source of tobacco for adolescents. They are likely to switch purchasing from official sources to unofficial (social) sources of tobacco when official sources are more tightly regulated (Dent and Biglan, 2004, Rimpela and Rainio, 2004).

11.2.6 Assessment of impacts

Based on the evidence presented above, we would expect the suggested measures to have the following impacts.

Vending machines

The evidence presented has shown that restrictions on vending machines are far from being completely foolproof and that many youths are still able to purchase tobacco products from vending machines when restrictions are in place. Given that currently only two Member States have no restrictions on vending machines (Table 11.1), the impact of enforcing restrictions on vending machines would be very small. Indeed, given the size of the population of the the Member States without restrictions on vending machines (Denmark and Malta), restrictions on vending machines would only apply to an additional 1 percent of the EU population (Eurostat, 2010); therefore health effects may be expected to be very low.

Even with technical solutions in place, the enforcement of restriction on the use of vending machines appears to be a substantial challenge, rendering restrictions less useful.

It would therefore appear that a ban on vending machines would be more effective in reducing youth access to tobacco products. Taking into account, however, that youths are

likely to shift to other sources of tobacco, this will still have only a minor effect on youth smoking. In particular, given that 13 Member States already have a ban on vending machines (Table 11.1), extending a ban on vending machines to all remaining Member States would affect only an additional 36 percent of the EU population (Eurostat, 2010).

In terms of the social impacts of this measure, youths are more likely to benefit from this measure than adult smokers, who have easier access to other sources for the purchase of tobacco products.

For both measures no estimates of prevalence changes on a population level could be obtained from the literature, despite evidence for the positive effects on young persons' smoking behaviour.

Promotion and displays of tobacco products in retail stores

The evidence on promotion and displays of tobacco products in retail stores has shown that they influence purchasing decisions and may have an impact on smoking uptake by youths. Therefore, it may be envisaged that the strongest of the three measures presented in Section 11.2.2, namely banning the display of products at the PoS, would have the greatest positive impact on both youths and adults, by removing cues to purchase tobacco products from retail stores. Therefore, it may be envisaged that youths would benefit more from this measure than other smokers or potential smokers, although these restrictions may also help adult smokers cut down or quit smoking altogether by removing smoking cues.

Although we have not been able to point to reliable quantitative data regarding the impact of promotion and display restrictions or bans in retail stores, we can estimate the proportion of the EU population that will be included in these measures, given the current state of play of regulation in EU Member States (Table 11.1). Given that currently only five Members States have no restrictions or bans on PoS advertising at all (Table 11.1), if these countries were to introduce restrictions to promotions and displays of tobacco products at retail stores, another 21 percent of the EU population would be included in this measure (based on population estimates) (Eurostat, 2010). On the other hand, if bans were introduced, they would apply to an additional 63 percent of the EU population (in the 16 countries that currently either have no restrictions in place at all or have some restrictions in place) (Eurostat, 2010).

For all three measures, again no good estimates of prevalence changes on a population level could be obtained from the literature, despite evidence for the positive effects of display and advertisement restrictions on purchasing decisions.

Size of packages

As has been shown in Section 11.2.3, there is mixed evidence regarding the impact of different package sizes on tobacco consumption, with some making the argument that larger, more expensive packs may limit youth smoking and others arguing that large packs may increase smokers' tobacco consumption.

While the evidence is mixed, we are able to estimate the proportion of the EU population that would be affected by a ban on cigarette packs of fewer than 19 cigarettes (i.e. effectively enforcing a minimum package size of more than 19 cigarettes). Currently 16 EU countries have banned the sale of cigarettes in packs of fewer than 19 cigarettes (Table

11.1). These countries represent about 79 percent of the EU population; therefore the measure to introduce a ban on packs of fewer than 19 cigarettes would affect an additional 21percent of the EU population (Eurostat, 2010).

From this evidence, it follows that the social impacts of enforcing minimum package size and standard package size would be mixed. For example, if the smaller package size were banned, some would argue that this would have a positive impact on youths while other would argue that it might contribute to adult smokers increasing their consumption of tobacco.

Cross-border internet sales

The proposed measure of banning cross-border internet sales is likely to have indirect health and social impacts by allowing Member States to maintain stringent tobacco control measures, such as high tobacco taxes or purchasing age restrictions, without the threat of cross-border trade undermining those measures. That said, any measure's effectiveness depends on enforcement, which is fraught with difficulties with internet purchasing.

Legal buying age

The evidence presented in this section has shown that the health impacts of introducing a harmonised legal purchasing age of 18 years across all Member States are likely to be very small. First, already more than 80 percent of the European population are subject to the age limit of 18, and in the remaining countries an age limit of 16 is in force. Therefore only 20 percent of the population would be affected by a tightening of existing regulation by two years. Secondly, the measure does not cover issues of enforcement and compliance, which appear to be of high importance in this context – in particular as enforcement is often done by local authorities with few extra resources to be shifted to new tasks. Thirdly, tobacco sold in official outlets constitutes only one source of tobacco for adolescents. They are likely to switch purchasing from official sources to unofficial (social) sources of tobacco if official sources are more tightly regulated (Dent and Biglan, 2004, Rimpela and Rainio, 2004).

11.2.7 Impact on mortality and morbidity through increased costs for tobacco retailers

Despite the difficulties in obtaining quantitative estimates for the direct impact on changes in prevalence, the increased costs for retailers could have an impact on prevalence, and thus on mortality and morbidity. As we demonstrate further in this section, the change in prevalence may be a 0.12 percent reduction. According to our model, this would result in approximately 200 fewer deaths in 2027. In terms of morbidity, a 0.12 percent decrease in smoking prevalence would produce an estimated decrease of 2,200 cases of lung cancer, aerodigestive cancer and COPD annually by 2027.

11.2.8 **Summary of health impacts**

Measure	Health and social impact	Effect
Make vending machines inaccessible to minors	Small reduction of youth access to tobacco through vending machines, however only small percentage of European population affected. Effect depending on enforcement and youth access to alternative sources of tobacco.	+
Ban vending machines	Reduction of youth access to tobacco and reduction in smoking prevalence of youths in particular is more likely to affect health than restrictions on vending machines, although no quantifiable estimate of this impact has been found. However, only small percentage of European population affected. Effect depending on enforcement and youth access to alternative sources of tobacco. This measure would be beneficial to youths in particular as it would remove an easy source of tobacco for them although youths typically use a range of other sources to purchase tobacco products. Some adult smokers would be affected as they would not be able to access vending machines as a source of tobacco products, but effect would be minimal as they could legally turn to other sources of purchase (e.g. retail shops). No negative social impact foreseen.	+
Ban promotion (sheers, billboards, big packets, discount banners, etc.) at retail outlets	Reduction in smoking prevalence among youths in particular is likely as evidence shows promotion at PoS influences youth smoking behaviour and uptake of smoking. A similar impact may be observed, albeit smaller, on adult smokers as bans on promotion remove smoking cues. However, no easily transferable quantitative estimates on prevalence are available.	+
Restrict the display of products at retail outlets	Reduction in smoking prevalence among youths in particular is likely as evidence shows promotion at PoS influences youth smoking behaviour and uptake of smoking. A similar impact may be observed, albeit smaller, on adult smokers as bans on promotion remove smoking cues. Impact likely to be strongest on youths although some adult smokers and would-be quitters may also be positively affected. No negative social impact foreseen. Effect would be enhanced through cost-price effect, reducing prevalence by 0.12%, resulting in 200 fewer deaths and 2,200 fewer cases of lung cancer, aerodigestive cancer and COPD annually by 2027.	++
Ban the display of products at PoS	Reduction in smoking prevalence among youths in particular is likely as evidence shows promotion at PoS influences youth smoking behaviour and uptake of smoking. A similar impact may be observed, albeit smaller, on adult smokers as bans on promotion remove smoking cues. Note that measures 3, 4 and 5 are interlinked; the strongest measure, which would consist of a complete ban on PoS promotions and displays, would have the strongest health impact of all the measures as it would remove all smoking cues from the sight of consumers. Impact likely to be strongest on youths although some adult smokers and would-be quitters may also be positively affected. No negative social impact foreseen.	++

Measure	Health and social impact	Effect
Introduce minimum pack size	Evidence of the impact of this measure is very mixed because bigger pack sizes have been shown to increase tobacco consumption and other evidence has pointed to smaller pack sizes increasing tobacco appeal to youths. The social impacts of these measures would also be mixed.	≈
Introduce a standard pack size	Evidence of the impact of this measure is very mixed because bigger pack sizes have been shown to increase tobacco consumption and other evidence has pointed to smaller pack sizes increasing tobacco appeal to youths. The social impacts of this measure would also be mixed because of different impacts on different groups (youths and adult smokers).	≈
Ban cross-border internet sales including the free distribution of product samples	Likely to have some indirect health and social impacts although unquantifiable due to the dependence of this measure on stringent enforcement of the ban and the overall limited extent of on-line cross-border sales.	≈
Harmonise legal buying age of 18 in order to avoid sales to minors	Some evidence of impact of raising legal buying age on tobacco consumption by youths. However, likely to produce very small health impacts as only 20% of the EU population would be affected by raising age from 16 to 18 (all EU Members States have a minimum legal buying age of at least 16) and size of impact will depend on the extent to which youths turn to other sources to obtain tobacco products (friends, family, etc.). Social impact of the measure would only affect youths from the age of 16 to 18.	+

11.3 Economic impacts

Regulation in the sales arrangements of tobacco restricts the ability of retailers to distribute products, affects the way in which producers package their products, and is intended to decrease demand by making tobacco products less available. Specifically, further regulation in the area of how tobacco products are distributed may result in the following economic impacts:

1. Compliance cost and administrative burden for retailers and manufacturers of the relevant products.
2. Employment in tobacco industry.
3. Governments' revenues from tobacco consumption taxation.
4. Healthcare costs.

The economic impact of adjusting the product package will affect producers, in the form of increased costs (impact 1). For the producers, there is a decrease in costs if all retailers are equally unable to promote their products. The way in which tobacco products may be distributed and to whom will affect retailers as they adjust their current set-up and enforce the regulation (impact 1).

The intention of the measure is to affect consumers' desire to consume tobacco and reduce the ability for minors to access tobacco. This will affect the demand and supply of tobacco products, which may alter the employment (impact 2) and tax revenues generated from tobacco (impact 3). With changes to the demand for tobacco, the health outcomes related to tobacco consumption will be affected (impact 4).

We discuss each of these in further detail below.

11.3.1 Compliance costs for retailers and manufacturers

In this section we provide a brief overview of the evidence on the compliance cost of tobacco products regulation in different sales areas of interest. The potential regulations discussed impose no administrative burden on tobacco retailers. By implication compliance costs only are discussed.

Minimum packet size

Minimum packet size or standard packet regulations are present in 15 EU Member States (Table 11.1). However, the defined minimum or standard packet sizes differ from country to country; it varies between 10, 19 and 20. When assessing the compliance costs of regulation in the EU-27 the details of Member States' existing regulations are taken into account.

For shops which have facilities fitted packet sizes other than the prospective regulation would prescribe, compliance costs may arise in the form of readjusting the storage facilities for packets, and the gantry, the counter and vending machines – which may also impact on crucial business processes such as restocking. Depending on the existing set-up for these facilities and the method of compliance chosen, the one-off compliance costs may vary from negligible up to 15,000 euros per shop, as reported by one of the retailers'

associations surveyed by RAND Europe. Taking the least-cost alternative, overall compliance costs for the EU-27's retail industry are considered to be marginal.

For manufacturers of cigarette products compliance costs arise as the production process regarding packaging and labelling has to be altered; however, a minimum or standard pack size would also lead to a reduction in the number of SKUs and different production lines, and that would substantially reduce costs over the long term.

Minimum legal purchasing age (vending machines inaccessible to minors)

Minimum legal purchasing age regulations are present in all EU Member States (see Table 11.2). However, the defined minimum legal purchasing age differs from country to country, varying from 16 to 18. When assessing the compliance costs of regulation in the EU-27 the details of Member States' existing regulations are taken into account.

Regarding the compliance costs of tobacco retailers owing to this measure, RAND Europe gauged only the costs of adjusting vending machines. Making vending machines inaccessible to minors necessitates the application of a control mechanism that allows for obtaining proof of the age of the consumer.

Making vending machines age restricted may be achieved in three different ways:[64]

- Electronic age verification: tobacco companies may provide an electronic ID card (after proof of age has been provided) which allows customers to unlock tobacco vending machines. Alternatively, an electronic chip or code can be inserted into the tobacco buyer's ATM card (on proof that the cardholder is 18 years or over); this requires the relevant bank's coooperation.
- ID coin mechanism: potential purchasers may be required to obtain an ID coin from the staff of the retail outlet where the machine is located, which is then used to unlock the tobacco vending machine to make a purchase.
- Remote control: the vending machine may be activated only by a remote control held by a staff member who obtains proof of the age of the tobacco costumer before unlocking the vending machine.

Any of these adjustments is costly in the case of those vending machines which have no locking mechanism. However, if such a mechanism already exists, changing the minimum buying age (i.e. the age at which the machine unlocks) bears no significant cost consequence. Installing the locking and card proofing elements in tobacco vending machines costs on average 823 euros per vending machine, according to the self-reported data of the retail industry. Their responses did not clearly state the technical solutions on which the cost was based. According to vending machine operators, there are no ongoing compliance costs for the potential regulation. Using the best available estimate[65] of the number of vending machines in Member States where they are neither banned nor already

[64] For more detailed discussion see, for example, ACS, *Acs Response to the Consultation on Proposed Tobacco Control Regulations for England (under the Health Bill 2009)*, London: Association of Convenience Stores, 2009.

[65] PMI hosts a database on vending machines per country in Europe.

compliant with the regulation, the overall EU-27 compliance cost figure is between 47.5 and 48.9 million euros (Table 11.4). The range of costs reflects the range of per

-shop costs based on retailers' responses.

According to the impact assessment of the UK Department of Health (Health, 2009) on the age restriction of sale of tobacco from vending machines, the cheapest option would minimally entail initial compliance costs of 160 euros (£125)[66] per vending machine. Recurring annual costs were estimated to amount to 12 euros (£9) per vending machine a year. Taken together, the compliance costs in the UK are considerably lower than estimates presented in this report – on average about five times lower. Even the compliance costs associated with the most expensive option identified by the UK Department of Heath's impact assessment (385 euros per vending machine) is less than half RAND Europe's responses' average.

Ban vending machines

Vending machines are banned in 13 EU Member States: Belgium, Bulgaria, Cyprus, Estonia, France, Greece, Hungary, Latvia, Lithuania, Poland, Romania, Slovakia and Slovenia (Table 11.1). Banning vending machines imposes compliance costs on their operators in terms of removing the machines, sunk costs (which would be lower if used machines could be sold to other companies), and foregone profits.

We could not obtain quantitative estimates for the potential overall compliance costs as per vending machine costs could not be gauged. There are no official statistics on the number of, value of, and revenue generated by cigarette vending machines. The only indicative data are collected by PMI, which report that there were 783,257 cigarette vending machines in the EU-27 in 2008.

Ban promotion at retail outlets

Most of the EU Member States already ban the promotion of tobacco products at retail outlets by such means as sheers, billboards, big packets and discount banners. Promotion is allowed only in the Czech Republic, Germany, Greece, Malta and Slovenia (Table 11.1). In these cases, the introduction of an EU-wide promotion ban would impose initial compliance costs on the retailers of tobacco products as they would have to refit their retail space (e.g. remove banners and billboards). Furthermore, this potential measure would deprive retailers of their regular income from promotion contracts with tobacco manufacturers.

According to two European retailers' associations, the one-off compliance costs would amount to about 19,414 euros per shop on average. Industry disclosed overall cost figures only, without their detailed break-down; thus we could not directly investigate the reliability of the overall estimates. Using the least-cost per shop solution the total initial compliance cost would be 44.1–394.2 million euros for the EU-27 (Table 11.4). This wide range of cost estimates is due to the fact that the exact number of retail outlets across the EU that would be affected is unclear.

[66] In this paragraph the euro/£ exchange rate = 0.779 (source: European Central Bank, 1st May 2008).

According to the two retailers' associations' responses that provided quantitative estimates, the ongoing compliance costs would amount to 898 euros a year per shop on average. This amount, however, constitutes a marketing cost for tobacco manufacturers (i.e. it represents a redistribution of income from manufacturers to retailers). Based on different assumptions regarding to what degree retailers would be able to replace their promotion contracts with tobacco manufacturers, the overall compliance cost for the EU-27 ranges from 0 to 70.8 million euros a year (Table 11.4). The lower bound of this range assumes close to complete substitutability of promotion contracts, while the upper bound reflects no substitutability.

Display of tobacco products in retail outlets

Restricting the display of tobacco products entails defining the size of area where customers can see tobacco products and the characteristics of displays (e.g. colourful frames, lighting). Banning the display of tobacco products means the complete or almost complete insulation of cigarette products from the customers' eyes; only a plain price list and a plain indication of the location of the products are allowed to remain.

Both restriction and prohibition impose compliance costs on retailers in terms of initial set-up costs as well as ongoing costs. Nevertheless, the amount of compliance costs varies with the technical solution used by the retailer. All else being equal, compliance with the ban on displaying tobacco products is at least as costly as the restriction. The reason is that the ban requires retailers to refit their retail space to a greater extent than the restriction would. Thus, the quantitative estimates below refer only to the ban on displaying tobacco products at the PoS, which is an upper bound estimate for the display restriction regulation.

Initial compliance costs arise as premises have to be refitted (e.g. the gantry changed). Ongoing compliance costs come about due to the increased time spent by staff on serving a client (i.e. finding the requested cigarette pack) and the increased time needed for restocking (restocking must be done concealed from consumers' eyes). Both of these ongoing compliance costs also imply increased amount of time spent on training staff.

Compliance with the display ban takes various forms depending on the characteristics of the retail area (e.g. size, height), the set-up of the counter and the availability of space for additional furniture. Retailers across the globe highlighted the fact that the most cost-efficient compliance results when retailers are free to choose the exact parameters for the solution.[67]

Based on the data reported by retailers' associations, the initial compliance cost of the display ban would amount to approximately 5,000 euros per shop on average, whereas the ongoing compliance cost would be about 10,000 euros per shop a year on average based on the cheapest available alternative. Industry only disclosed overall cost figures without their detailed break-down, thus we could not directly investigate the reliability of the overall estimates. Those per shop numbers imply an overall initial compliance cost for the EU-27 of between 321.3 and 2,297.9 million euros (Table 11.4). Following a similar method for scaling up data per shop to EU level, the overall ongoing compliance cost would be

[67] ACS, *Acs Response to the Consultation on Proposed Tobacco Control Regulations for England (under the Health Bill 2009)*, London: Association of Convenience Stores, 2009.

between 642.5 and 4,595.7 million euros a year. From the literature, it is known that compliance costs result from increased staff time required for performing standard procedures. However, the members of staff are likely to learn over time, and thus compliance costs would decrease (for a similar approach see (UK Department of Health, 2008b). Following the calculations of the UK Department of Health we assume that ongoing costs would be approximately halved owing to learning (UK Department of Health, 2008b). Thus, the overall ongoing compliance cost in the EU-27 would be between 321.3 and 2,297.9 million euros a year.[68]

Per shop data were scaled up by using the cheapest alternative available. The wide range of cost estimates is due to the fact that the exact number of retail outlets across the EU that would be affected is unclear.

There is evidence on compliance costs from the UK, Australia and Canada, both from government and industry sources. The estimates are summarised in Table 11.3. Our estimates are in line with the estimates reported by the industry (second and third rows), though they are closer to the higher end of the range of estimates. Nevertheless, our results are considerably higher than the estimates of governments (first and fourth rows).

Table 11.3: International evidence on retailer compliance costs due to display ban

Estimation source / cost type	Initial compliance costs (euros per shop)	Ongoing compliance costs (euros per shop a year)
UK – Department of Health (2009a)	1,110	330
UK – CEBR (2009)	5,550	2,380
Australia: New South Wales – AACS (2009)	2,750–5,500	5,247–10,825
Canada: Saskatchewan – Ministry of Health	611	Not available
RAND Europe	5,000	10,000

Internet sales

Tobacco retailers who responded to our compliance cost questionnaire were not engaged in cross-border internet sales of tobacco products (for a list of respondents to questionnaires see Section 2.5). Thus, no data were gathered on the exact nature and monetary value of the compliance costs of banning cross-border internet sales. It is suggested, nevertheless, that banning cross-border internet sales would result in one-off compliance cost for those retailers who engage in this type of business as they would have to close down their operations and their non-transferable investments would be lost. Ongoing compliance cost would emanate from the foregone profits of these retailers.

[68] The ranges of initial and ongoing costs at the EU-27 level are the same, which is due to the same per shop figure taken for the up scaling. Nevertheless, it must be noted that there are different cost elements behind the estimations.

Table 11.4: Summary of compliance costs of retailers for the EU-27 (initial costs: million euros, ongoing costs: million euros/year)

	RAND Europe estimate		UK Department of Health	
	Initial compliance costs	Ongoing compliance costs	Initial compliance costs	Ongoing compliance costs
Introduce minimum pack size	0	0	Not available	Not available
Harmonise legal buying age of 18 in order to avoid sales to minors (impact on vending machines)	47.5–48.9	0	Not available	Not available
Ban vending machines	Not available	Not available	Not available	Not available
Ban promotion at retail outlets	44.1–394.2	0–70.8	Not available	Not available
Ban cross-border internet sales	Not available	Not available	Not available	Not available
Ban the display of products at points of sale	321.3–2,297.9	321.3–2,297.9	9.8–87.5[69]	2.9–26[70]

11.3.2 Revenues/profits

These profits may fall in the following two ways:

- **Reduce demand.** This would reduce the scale of production, which increases the marginal cost of producing another unit of tobacco, thereby reducing profitability.
- **Increase costs of production.** For no change in price, the labelling and packaging revision will increase the marginal cost of producing another unit of tobacco, thereby leading to smaller profit margins.

Regarding changes in revenues, we can see in Table 11.5 the short-term changes in revenues and profits for each measure. Assuming the reduction in prevalence leads to a proportionate change in revenues, that would be the equivalent of self-reported, short-term revenues of the five major firms shifting from €41.888 billion (2008) to a range of €41.899–41.837 billion.

Regarding profits, the self-reported increases in the cost of production may adjust profits margins for the manufacture and sales tobacco products. From examining self-reported profits of the major cigarette firms (approximately €7.06 billion in 2008), it seems that the annual profits may be in the range of €7.051–7.062 billion.

[69] Range of estimate is obtained by multiplying the UK per shop figure with the range of available shop number estimates across the EU-27.

[70] Range of estimate is obtained by multiplying the UK per shop figure with the range of available shop number estimates across the EU-27.

Table 11.5: Potential short-term change in revenues/profits for top businesses in tobacco, by measure of sales arrangement

	Potential change in demand	Potential revenues	Potential profits
Minimum pack size (largely independent of the actual size)	0.00%	41.888	7.060
Make vending machines inaccessible to minors (below 18 years)	0.00%	41.888	7.060
Ban promotion at retail outlets	0.03%	41.899	7.062
Ban vending machines	n/a	n/a	n/a
Ban cross-border sales	n/a	n/a	n/a
Ban display of products at sale points	–0.12%	41.837	7.051

11.3.3 Employment changes

An overall reduction in demand for cigarettes and increase in costs may lead to a smaller share of employment in tobacco industry. Assuming that increased administration costs to retailers flow downwards to consumers and upwards to producers, prevalence may fall. Our estimates, as seen in Table 11.6, suggest that this might affect employment by increasing shares slightly, to decreasing upwards of approximately 18 percent.

Table 11.6: Potential short-term change in employment share due to sales arrangements measures

	Manufacturing	Wholesale of manufactured tobacco	Retail
Minimum pack size (largely independent of the actual size)	0.00%	–1.68% to 0.00%	0.00%
Make vending machines inaccessible to minors (below 18 years)	0.00%	–1.68% to 0.00%	0.00%
Ban promotion at retail outlets	0.20%	–1.69% to –0.02%	0.15% to 0.06%
Ban vending machines	n/a	n/a	n/a
Ban cross-border sales	n/a	n/a	n/a
Ban display of products at sale points	–0.11%	–1.69% to –0.02%	–0.69% to –0.29%

Using both Forecasts A and D on the average potential effect.

11.3.4 Tax revenues

Assuming full pass-through of the self-reported administration costs on to price and the responsiveness to price, there may be increases or decreases (from the measure to ban display of products at sales points) in excise duty revenues due to measures on sales arrangements (see Table 11.7).

Table 11.7: Change in total excise duty collection due to sales arrangement measures, in billions of euros and percentage difference

		Potential total excise duty collection (€ millions)	Difference between status quo and measure in 2007 (percent)
Status quo		62,088–78,527	
Sales	Minimum pack size (largely independent of the actual size)	63,540–78,526	0.00% to 2.34%

	Potential total excise duty collection (€ millions)	Difference between status quo and measure in 2007 (percent)
Make vending machines inaccessible to minors (below 18 years)	63,540–78,526	0.00% to 2.34%
Ban promotion at retail outlets	63,557–78,547	0.03% to 2.37%
Ban vending machines	n/a	n/a
Ban cross-border sales	n/a	n/a
Banned display of products at sale points	63,459–78,433	–0.12% to 2.21%

11.3.5 Direct and indirect costs of healthcare and ill health

To assess how these estimates for mortality and costs in 2027 would change as the result of changes in the prevalence of smoking in 2010 (which in turn would change as the result of change in tobacco regulation), we adopted a conservative approach, assuming that only half of the percentage change in prevalence would translate into a change in mortality and costs in 2027.

Figure 3.15 and Figure 3.16 show how any reductions in prevalence (in 2010) under those assumptions would lead to corresponding reductions in direct and indirect mortality costs in 2027.

Only for the full display ban of tobacco products do we expect a cost induced change in prevalence and thus related healthcare costs, with a possible 0.12 percent reduction in prevalence; this corresponds to healthcare cost savings of approximately €22 million in direct costs and approximately €24 million in indirect costs.

11.3.6 Summary of economic impacts

Impact type Measure	Administrative burden		Industry revenues/profits		Employment		Tax revenues		Direct and indirect costs of healthcare and ill health		Other
Make vending machines inaccessible to minors	Implies additional one-off compliance costs on tobacco retailers, approx 47.5–48.9m euros	-	No substantial impact expected	≈	Reduced sales result in reduction of employment share by 1.7% to 0% for wholesale	–	Increased tax revenue of 1,452 to 0m euros in 2020 (2007 prices)	+	No substantial impact expected	≈	None
Ban vending machines	Substantial costs for tobacco retailers using vending machines (sunk costs) could not be quantified	(–)	Loss of part of the market in some Member States, not quantified	(–)	Loss of employment in vending machine business	(–)	No substantial impact expected	≈	No substantial impact expected	≈	None
Harmonise legal buying age of 18 in order to avoid sales to minors	Potential small one-off costs for retailers for trading and adjusting	(–)	Loss of a very small part of the market in a few Member States	(–)	No substantial impact expected	≈	No substantial impact expected	≈	No substantial impact expected	≈	None
Ban promotion (sheers, billboards, big packets, discount banners, etc.) at retail outlets	Implies one-off and ongoing compliance costs for tobacco retailers: one-off costs: 44.1–394.2m euros; ongoing costs: 0–70.8m euros/year	–	No substantial impact expected	≈	Reduced sales result in change of employment share by 0.2% for manufacturers; –1.7% to 0% for wholesale; 0.2% to 0.1% for retailers	–	Increased tax revenue of 1,469 to 20m euros in 2020 (2007 prices)	+	No substantial impact expected	≈	None
Restrict the display of products at retail outlets	Implies one-off and ongoing compliance costs for tobacco retailers, lower than compliance costs of display ban	--	Reduced prevalence and increased cost lead to reduction in revenues and profits, smaller impact than impacts due to display ban	–	Reduced sales result in reduction of employment share, smaller impact than impacts due to display ban	–	Reduced tax revenue, smaller impact than impacts due to display ban	+–	Reduction in prevalence, thus decrease in healthcare costs, savings are expected to be lower than those of display ban	+	None
Ban the display of products at	Implies one-off and ongoing compliance	--	Reduced prevalence and increased cost	–	Reduced sales result in reduction of	–	Changed tax revenue between	+–	Reduction in prevalence of	+	none

Impact type / Measure	Administrative burden		Industry revenues/profits		Employment		Tax revenues		Direct and indirect costs of healthcare and ill health		Other	
PoS	costs for tobacco retailers: one-off costs: 321.3–2,297.9m euros; ongoing costs: 321.3 – 2,297.9m euros/year		lead to reduction in revenues of 51m euros and profits of 11m euros p.a.		employment share by 0.1% for manufacturers; 1.7% to 0% for wholesale; 0.7% to 0.3% for retailers		1371 and –94m euros in 2027 (2007 prices)		0.12%, corresponds to healthcare cost savings near 22m euros in direct costs and 24m euros in indirect costs			
Introduce minimum pack size	Implies no additional admin burden and compliance cost	(–)	No substantial impact expected	≈	Reduced sales result in reduction of employment share by 1.7% to 0% for wholesale	–	Increased tax revenue of 1,452 to 0m euros in 2027 (2007 prices)	+	No substantial impact expected	≈	Cost savings for industry through reduction in SKU	(+)
Introduce a standard pack size	Implies no additional admin burden and compliance cost	(–)	No substantial impact expected	≈	n.a.	( )	n.a.	( )	No substantial impact expected	≈	Cost savings for industry through reduction in SKU	(+)
Ban cross-border internet sales including the free distribution of product samples	Potential one-off and ongoing compliance cost for retailers active in cross-border sales, not quantified	(–)	n.a.	( )	n.a.	( )	n.a.	( )	n.a.	( )	None	≈

CHAPTER 12 Comparing the options

12.1 Introduction

In this chapter we combine the different measures into policy options, three of which include more or less substantive changes to the current directive, while Option 1 constitutes the baseline or no-change option and Option 2 constitutes no binding measures. In this chapter we briefly discuss the health and economic benefits of each option.

12.2 Option 1: No change

The no-change option has been described in the baseline scenario and through the discussion of the emerging problems and issues in the assessment of the five areas of change. In this section we summarise the consequences of no additional policy measures in the field of tobacco product regulation, again grouped in health and economic impacts.

12.2.1 Health impact

Even in the absence of tightened tobacco product regulation, we forecast prevalence of use to fall across the EU over the next decades – however, not necessarily in all countries equally. This result is based on a strong trend in prevalence reduction over the last decade or so, which has seen significant tobacco control policies being implemented in the EU, and the scenario may therefore overestimate the reduction in prevalence if regulatory activity in fields such as taxation and smoke-free environments is not maintained at the current level. Nevertheless tobacco attributable deaths would still remain at the very high level of around 342,000 per annum; a further 3.7 million Europeans would be suffering from lung cancer, aerodigestive cancers and COPD; and further morbidity may be linked to tobacco smoking.

Furthermore, the no-change option would not address the problems and issues reported in the first and the second reports on the application of the Tobacco Products Directive (DG SANCO, 2005, 2007b):

- New tobacco and nicotine products such as electronic cigarettes/ENDS pose uncertain risks to consumers and are currently insufficiently regulated.
- A trend of diversification of tobacco consumption towards alternative forms such as water pipe and RYO happens against a background of poor consumer understanding of the related health risks. Many smokers of these products wrongly believe that they have lower health risks than other forms of smoking, such as manufactured cigarettes.
- Some elements of the current tobacco labelling requirements are not well understood by consumers, and some are even misleading. Consumers wrongly believe, for example, that cigarettes with lower yields are less harmful than those with higher yields.
- The currently unsatisfactory situation of poor ingredient reporting from industry, which does not allow for a systematic (scientific) analysis, would remain if no further actions were taken.

- Other financial sources would need to be found to finance future work on ingredients.
- Sales arrangements that encourage impulse tobacco purchasing by consumers and do not provide adequate protection of adolescents would continue, or would be regulated in diverse ways by Member States.

12.2.2 Economic impact

Based on falling prevalence, the baseline scenario forecasts a continuing fall in employment in the tobacco manufacturing and tobacco retail sectors. In all but one of the different forecasts available, tax revenues are likely to increase despite changes in prevalence, assuming the relationship between consumption and tax revenues remains the same as in previous years. From 2027 onwards the Member States of the EU would incur direct healthcare costs of €36 billion and indirect costs of €43 billion per annum if no further reduction in prevalence rates were achieved.

Administrative burden arising from continuing reporting requirements would be continuously incurred by the tobacco industry. This is estimated to be around €1 million to €10 million for cigarette manufacture, and €0.3 million and €1.7 million for cigar manufacture per annum.

12.3 Option 2: No binding measures

The impact assessment guidelines encourage EC services to explore non-binding measures also as an alternative to binding legislation. In the case of tobacco product regulation, where a range of binding legislation is already in place, such an approach is likely to encounter difficulties as the current legislative framework could not be amended or changed. In terms of effectiveness, experience with previous non-binding measures such as the harmonised reporting formats or laboratory cooperation have not proved very successful. Against this background, no detailed list of non-binding measures has been developed by DG SANCO to be assessed in this study; nevertheless we should like to explore potential health and economic impacts briefly.

In terms of achieving positive health impacts, some impacts might be achieved by Member States implementing stricter measures on their own, as is already the case for the introduction of pictorial warnings, displays bans and restrictions or bans on vending machines. Other measures such as introducing large pictorial warnings or plain packaging would be possible only after a change in current regulations. This might lead to more diverse tobacco product regulation in the areas where the current Tobacco Products Directive allows further measures by Member States, and to no change in the areas where a revision of the directive would be required. Thus, overall, health impacts would likely be lower than in scenarios where a revision of the current directive is implemented.

More diverse national tobacco control regulations would, however, certainly have a negative impact on tobacco manufacturers across Europe. It would increase the cost of compliance as more national particularities have to be taken into account. This includes, for example, a search for relevant information on regulation and adapting products to meet national requirements, and has the potential to undermine the functioning of the single European market.

12.4 Option 3: Minimum revision

Option 3 is the first legislative option, combining measures in all areas of change. It has been designed as a minimum revision to the directive, bringing it in line with scientific and international developments. Our assessment starts with the health impact.

12.4.1 **Health impact**

Analysing this option, the strongest health impact may be expected from the introduction of mandatory pictorial warnings, which – according to a UK impact assessment – could reduce tobacco product use by at least 0.5 percent, leading to reduced mortality and morbidity (900 lives a year from 2027 and 9,300 fewer cases of lung cancer, aerodigestive cancer and COPD annually) with related savings in healthcare costs.

Especially targeted at adolescent smokers are the measures relating to underage sales, vending machines and the promotion of tobacco products in retail stores. For all these measures, positive health impacts – albeit not quantifiable ones – may be expected as these measures have been shown to influence purchasing decisions. The overall scope of the impacts will, however, remain limited as many Member States have implemented similar measures already. The changes would mean a further institutionalisation of common practice in the Member States. All but two Member States have already instituted a minimum purchasing age of 18 years, for example.

Introducing a minimum package size is also a measure designed to protect adolescent smokers. The reasoning here is that larger packets are more expensive and would therefore be less likely to be bought by cash-strapped youths. Evidence of the impact of this measure is, however, very mixed because bigger pack sizes have been shown to increase tobacco consumption; therefore we do not expect positive, population-wide health effects from this measure.

Changes in the labelling of tobacco yields will without a doubt benefit consumers, as it had been shown that quantitative yield information confuses consumers about the relative harmfulness of different tobacco products. This has to be seen against the background that the evidence is so far inconclusive on whether reduced yields in cigarettes actually result in less harm for smokers. For that reason we do not expect additional measurement methods and a further reduction of yields to have substantial health impacts. This is somewhat different for the ban on carcinogenic ingredients, which may reduce the presence of specific high-risk additives of tobacco products. There is currently, however, not sufficient knowledge about this, nor is there a common list of the most harmful ingredients.

The primary benefit of extending the scope of regulation to paraphernalia and other non-tobacco nicotine products would be to increase consumers' awareness of the risks of these products. Smokers of RYO, pipes and water pipes often wrongly believe that these products are less harmful than manufactured cigarettes. There are, however, difficulties regarding how far the current regulations could meaningfully be applied to the other product categories.

This leads us to a set of measures contained in Option 3, concerning the reporting and registration of tobacco products. While these measures do not have direct health impacts, they are set out to develop the (scientific) infrastructure to improve both scientific and regulatory knowledge about tobacco products, as well as to increase information available to consumers and thus bring about clear long-term benefits.

Table 12.1: Summary of Option 3 health impacts

Measure	Health and social impact	Effect
Scope		
Scope of the directive will be extended to include non-regulated nicotine products, non-tobacco/non-nicotine smoking products, paraphernalia and the tobacco leaf.	Could improve consumer understanding of the risks of tobacco products that are frequently used but wrongly considered less harmful by consumers. Inclusion of alternative nicotine products under tobacco regulation would increase regulators' knowledge and consumers' awareness of the risks of these products.	+
Labelling		
Make pictorial warnings mandatory	A reduction in smoking prevalence across the EU by at least 0.5% likely, would lead to around 900 fewer tobacco-related deaths in the EU and 9,300 fewer cases of lung cancer, aerodigestive cancer and COPD annually by 2027.Less literate and less educated smokers would understand health warnings better.	+
Update and enlarge warnings to 50% of both sides of the pack and place them towards the top of the pack	Reduction in smoking prevalence possible and more likely than for smaller pictures. A minimum of a 0.5% reduction of smoking prevalence across the EU by 0.5% would lead to around 900 fewer tobacco-related deaths and 9,300 fewer cases of lung cancer, aerodigestive cancer and COPD annually in the EU by 2027. Warnings will be more effective and smokers who are less literate and less educated will understand health warnings better.	+
Replace TNCO quantitative labelling with qualitative information on contents and emissions and quit-lines	Consumers would be better informed about the harms of smoking and the unintended misleading effects of quantified TNCO yield labelling.	+
Registration and market control		
Make reporting formats for product ingredients compulsory	Improved usefulness of ingredient information could lead to better protection from harmful ingredients in the future and better consumer information.	≈
Introduce fixed yearly registration fees in order to finance ingredients work; only registered products may be marketed	Improved compliance with reporting requirements and usefulness of ingredient information could lead to better protection from harmful ingredients in the future and better consumer information. Analysis of ingredients could lead to a ban on particularly harmful ingredients in the future.	≈
Introduce fines for industry in case of non-delivery of ingredients data	Improved compliance with reporting requirements and usefulness of ingredient information could lead to better protection from harmful ingredients in the future and better consumer information.	≈
Ingredients		
Ban additives that are CMRs or that form CMRs during pyrolysis in order to establish a common list of ingredients	There is some evidence, albeit limited, that some ingredients currently included in tobacco products have negative health effects on consumers. There is some general evidence, albeit qualitative, that some ingredients currently contained in tobacco products can increase addictiveness, make tobacco products more palatable and contribute to attracting young people to smoking (e.g. through flavours added to tobacco products, such as bubble gum).	(+)
Introduce an additional measurement method for TNCO (the modified ISO method) and set maximum limits accordingly	A lot of evidence points to the misleading character of such measures for two main reasons:1) the measuring methods (ISO) used to measure these yields are inherently flawed as they are based on machine readings and not on the way humans smoke; and 2) there is ample evidence that consumers assume that tobacco products with lower TNCO yield readings are less risky to their health, which is not the case – hence no matter what the limits on these yields are, this is not an effective measure to reduce the health impacts of smoking.	≈
Introduce maximum limits for other yields and ingredients	See evidence in above cell.	≈
Sales arrangements		

Introduce minimum pack size	Evidence of the impact of this measure is very mixed because bigger pack sizes have been shown to increase tobacco consumption and other evidence has pointed to smaller pack sizes increasing tobacco appeal to youths. The social impacts of these measures will also be mixed.	≈
Harmonise legal buying age of 18 in order to avoid sales to minors	Some evidence of impact of raising legal buying age on tobacco consumption by youths. However, likely to produce very small health impacts as only 20% of the EU population would be affected by raising age from 16 to 18 (all EU Member States have a minimum legal buying age of at least 16) and size of impact will depend on the extent to which youths turn to other sources to obtain tobacco products (friends, family, etc.). Social impact of the measure would impact only on youths from the age of 16 to 18.	+
Make vending machines inaccessible to minors	Small reduction of youth access to tobacco through vending machines; however, only small percentage of European population affected. Effect dependent on enforcement and youth access to alternative sources of tobacco.	+
Ban promotion (sheers, billboards, big packets, discount banners, etc.) at retail outlets	Reduction in smoking prevalence among youths in particular is likely as evidence shows promotion at PoS influences youth smoking behaviour and uptake of smoking. A similar impact might be observed, albeit smaller, on adult smokers as bans on promotion remove smoking cues. However, no easily transferable quantitative estimates on prevalence are available.	+

12.4.2 **Economic impact**

For all options, changes in prevalence – either directly induced by policies such as labelling, or as a result of increasing costs to industry – have the most wide-ranging economic impacts. For Option 3 we expect a decline in prevalence by 0.5 percent through labelling measures. Prevalence changes are likely to have an impact on industry revenue and profits (€200m and €35m), employment (–0.5 for manufacturers, retailers (–2.9 percent to –1.3 percent) and wholesalers (–1.5 percent to 0.1 percent).

Tax revenues may fluctuate in the range of –€350 million reduction or an increase of €1.1 billion if current trends of increased revenues continue. Due to labelling, induced prevalence changes in direct healthcare costs in the region of €91 million and indirect costs of mortality and morbidity of €108 million could be saved.

For industry, the economic impact of Options 3 to 5 arises out of administrative burden for manufacturers and compliance costs for retailers. A number of measures in Option 3 are likely to result in administrative burden as they require changes to the packaging and labelling of tobacco products. These occur primarily as one-off costs for the change of a label, while ongoing costs seem to be low. It is important to note that these costs do not simply add up, but the maximum cost incurred by industry will be that of the most comprehensive labelling change.

In this option these costs would range between one-off costs of €101.8 million and €198.8 million, with only marginally increased ongoing costs. Indeed, introducing qualitative TNCO labelling might increase annual running costs by between €4.8 million and €9.8 million a year. Adjustments to the reporting and registration requirements will cause additional administrative burden, but are overall relatively low, as shown. The introduction of standardised electronic reporting might even reduce the burden for tobacco manufacturers.

Due to the large number of businesses, retailers face the most substantial economic cost in adapting to measures proposed in this option. The one-off costs for retailers have been estimated to be between €44.1 million and €394.2 million, and ongoing compliance costs to be between €0 and €70.8 million a year. Another cost for retailers will be that of the introduction of age restrictions for vending machines. However, these will be relatively low (up to €48m) as many Member States already have such measures in place.

Costs that could not be quantified, due to uncertainty in the required action as well as a lack of data, include the those of reformulating products owing to changed ingredient regulation and the introduction of minimum package sizes.

Table 12.2: Summary of Option 3 economic impacts

Measure	Impact type	Administrative burden		Industry revenues/profits		Employment		Tax revenues		Direct and indirect costs of healthcare and ill health		Other	
Scope													
Scope of the directive will be extended		Reporting and labelling costs for manufacture of paraphernalia and electronic cigarettes; not quantified	(–)	Shift between tobacco products towards manufactured cigarettes and potentially approved NRTs	≈	No substantial impact expected	≈	No substantial impact expected	≈	No substantial impact expected	≈	More equal (but not identical) regulation for all nicotine products	+
Labelling													
Make pictorial warnings mandatory (no size change)		Admin burden through label change One-off costs 33.9–130.9m euros	-	Reduced prevalence and increased cost, decrease in revenues by 200m and profits reduced by 35m euros p.a.	-	Reduced sales, change of employment share by –0.5% for manufacturers, –-1.5 to 0.4 for wholesale, –2.9% to –1.3% for retailers	-	Change in tax revenue: €1,120 to – € 384m in 2027 (2007 prices)	-/+	Reduction in prevalence of 0.5% corresponds to healthcare cost savings near €91m in direct costs and €108m in indirect costs.	++	None	
Update and enlarge warnings to 50% of both sides of the pack and place them towards the top of the pack		Admin burden through label change One-off costs 101.8–198.8m euros	--	Reduced prevalence and increased cost, decrease in revenues by 200m and profits reduced by 35m euros p.a.	-	Reduced sales, change of employment share by –0.5% for manufacturers, –1.5 to 0.4 for wholesale, –2.9% to –1.3% for retailers	-	Change in tax revenue: €1,120 to – €384m in 2027 (2007 prices)	-/+	Reduction in prevalence of 0.5% corresponds to healthcare cost savings near €91m in direct costs and €108m in indirect costs.	++	None	
Replace TNCO quantitative labelling with qualitative information on contents and emissions and quit-lines		On-off admin burden through label change, minor costs Ongoing admin burden saving, 4.8 – 9.8m euros/year	+	Reduced prevalence and increased cost, increase in revenues by 1m euros p.a. and no change to profits	+	Reduced sales, change of employment share by –0.4% for manufacturers, –1.5 to 0.4 for wholesale, –2.9% to –1.2% for retailers	-	Change in tax revenue: €1,452 to €0m in 2020 (2007 prices)	-/+	No substantial impact expected	≈	None	

Measure	Impact type	Administrative burden		Industry revenues/profits		Employment		Tax revenues		Direct and indirect costs of healthcare and ill health		Other	
Registration and market control													
Make reporting formats for product ingredients compulsory		Additional one-off admin burden for tobacco manufacturers: 0.1 –0.5m euros	-	No substantial impact expected	≈	No substantial impact expected	≈	No substantial impact expected	≈	No substantial impact expected	≈	Potential savings through standardised and electronic reporting	(+)
Introduce fixed yearly registration fees in order to finance ingredients work; only registered products may be marketed		Industry must pay fee, but overall expected to be low	(–)	No substantial impact expected	≈	No substantial impact expected	≈	No substantial impact expected	≈	No substantial impact expected	≈	None	
Introduce fines for industry in case of non-delivery of ingredients data		No substantial impact expected, and can be avoided by business	(≈)	No substantial impact expected	≈	No substantial impact expected	≈	No substantial impact expected	≈	No substantial impact expected	≈	None	

Measure	Impact type	Administrative burden		Industry revenues/profits		Employment		Tax revenues		Direct and indirect costs of healthcare and ill health		Other	
Ingredients and yields													
Ban additives that are CMRs or that form CMRs during pyrolysis in order to establish a common list of ingredients		Product reformulation and adjustment costs for industry	(–)	No substantial impact expected	≈	No substantial impact expected		No substantial impact expected	≈	No substantial impact expected	≈	None	
Introduce an additional measurement method for TNCO (the modified ISO method) and set maximum limits accordingly		€1.1m– €10.2m for running second measurement method One-off compliance cost from production process adjustment and product repositioning in the market	–	No substantial impact expected	≈	No substantial impact expected	≈	No substantial impact expected	≈	No substantial impact expected	≈	None	≈
Introduce maximum limits for other yields and ingredients		One-off compliance cost for production process adjustment and product repositioning in the market	(–)	No substantial impact expected	≈	No substantial impact expected	≈	No substantial impact expected	≈	No substantial impact expected	≈	None	≈

Measure	Impact type	Administrative burden		Industry revenues/profits		Employment		Tax revenues		Direct and indirect costs of healthcare and ill health		Other	
Sales arrangements													
Introduce minimum pack size		Implies no additional admin burden and compliance cost	(–)	No substantial impact expected	≈	Reduced sales result in reduction of employment share by 1.7% to 0% for wholesale	-	Increased tax revenue of 1,452–0m euros in 2027 (2007 prices)	+	No substantial impact expected	≈	Cost savings for industry through reduction in SKU	(+)
Harmonise legal buying age of 18 in order to avoid sales to minors		Potential small one-off costs for retailers for trading and adjusting	(–)	Loss of a very small part of the market in a few Member States	(–)	No substantial impact expected	≈	No substantial impact expected	≈	No substantial impact expected	≈	None	
Make vending machines inaccessible to minors		Implies additional one-off compliance costs for tobacco retailers, approx 47.5–48.9m euros	-	No substantial impact expected	≈	Reduced sales result in reduction of employment share by 1.7% to 0% for wholesale	-	Increased tax revenue of 1,452 to 0m euros in 2020 (2007 prices)	+	No substantial impact expected	≈	None	
Ban promotion (sheers, billboards, big packets, discount banners, etc.) at retail outlets		Implies one-off and ongoing compliance costs for tobacco retailers: one-off costs: 44.1–394.2m euros; ongoing costs: 0–70.8m euros/year	-	No substantial impact expected	≈	Reduced sales result in change of employment share by 0.2% for manufacturers; –1.7% to 0% for wholesale; 0.2% to 0.1% for retailers	-	Increased tax revenue of 1,469 to 20m euros in 2020 (2007 prices)	+	No substantial impact expected	≈	None	

12.5 Option 4: Revision of the directive bringing it in line with scientific and international developments and strengthening the protection of vulnerable groups

Option 4 is the second option that requires changes to the legislative framework. The suggested measures have been in particular designed to bring the directive in line with scientific and international development and strengthening the protection of vulnerable groups – in particular adolescents. Again we shall start by looking at the health impacts of this option, however focusing only on the new elements in it, indicated by the shading of the relevant rows in Table 12.3.

12.5.1 Health impact

In this option even stronger labelling requirements are suggested, with the mandatory introduction of pictorial warnings covering 75 percent of the pack in combination with generic or plain packaging. These two measures are likely to have an even stronger impact on prevalence rate, so the conservatively estimated 0.5 percent reduction in prevalence – leading to reduced mortality of 900 lives and 9,300 fewer cases of lung cancer, aerodigestive cancer and COPD annually, from 2027 with related savings in healthcare costs – will be the lower boundary of the expected effect.

Measures targeted at protecting adolescents from smoking are further strengthened in this option by a complete ban on vending machines for adolescents, which would solve the enforcement problems related to age restrictions on vending machines and could lead to small reductions in youth smoking. It has, however, to be stated that this effect will be far less than the current percentage of youths using vending machines. They are likely to compensate at least partially by using other sources of supply such as older friends and acquaintances.

A ban on cross-border internet sales of tobacco products may help Member States to enforce their wider tobacco control policies, in particular taxes and age restrictions. Overall, internet purchases of tobacco products constitute only a very small proportion of tobacco purchases; therefore we do not expect this measure to have a measurable health effect.

Widening the definition of ingredients to cover the tobacco leaf, as well as introducing higher market control fees to cover the costs of ingredient work, will contribute to a better understanding of the harmfulness of specific ingredients and the tobacco leaf, but health impacts would be achieved in the long term only if further action is taken on the basis of this information.

Finally, this option contains a measure to decrease the yield limits of tobacco products continuously. As discussed earlier, given the evidence that shows that smokers compensate for lower yield cigarettes by smoking more intensely or more, there is little evidence that such a measure would produce positive health impacts on consumers.

The economic impacts of Option 4 are only slightly higher than those for Option 3, with slightly increased costs for manufacturers and retailers, and with the same effect on smoking prevalence.

Table 12.3: Summary of Option 4 health impacts

Measure	Health and social impact	Effect
Scope		
Scope of the directive will be extended to include non-regulated nicotine products, non-tobacco/non-nicotine smoking products, paraphernalia and the tobacco leaf	Could improve consumer understanding of the risks of tobacco products that are frequently smoked but that consumers wrongly consider less harmful. Inclusion of alternative nicotine products under tobacco regulation would increase regulators' knowledge about and consumers' awareness of the risks of these products.	+
Labelling		
Make pictorial warnings mandatory	A reduction of smoking prevalence across the EU by at least 0.5% likely, leading to around 900 fewer tobacco-related deaths and 9,300 fewer cases of lung cancer, aerodigestive cancer and COPD annually in the EU by 2027. Less literate and less educated smokers will understand health warnings better.	+
Further increase of the size of warnings to 75% of both sides of the pack	Reduction in smoking prevalence possible and more likely than for smaller pictures. A minimum of a percentage reduction of smoking prevalence across the EU of 0.5% would lead to around 900 fewer tobacco-related deaths and 9,300 fewer cases of lung cancer, aerodigestive cancer and COPD p.a. in the EU by 2027. Warnings will be more effective, and less literate and less educated smokers will understand health warnings better.	++
Introduce generic packaging	Reduction of smoking prevalence through reduced brand and pack attractiveness likely, but effect currently not quantifiable on a population level. Warning labels would be more visible and consumers would benefit from readability of warnings.	++
Replace TNCO quantitative labelling with qualitative information on contents and emissions and quit-lines	Consumers would be better informed about the harms of smoking and the unintended misleading effects of quantified TNCO yield labelling.	+
Registration and market control		
Make reporting formats for product ingredients compulsory	Improved usefulness of ingredient information may lead to better protection from harmful ingredients in the future and better consumer information.	≈
Introduce market control fees proportionate to the number of outlets the product is sold in	Improved compliance with reporting requirements and usefulness of ingredient information could lead to better protection from harmful ingredients in the future and better consumer information. Analysis of ingredients may lead to a ban on particularly harmful ingredients in the future.	≈
Introduce fines for industry in the case of non-delivery of ingredients data	Improved compliance with reporting requirements and usefulness of ingredient information may lead to better protection from harmful ingredients in the future and better consumer information.	≈
Ingredients		
Ban additives that are CMRs or that form CMRs during pyrolysis in order to establish a common list of ingredients	There is some general evidence, albeit qualitative, that some ingredients currently contained in tobacco products may increase addictiveness, make tobacco products more palatable and contribute to attracting young people to smoking (e.g. through flavours added to tobacco products, such as bubble gum).	(+)
Introduce an additional measurement method for TNCO (the modified ISO method) and set maximum limits accordingly	A lot of evidence points to the misleading character of such measures for two main reasons: 1) the measuring methods (ISO) used to measure these yields are inherently flawed as they are based on machine readings and not on the way humans smoke; and 2) there is ample evidence that consumers assume that tobacco products with lower TNCO yield readings are less risky to their health, which is not the case; hence no matter what the limits on these yields are, this is not an effective measure to reduce the health impacts of smoking.	≈
Continuously decrease the maximum limits for TNCO and other yields and ingredients	See evidence in above cell.	≈
Refine the definition of ingredients to include the tobacco leaf	There is no evidence of this measure having been applied in any country. However, there is evidence that the tobacco leaf contains ammonia, which is a substance that has been found to increase the addictiveness of tobacco (ASPECT Consortium, 2004p.3). Ammonia is found naturally in the tobacco plant and also added to the growing process; therefore including the tobacco leaf in a definition of ingredients would contribute to informing consumers better about what they are consuming.	≈
Sales arrangements		

Introduce minimum pack size	Evidence of the impact of this measure is very mixed because bigger pack sizes have been shown to increase tobacco consumption and other evidence has pointed to smaller pack sizes increasing tobacco appeal to youths. The social impacts of these measures will also be mixed.	≈
Harmonise legal buying age of 18 in order to avoid sales to minors	Some evidence of impact of raising legal buying age on tobacco consumption by youths. However, likely to produce very small health impacts as only 20% of the EU population would be affected by raising age from 16 to 18 (all EU Member States have a minimum legal buying age of at least 16), and size of impact will depend on the extent to which youths turn to other sources to obtain tobacco products (friends, family, etc.). Social impact of the measure would be limited to youths from the age of 16 to 18.	+
Ban vending machines	Reduction of youth access to tobacco and reduction in smoking prevalence of youths in particular is more likely to affect consumption than restrictions on vending machines, although no quantifiable estimate of this impact has been found. However, only small percentage of European population affected. Effect dependent on enforcement and youth access to alternative sources of tobacco. This measure will be beneficial to youths in particular as it would remove an easy source of tobacco for them, although youths typically use a range of other sources to purchase tobacco products. Some adult smokers will be affected as they won't be able to access vending machines as a source of tobacco products, but effect will be minimal as they can legally turn to other sources of purchase (e.g. retail shops). No negative social impact foreseen.	+
Ban promotion (sheers, billboards, big packets, discount banners, etc.) at retail outlets	Reduction in smoking prevalence among youths in particular is likely as evidence shows promotion at PoS influences youth smoking behaviour and uptake of smoking. A similar impact may be observed, albeit smaller, on adult smokers as bans on promotion remove smoking cues. However, no easily transferable quantitative estimates on prevalence are available.	+
Restrict the display of products at retail outlets	Reduction in smoking prevalence among youths in particular is likely as evidence shows promotion at PoS influences youth smoking behaviour and uptake of smoking. A similar impact may be observed, albeit smaller, on adult smokers as bans on promotion remove smoking cues. Impact likely to be strongest on youths, although some adult smokers and would-be quitters could also be positively impacted. No negative social impact foreseen. Effect would be enhanced through cost–price effect, reducing prevalence by 0.12% and resulting in 200 fewer deaths and 2,200 fewer cases of lung cancer, aerodigestive cancer and COPD annually by 2027.	++
Ban cross-border internet sales including the free distribution of product samples	Likely to have some indirect health and social impacts although unquantifiable due to the dependence of this measure on stringent enforcement of the ban and the overall limited extent of on-line cross-border sales.	≈

12.5.2 **Economic impact**

The economic impacts of Option 4 are only slightly higher than those for Option 3, primarily in the form of increased costs for manufacturers and retailers, and with the same effect on smoking prevalence.

For Option 4 we thus expect a decline in prevalence of 0.5 percent through labelling measures. Prevalence changes are likely to have an impact on industry revenue and profits (€200m and €35m), employment (–0.5 for manufacturers, retailers (–2.9 percent to –1.3 percent) and wholesalers (–1.5 percent to 0.1 percent).

Tax revenues may fluctuate in the range of –€350 million reduction or an increase of €1.1 billion if current trends of increased revenues continue. Due to labelling-induced smoking prevalence changes, savings in direct healthcare costs in the region of €91 million, and in indirect costs of mortality and morbidity of €108 million, may be made.

Labelling costs for industry may be expected to stay the same between options as they already include the costs incurred for a substantial redesign of the labels. However, the costs for retailers of implementing restrictions on the display of tobacco products are potentially substantial.

In this option there are, however, important cost impacts that could not be quantified. The first are the costs of introducing a comprehensive ban on vending machines across Europe, which are likely to be substantial in terms of sunk costs, but which could be reduced by long transition periods. The second important cost that could not be quantified concerns tobacco manufacturers' brand equity, which would be substantially reduced if plain packaging were introduced and other possibilities of maintaining brands – such as in-store advertising – were banned as well.

Table 12.4: Summary of economic impacts of Option 4

Measure	Impact type	Administrative burden		Industry revenues/profits		Employment		Tax revenues		Direct and indirect costs of healthcare and ill health		Other	
Scope													
Scope of the directive will be extended		Reporting and labelling costs for manufacturer of paraphernalia and electronic cigarettes; not quantified	(–)	Shift between tobacco products towards manufactured cigarettes and potentially approved NRTs	≈	No substantial impact expected	≈	No substantial impact expected	≈	No substantial impact expected	≈	More equal (but not identical) regulation for all nicotine products	+
Labelling													
Make pictorial warnings mandatory (no size change)		Admin burden through label change One - off costs 33.9 - 130.9m euros	–	Reduced prevalence and increased cost, decrease in revenues by 200m and profits reduced by 35m euros p.a.	–	Reduced sales, change of employment share by - 0.5% for manufacturers, - 1.5 to 0.4% for wholesale, - 2.9% to - 1.3% for retailers	–	Change in tax revenue: €1,120 to - € 384m in 2027 (2007 prices)	– /+	Reduction in prevalence of 0.5% corresponds to healthcare cost savings near €91m in direct costs and €108m in indirect costs	++	None	
Further increase of the size of warnings to 75% of both sides of the pack		Admin burden through label change One-off costs 101.8 - 198.8m euros	–	Reduced prevalence and increased cost, decrease in revenues by 200m and profits reduced by 35m euros p.a.	–	Reduced sales, change of employment share by - 0.5% for manufacturers, - 1.5 to 0.4% for wholesale, - 2.9% to –1.3% for retailers	–	Change in tax revenue: €1,120 to - €384m in 2027 (2007 prices)	– /+	Reduction in prevalence of 0.5% corresponds to healthcare cost savings near €91m in direct costs and €108m in indirect costs	++	Impact on brand equity for branded producers	(–)
Further increase of the size of warnings to 100% of the back of the pack		Admin burden through label change One-off costs 101.8 - 198.8m euros	–	Reduced prevalence and increased cost, decrease in revenues by 200m and profits reduced by 35m euros p.a.	–	Reduced sales, change of employment share by - 0.5% for anufacturers, - 1.5 to 0.4 for wholesale, –2.9% to – 1.3% for retailers	–	Change in tax revenue: €1,120 to - €384m in 2027 (2007 prices)	– /+	Reduction in prevalence of 0.5% corresponds to healthcare cost savings near €91m in direct costs and €108m in indirect costs	++	Impact on brand equity for branded producers; commoditisation of tobacco products	(–)
Introduce generic packaging		Admin burden through label change One-off costs 32.5 - 125.4m euros	–	Reduced prevalence and increased cost, decrease in revenues by 200m and profits reduced by 35m euros p.a.	–	Reduced sales, change of employment share by - 0.5% for manufacturers, –1.5 to 0.4% for wholesale, - 2.9% to - 1.3% for	–	Change in tax revenue: €1,120 to - €384m in 2020 (2007 prices)	– /+	Reduction in prevalence of 0.5% corresponds to healthcare cost savings near €91m in direct costs and €108m in indirect	++	Strong impact on brand equity for branded producers; commoditisation of tobacco products	–

Measure / Impact type	Administrative burden		Industry revenues/profits		Employment		Tax revenues		Direct and indirect costs of healthcare and ill health		Other	
					retailers				costs			
Replace TNCO quantitative labelling with qualitative information on contents and emissions and quitlines	One-off admin burden through label change, minor costs Ongoing admin burden saving, 4.8 - 9.8m euros/year	+	Reduced prevalence and increased cost, increase in revenues by 1m euros p.a. and no change to profits	+	Reduced sales, change of employment share by - 0.4% for manufacturers, - 1.5 to 0.4 for wholesale, - 2.9% to - 1.2% for retailers	–	Change in tax revenue: €1,452 to €0m in 2020 (2007 prices)	– /+	No substantial impact expected	≈	None	
Registration and market control												
Make reporting formats for product ingredients compulsory	Additional one-off admin burden for tobacco manufacturers: 0.1 - 0.5m euros	–	No substantial impact expected	≈	No substantial impact expected	≈	No substantial impact expected	≈	No substantial impact expected	≈	Potential savings through standardised and electronic reporting	(+)
Introduce market control fees proportionate to the number of outlets the product is sold in	Costs for maintaining and delivering register of retailers	(–)	n.a.	( )	n.a.	( )	n.a.	()	n.a.	()	Industry must pay market control fees	(–)
Introduce fines for industry in case of non-delivery of ingredients data	No substantial impact expected, and can be avoided by business	(≈)	No substantial impact expected	≈	No substantial impact expected	≈	No substantial impact expected	≈	No substantial impact expected	≈	None	

Measure	Impact type	Administrative burden		Industry revenues/profits		Employment		Tax revenues		Direct and indirect costs of healthcare and ill health		Other	
Ingredients and yields													
Ban additives that are CMRs or that form CMRs during pyrolysis in order to establish a common list of ingredients		Product reformulation and adjustment costs for industry	(–)	No substantial impact expected	≈	No substantial impact expected		No substantial impact expected	≈	No substantial impact expected	≈	None	
Introduce an additional measurement method for TNCO (the modified ISO method) and set maximum limits accordingly		€1.1m–€10.2m for running second measurement method One-off compliance cost from production process adjustment and product repositioning in the market	–	No substantial impact expected	≈	No substantial impact expected	≈	No substantial impact expected	≈	No substantial impact expected	≈	None	≈
Continuously decrease the maximum limits for TNCO and other yields and ingredients		One-off compliance cost from production process adjustment and product repositioning in the market	(–)	No substantial impact expected	≈	No substantial impact expected	≈	No substantial impact expected	≈	No substantial impact expected	≈	None	≈
Refine the definition of ingredients to include the tobacco leaf		Costs for new reporting and testing processes and for ensuring characteristics of tobacco used	(+)	No substantial impact expected	≈	No substantial impact expected	≈	No substantial impact expected		No substantial impact expected		None	≈

Measure	Impact type	Administrative burden		Industry revenues/profits		Employment		Tax revenues		Direct and indirect costs of healthcare and ill health		Other	
Sales arrangements													
Introduce minimum pack size		Implies no additional admin burden and compliance cost	(–)	No substantial impact expected	≈	Reduced sales result in reduction of employment share by 1.7% to 0% for wholesale	–	Increased tax revenue of 1,452 to 0m euros in 2027 (2007 prices)	+	No substantial impact expected	≈	Cost savings for industry through reduction in SKU	(+)
Harmonise legal buying age of 18 in order to avoid sales to minors		Potential small one-off costs for retailers for trading and adjusting	(–)	Loss of very small part of the market in a few Member States	(–)	No substantial impact expected	≈	No substantial impact expected	≈	No substantial impact expected	≈	None	
Ban vending machines		Substantial costs for tobacco retailers, using vending machines (sunk costs) could not be quantified	(–)	Loss of part of the market in some Member States, not quantified	(–)	Loss of employment in vending machine business	(–)	No substantial impact expected	≈	No substantial impact expected	≈	None	≈
Ban promotion (sheers, billboards, big packets, discount banners, etc.) at retail outlets		Implies one-off and ongoing compliance costs for tobacco retailers: one-off costs: 44.1–394.2m euros; ongoing costs: 0–70.8m euros/year	-	No substantial impact expected	≈	Reduced sales result in change of employment share by 0.2% for manufacturers; –1.7% to 0% for wholesale; 0.2% to 0.1% for retailers	–	Increased tax revenue of 1,469 to 20m euros in 2020 (2007 prices)	+	No substantial impact expected	≈	None	
Restrict the display of products at retail outlets		Implies one-off and ongoing compliance costs for tobacco retailers Lower than compliance costs of display ban	–	Reduced prevalence and increased cost lead to reduction in revenues and profits, smaller impact than impacts due to display ban	–	Reduced sales result in reduction of employment share, smaller impact than impacts due to display ban	–	Reduced tax revenue, smaller impact than impacts due to display ban	+ –	Reduction in prevalence, thus decrease in healthcare costs, savings expected to be lower than that of display ban	+	None	
Ban cross-border internet sales including free distribution of product samples		Potential one-off and ongoing compliance cost for retailers active in cross-border sales Not quantified	(–)	n.a.	( )	n.a.	( )	n.a.	( )	n.a.	( )	None	≈

12.6 Option 5: Revision of the directive with the objective of strengthening product regulation and full implementation of the polluter pays principle

In Option 5 a further strengthening of the directive is foreseen, with the objective of strengthening the product regulation and full implementation of the polluter pays principle.

12.6.1 Health impacts

Option 5 is characterised by a further tightening of the labelling requirements, with pictorial health warnings covering most of the package surface of a plain tobacco pack. Compared to the other options, this is likely to have the largest health impact, which is likely to exceed the conservative estimate we used in the quantitative estimation. For this option pictorial warnings are very large and there is no possibility of branding or other distracting designs. The success of producing inserts is less certain. There is only sparse effectiveness on the measure, and information, if provided in a text heavy format, may be less effective in reaching less literate smokers.

The largest health effects of all options may, however, be expected through two different approaches for internalising the external costs of smoking: through fees or by making cigarette manufacturers liable for the external costs engendered by tobacco consumption. If the currently approximate €100 billion in indirect costs are passed on to tobacco manufacturers, that will have a substantial impact on the price of tobacco products and thus on the prevalence of tobacco use. Our calculation estimated a 25 percent reduction in prevalence, which would result in a reduction of around 45,000 in smoking-related deaths and 465,000 fewer cases of lung cancer, aerodigestive cancer and COPD annually by 2027.

The complete ban of tobacco promotion and displays in store is likely to have a positive impact on adolescent smoking, and to a lesser extent also on adult smokers – in particular those attempting to quit or stay quit, as all smoking cues would be removed from stores. As the implementation of this measure is connected to considerable costs, this would have an additional impact on the price of tobacco products, and could lead to further reductions in prevalence, estimated at 0.12 percent and resulting in 200 fewer deaths and 2,200 fewer cases of lung cancer, aerodigestive cancer and COPD annually by 2027.

From the introduction of a minimum package size, we do not expect population-wide health effects as there is conflicting evidence on the health impact of such a measure.

Further measures in this final option concern the infrastructure to collect and analyse ingredients, which may have long-term positive health impacts.

Table 12.5: Summary of health impacts of Option 5

Measure	Health and social impact	Effect
Scope		
Scope of the directive will be extended to include non-regulated nicotine products, non-tobacco/non-nicotine smoking products, paraphernalia and the tobacco leaf	May improve consumer understanding of the risks of tobacco products that are frequently smoked but that consumers wrongly consider less harmful. Inclusion of alternative nicotine products under tobacco regulation would increase regulators' knowledge about and consumers' awareness of the risks of these products.	+
Labelling		
Make pictorial warnings mandatory	A reduction in smoking prevalence across the EU by at least 0.5% likely, which would lead to around 900 fewer tobacco-related deaths and 9,300 fewer cases of lung cancer, aerodigestive cancer and COPD annually in the EU by 2027. Less literate and less educated smokers will understand health warnings better.	+
Further increase of the size of warnings to 75% of both sides of the pack	Reduction in smoking prevalence possible and more likely than for smaller pictures. A minimum of a 0.5% reduction in smoking prevalence across the EU by 0.5% would lead to around 900 fewer tobacco-related deaths and 9,300 fewer cases of lung cancer, aerodigestive cancer and COPD annually in the EU by 2027. Warnings will be more effective and less literate and less educated smokers will understand health warnings better.	++
Further increase the size of the warnings on the back of the pack to 100%	Reduction in smoking prevalence possible and more likely than for smaller pictures. A minimum of a 0.5% reduction in smoking prevalence across the EU by 0.5% would lead to around 900 fewer tobacco-related deaths and 9,300 fewer cases of lung cancer, aerodigestive cancer and COPD annually in the EU by 2027. Warnings will be more effective and less literate and less educated smokers will understand health warnings better.	++
Introduce generic packaging	Reduction of smoking prevalence through reduced brand and pack attractiveness likely, but effect currently not quantifiable on a population level. Warning labels would be more visible and consumers would benefit from readability of warnings.	++
Introduce inserts with supplementary information (e.g. on the potential risks)	Better consumer information on harms of tobacco smoking. Lower socioeconomic groups, in particular those consumers who are less literate and less educated, may not be able to understand fully the information presented in the inserts. This will to a great extent depend on the way this information is conveyed.	(+)
Replace TNCO quantitative labelling with qualitative information on contents and emissions and quit-lines	Consumers would be informed better about the harms of smoking and the unintended misleading effects of quantified TNCO yield labelling.	+
Registration and market control		
Make reporting formats for product ingredients compulsory	Improved usefulness of ingredient information could lead to better protection from harmful ingredients in the future and better consumer information,	≈
Introduce market control fees proportionate to the number of outlets the product is sold in	Improved compliance with reporting requirements and usefulness of ingredient information could lead to better protection from harmful ingredients in the future and better consumer information. Analysis of ingredients could lead to overall 'healthier' cigarette consumption in the future.	≈
Introduce fines for industry in case of non-delivery of ingredients data	Improved compliance with reporting requirements and usefulness of ingredient information could lead to better protection from harmful ingredients in the future and better consumer information.	≈
Integrate the health costs of smoking into the calculation of the fees	Integration of healthcare costs would lead to a substantial increase in price of tobacco products. A possible 25% reduction in prevalence could prevent 45,000 smoking-related deaths and 465,000 cases of lung cancer, aerodigestive cancer and COPD annually by 2027.	++
Based on the polluter pays principle, internalise the external health costs of smoking by requiring full liability and payment of the health costs of smoking by the tobacco industry to national health systems	Integration of healthcare costs would lead to a substantial increase in price of tobacco products. A possible 25% reduction in prevalence could prevent 45,000 smoking-related deaths and 465,000 cases of lung cancer, aerodigestive cancer and COPD annually by 2027.	++
Ingredients		
Ban additives that are CMRs, or that form CMRs during pyrolysis,	There is some general evidence, albeit qualitative, that some ingredients currently contained in tobacco products may increase addictiveness, make	(+)

in order to establish a common list of ingredients	tobacco products more palatable and contribute to attracting young people to smoking (e.g. through flavours added to tobacco products, such as bubble gum).	
Introduce an additional measurement method for TNCO (the modified ISO method) and set maximum limits accordingly	A lot of evidence points to the misleading character of such measures, for two main reasons:1) the measuring methods (ISO) used to measure these yields are inherently flawed as they are based on machine readings, not on the way humans smoke; and 2) there is ample evidence that consumers assume that tobacco products with lower TNCO yield readings are less risky to their health, which is not the case; hence no matter what the limits on these yields are, this is not an effective way to reduce the health impacts of smoking.	≈
Continuously decrease the maximum limits for TNCO and other yields and ingredients	See evidence in above cell.	≈
Refine the definition of ingredients to include the tobacco leaf	There is no evidence of this measure having been applied in any country. However, there is evidence that the tobacco leaf contains ammonia, which is a substance that has been found to increase the addictiveness of tobacco (ASPECT Consortium, 2004p.3). Ammonia is found naturally in the tobacco plant and also added to the growing process. Thus, including the tobacco leaf in a definition of ingredients would contribute to informing consumers better about what they are consuming.	≈
Set up an EC laboratory for evaluation of tobacco and smoking products	An EC laboratory could improve the knowledge base for regulating tobacco products, and thus have indirect health effects in the future.	(+)
Sales arrangements		
Introduce a standard pack size	Evidence of the impact of this measure is very mixed because bigger pack sizes have been shown to increase tobacco consumption and other evidence has pointed to smaller pack sizes increasing tobacco appeal to youths. The social impacts of this measures will also be mixed because they impact differently on different groups (youths and adult smokers).	≈
Harmonise legal buying age of 18 in order to avoid sales to minors	Some evidence of impact of raising legal buying age on tobacco consumption by youths. However, likely to produce very small health impacts as only 20% of the EU population would be affected by raising age from 16 to 18 (all EU Member States have a minimum legal buying age of at least 16), and size of impact will depend on the extent to which youths turn to other sources to obtain tobacco products (friends, family, etc.). Social impact of the measure would affect only youths from the age of 16 to 18.	+
Ban vending machines	Reduction of youth access to tobacco and reduction in smoking prevalence of youths in particular is more likely to affect consumption than restrictions on vending machines, although no quantifiable estimate of this impact has been found. However, only small percentage of European population affected. Effect dependemt on enforcement and youth access to alternative sources of tobacco. This measure would be beneficial to youths in particular as it would remove an easy source of tobacco for them, although youths typically use a range of other sources to purchase tobacco products. Some adult smokers will be affected as they won't be able to access vending machines as a source of tobacco products, but effect will be minimal as they can legally turn to other sources of purchase (e.g. retail shops). No negative social impact foreseen.	+
Ban promotion (sheers, billboards, big packets, discount banners, etc.) at retail outlets	Reduction in smoking prevalence among youths in particular is likely as evidence shows promotion at PoS influences youth smoking behaviour and uptake of smoking. A similar impact may be observed, albeit smaller, on adult smokers, as bans on promotion remove smoking cues. However, no easily transferable quantitative estimates on prevalence are available.	+
Ban the display of products at PoS	Reduction in smoking prevalence among youths in particular is likely as evidence shows promotion at PoS influences youth smoking behaviour and uptake of smoking. A similar impact may be observed, albeit smaller, on adult smokers as bans on promotion remove smoking cues. Note that measures 3, 4 and 5 are interlinked. The strongest measure, which would consist of a complete ban on PoS promotions and displays, would have the strongest health impact of all the measures as it would remove all smoking cues from the sight of consumers. Impact likely to be strongest on youths although some adult smokers and would-be quitters may also be positively affected. No negative social impact foreseen.	++
Ban cross-border internet sales, including the free distribution of product samples	Likely to have some indirect health and social impacts although unquantifiable due to the dependence of this measure on stringent enforcement of the ban and the overall limited extent of on-line cross-border sales.	≈

12.6.2 **Economic impact**

Without a doubt, Option 5 would have the most substantial economic impacts, in terms of costs for industry as well as in terms of potential economic benefits such as saved healthcare costs. This is due to the idea of transferring healthcare costs to the tobacco manufacturers, who would in turn be required to increase the price of their products, leading to an overall reduction in prevalence.

Using the data available, we would expect a 25 percent reduction in prevalence, with related reduction in revenues of €10 billion; a reduction in profits of €1.7 billion; and reduced employment for manufacturers of between 13 percent and 17 percent, 15 percent to 22 percent for wholesalers and 50 percent to 70 percent for retailers.

Lost tax revenues would constitute around €15 billion (a reduction of around 24 percent), while direct healthcare cost of €4.5 billion and indirect costs of €5 billion to €6 billion might be saved annually.

We expect the impacts of labelling costs and changes in prevalence related to these to be along the same lines as for the other two regulatory options, but with even higher one-off and ongoing costs for banning the display of tobacco products in retail stores. These have been estimated as set-up costs of between €321 million and €2,297 million, with ongoing costs of around the same scale.

In addition to these impacts, other important unquantified impacts include the cost of setting up an EC laboratory to conduct ingredient work, which would be likely to be transferred to industry through fees.

Table 12.6: Summary of economic impacts of Option 5

Measure	Impact type	Administrative burden		Industry revenues/profits		Employment		Tax revenues		Direct and indirect costs of healthcare and ill health		Other	
Scope													
Scope of the directive will be extended		Reporting and labelling costs for manufacturer of paraphernalia and electronic cigarettes; not quantified	(–)	Shift between tobacco products towards manufactured cigarettes and potentially approved NRTs	≈	No substantial impact expected	≈	No substantial impact expected	≈	No substantial impact expected	≈	More equal (but not identical) regulation for all nicotine products	+

Measure	Impact type	Administrative burden		Industry revenues/profits		Employment		Tax revenues		Direct and indirect costs of healthcare and ill health		Other	
Labelling													
Make pictorial warnings mandatory (no size change)		Admin burden through label change One-off costs 33.9–130.9m euros	–	Reduced prevalence and increased cost, decrease in revenues of 200m and profits reduced by 35m euros p.a.	–	Reduced sales, change of employment share by –0.5% for manufacturers, –1.5 to 0.4 for wholesale, –2.9% to –1.3% for retailers	–	Change in tax revenue: €1,120 to –€ 384m in 2027 (2007 prices)	– /+	Reduction in prevalence of 0.5% corresponds to healthcare cost savings near €91m in direct costs and €108m in indirect costs.	++	None	≈
Further increase of the size of warnings to 75% of both sides of the pack		Admin burden through label change One-off costs 101.8–198.8m euros	--	Reduced prevalence and increased cost, decrease in revenues by 200m and profits reduced by 35m euros p.a.	–	Reduced sales, change of employment share by –0.5% for manufacturers, –1.5 to 0.4 for wholesale, –2.9% to –1.3% for retailers	-	Change in tax revenue: €1,120 to –€ 384m in 2027 (2007 prices)	- /+	Reduction in prevalence of 0.5% corresponds to healthcare cost savings near €91m in direct costs and €108m in indirect costs.	++	Impact on brand equity for branded producers	(–)
Further increase in the size of warnings to 100% of the back of the pack		Admin burden through label change One-off costs 101.8–198.8m euros	--	Reduced prevalence and increased cost, decrease in revenues by 200m and profits reduced by 35m euros p.a.	-	Reduced sales, change of employment share by –0.5% for manufacturers, –1.5 to 0.4 for wholesale, –2.9% to –1.3% for retailers	-	Change in tax revenue: €1,120 to –€ 384m in 2027 (2007 prices)	- /+	Reduction in prevalence of 0.5% corresponds to healthcare cost savings near €91m in direct costs and €108m in indirect costs.	++	Impact on brand equity for branded producers; commoditisation of tobacco products	(–)
Introduce generic packaging		Admin burden through label change One-off costs 32.5–125.4m euros	--	Reduced prevalence and increased cost, decrease in revenues by 200m and profits reduced by 35m euros p.a.	-	Reduced sales, change of employment share by –0.5% for manufacturers, –1.5 to 0.4 for wholesale, –2.9% to –1.3% for retailers	-	Change in tax revenue: €1,120 to –€384m in 2020 (2007 prices)	- /+	Reduction in prevalence of 0.5% corresponds to healthcare cost savings near €91m in direct costs and €108m in indirect costs.	++	Strong impact on brand equity for branded producers; commoditisation of tobacco products	-
Replace TNCO quantitative labelling		On-off admin burden through label change, minor	+	Reduced prevalence and	+	Reduced sales, change of employment share by	-	Change in tax revenue: €1,452	- /+	No substantial impact expected	≈	None	≈

Measure	Impact type	Administrative burden		Industry revenues/profits		Employment		Tax revenues		Direct and indirect costs of healthcare and ill health		Other	
with qualitative information on contents and emissions and quit-lines		costs Ongoing admin burden saving, 4.8–9.8m euros/year		increased cost, increase in revenues by 1m euros p.a. and no change to profits		–0.4% for manufacturers, –1.5 to 0.4 for wholesale, –2.9% to –1.2% for retailers		to €0m in 2020 (2007 prices)					
Introduce inserts with supplementary information (e.g. on potential risks)		Admin burden through changes in production process 47.2m euros one-off costs for cigarette manufacturers and 40.9–60.8m euros/year ongoing costs	+ +	Reduced prevalence and increased cost, decrease in revenues by 7m and profits reduced by 1m euros p.a.	–	Reduced sales, change of employment share by – 0.4% for manufacturers, –1.5–0.4 for wholesale, –3% to 1.2% for retailers	–	Change in tax revenue: €1,441 to –€13m in 2020 (2007 prices)	- /+	No substantial impact expected	≈	None	≈

Measure	Impact type	Administrative burden		Industry revenues/profits		Employment		Tax revenues		Direct and indirect costs of healthcare and ill health		Other	
Registration and market control													
Make reporting formats for product ingredients compulsory		Additional one-off admin burden for tobacco manufacturers: 0.1–0.5m euros	-	No substantial impact expected	≈	No substantial impact expected	≈	No substantial impact expected	≈	No substantial impact expected	≈	Potential savings through standardised and electronic reporting	(+)
Introduce market control fees proportionate to the number of outlets the product is sold in		Costs of maintaining and delivering register of retailers	(–)	n.a.	( )	n.a.	( )	n.a.	()	n.a.	()	Industry must pay market control fees	(–)
Introduce fines for industry in case of non-delivery of ingredients data		No substantial impact, expected, and can be avoided by business	(≈)	No substantial impact expected	≈	No substantial impact expected	≈	No substantial impact expected	≈	No substantial impact expected	≈	None	
Integrate the health costs of smoking into the calculation of the fees		No substantial impact	≈	Reduction in revenues by €10,472m, and profits of € 1,765m	- -	Change in employment share, manufacture: –22.3% to 22%, wholesale: 10% to18%. retail: –10% to –50%	-	Reduction of tax revenues by €15,109 to €19,140m	--	Reduction of healthcare costs in 2027 near €4.5bn in direct costs and €5–€6bn indirect costs	++	Cost for healthcare (€100bn) transferred to industry	--
Based on the polluter pays principle, internalise the external health costs of smoking by requiring full liability and payment of the health costs of smoking by the tobacco industry to national health systems		No substantial impact	≈	Reduction in revenues by €10,472m, and profits of €1,765m	- -	Change in employment share, manufacture: –22.3% to 22%, wholesale: 10% to 18%, retail: –10% to –50%	-	Reduction of tax revenues by €15,109 to €19,140m	+	Reduction of healthcare costs in 2027 near €4.5bn in direct costs and €5–€6bn indirect costs	++	Cost for healthcare (€100bn) transferred to industry	--

Measure / Impact type	Administrative burden		Industry revenues/profits		Employment		Tax revenues		Direct and indirect costs of healthcare and ill health		Other	
Ingredients and yields												
Ban additives that are CMRs, or that form CMRs during pyrolysis, in order to establish a common list of ingredients	Product reformulation and adjustment costs for industry	(–)	No substantial impact expected	≈	No substantial impact expected	≈	No substantial impact expected	≈	No substantial impact expected	≈	None	
Introduce an additional measurement method for TNCO (the modified ISO method) and set maximum limits accordingly	€1.1m–€10.2m.for running second measurement method One-off compliance cost from production process adjustment and product repositioning in the market	-	No substantial impact expected	≈	No substantial impact expected	≈	No substantial impact expected	≈	No substantial impact expected	≈	None	
Continuously decrease the maximum limits for TNCO and other yields and ingredients	One-off compliance cost from production process adjustment and product repositioning in the market	(–)	No substantial impact expected	≈	No substantial impact expected	≈	No substantial impact expected	≈	No substantial impact expected	≈	None	
Refine the definition of ingredients to include the tobacco leaf	Costs for new reporting and testing processes and for ensuring characteristics of tobacco used	(+)	No substantial impact expected	≈	No substantial impact expected	≈	No substantial impact expected	≈	No substantial impact expected	≈	None	
Set up an EC laboratory for evaluation of tobacco and smoking products	Fees for business if costs are transferred	(–)	No substantial impact expected	≈	No substantial impact expected	≈	No substantial impact expected	≈	No substantial impact expected	≈	Costs for Member States or EC to finance laboratory, unless charged to industry	(–)

Measure / Impact type	Administrative burden		Industry revenues/profits		Employment		Tax revenues		Direct and indirect costs of healthcare and ill health		Other	
Sales arrangements												
Introduce a standard pack size	Implies no additional admin burden and compliance cost	(–)	No substantial impact expected	≈	n.a.	( )	n.a.	( )	No substantial impact expected	≈	Cost savings for industry through reduction in SKU	(+)
Harmonise legal buying age of 18 in order to avoid sales to minors	Potential small one-off costs for retailers for trading and adjusting	(–)	Loss of a very small part of the market in a few Member States	(–)	No substantial impact expected	≈	No substantial impact expected	≈	No substantial impact expected	≈	None	
Ban vending machines	Substantial costs for tobacco retailers, using vending machines (sunk costs) could not be quantified	(--)	Loss of a part of the market in some Member States, not quantified	(–)	Loss of employment in the vending machine business	(–)	No substantial impact expected	≈	No substantial impact expected	≈	None	
Ban promotion (sheers, billboards, big packets, discount banners, etc.) at retail outlets	Implies one-off and ongoing compliance costs for tobacco retailers: one-off costs: 44.1–394.2m euros; ongoing costs: 0–70.8m euros/year	–	No substantial impact expected	≈	Reduced sales result in change of employment share by 0.2% for manufacturers; –1.7% to 0% for wholesale; 0.2% to 0.1% for retailers	–	Increased tax revenue of 1,469 to 20m euros in 2020 (2007 prices)	+	No substantial impact expected	≈	None	
Ban the display of products at PoS	Implies one-off and ongoing compliance costs for tobacco retailers: one-off costs: 321.3–2,297.9m euros; ongoing costs: 321.3–2,297.9m euros/year	--	Reduced prevalence and increased cost lead to reduction in revenues of 51m and profits of 11m euros p.a.	–	Reduced sales result in reduction of employment share by 0.1% for manufacturers; 1.7% to 0% for wholesale; 0.7% to 0.3% for retailers	–	Changed tax revenue between 1371 to –94m euros in 2027 (2007 prices)	+ –	Reduction in prevalence of 0.12% corresponds to healthcare cost savings near 22m euros in direct costs and 24m euros in indirect costs.	+	None	
Ban cross-border internet sales including the free distribution of product samples	Potential one-off and ongoing compliance cost for retailers active in cross-border sales Not quantified	(–)	n.a.	( )	n.a.	( )	n.a.	( )	n.a.	( )	None	

CHAPTER 13 Monitoring and evaluation

13.1 Developing a monitoring and evaluation framework

The EC's impact assessment guidelines (European Commission, 2009) require a full impact assessment to be accompanied by a list of indicators for future monitoring and evaluation of policies. This chapter develops an approach for how such indicators could be chosen by DG SANCO and what the most important areas for monitoring and evaluation are. This approach, which sits within the 'theory of change' tradition of evaluation,[71] consists of three analytical steps, each with a specific tool that could be used by DG SANCO in defining key top-level indicators:

1. mapping the intervention logic using logic models;
2. identifying and defining indicators;
3. presenting the findings in a dashboard.

13.1.1 Intervention logic

At the core of this approach stands the development of a so-called intervention logic – that is, a representation of how the policy (i.e. the Tobacco Products Directive) is intended to meet its two main objectives of creating a well-functioning single market and ensuring a high level of public health protection in the EU.

The aim of this step is to identify the key causal chains that lead from a policy measure to its desired outcomes. If these causal chains are identified and isolated, they can be used later to structure and focus the measurement activities. One such causal chain would be, for example, the ban of tobacco product PoS promotions, which should reduce impulse purchases and 'de-normalise' tobacco consumption. A key tool for establishing intervention logics is logic modelling.

Logic models[72] enable us to produce a graphic representation of how a policy is intended to work – that is, how resources are converted into programme activities, and how those

[71] For a more detailed discussion of this approach see, for example, Tiessen, J., C. Celia, L.V.v. Dijk, A. Reding, C.v. Stolk, T. Ling, RAND Europe., Rand Corporation. and Great Britain. Local Better Regulation Office., *Impacts and Outcomes of Local Authority Regulatory Services : Final Report*, Santa Monica, CA: RAND, 2009.

[72] For more information on logic models see, for example, Kellogg Foundation, Logic Model Development Guide, on-line, available at: http://www.wkkf.org/Pubs/Tools/Evaluation/Pub3669.pdf (last accessed July 2009); see also see Villalba-van-Dijk (2009).

activities in turn produce the results intended. Therefore, logic models generally allow a researcher to analyse the relationship between inputs and outputs, and between inputs and outcomes. Logic models provide an opportunity within an 'accountability area' (Osborne and Gaebler, 1992) to measure results, correct problems and identify successes. It also ensures a shared understanding of the intervention and helps uncover any implicit disagreements and confusions. An abstract version of a logic model is shown in Figure 13.1 below.

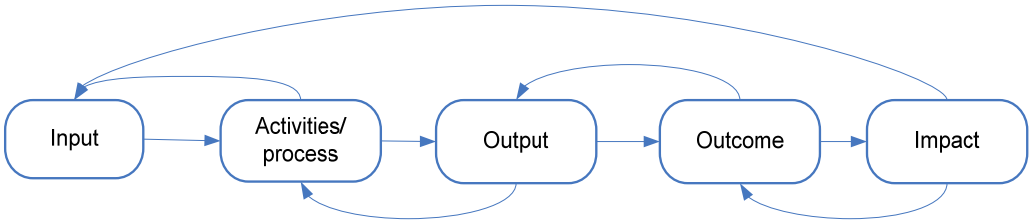


Figure 13.1: Outline of a basic logic model

Source: Villalba-van-Dijk (2009)

Logic models usually stop short of formulating specific links between the elements within each category. A logic model would, for example, list a number of activities as well as a number of outputs, without linking the specific activity to a specific output and then a specific outcome. For the purpose of developing the intervention logic for tobacco product regulation, we would therefore suggest supplementing the logic models with elements known from process mapping, by indicating links between the elements of the logic model. An illustration of how such a model of the intervention logic might look like is shown in Figure 13.2.

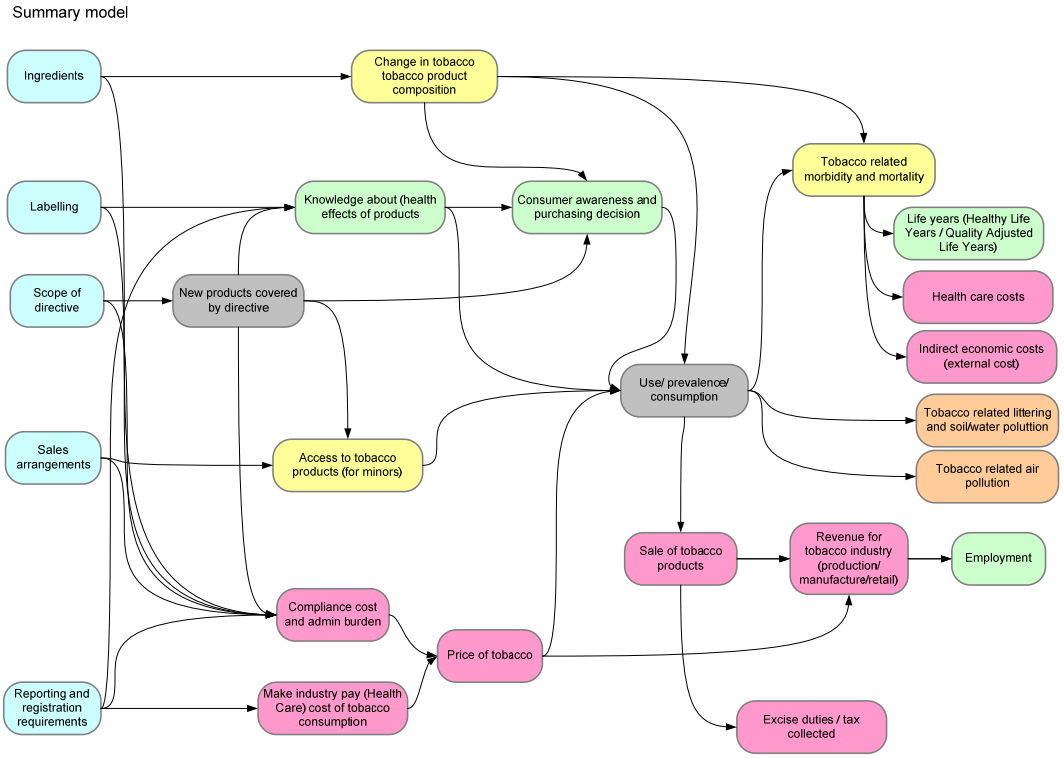


Figure 13.2: Model of the intervention logic

A final model should, however, be more detailed than Figure 13.2 to ensure that all steps of the five key policies included in the revision of tobacco product regulation are covered.

13.1.2 Indicators and measurement

Once the intervention logic has been established and the key causal chains have been mapped out, the next stage is the identification of potential indicators that would provide a fair description of changes along the causal chain.

This list of indicators may be informed by the very rich knowledge of the specific policy areas available within DG SANCO. The outcome of this mapping stage would be a long list of indicators that could be used to measure the elements of the causal chain and an assessment of whether these indicators are readily available or not. The overall impression from the research conducted for this study is, however, that there are substantial data gaps along these causal pathways. If we group the data needs by the stages of the logic model, the following key data needs may be identified.

1. Activities and outputs

Tobacco product regulation is only one of the many tobacco policy measures undertaken by Member States, and the directive may be applied in different ways in the EU-27. To assess the effectiveness of tobacco product regulation, it is crucial to know what Member States are currently doing in the field of tobacco control. Only in this way can an evaluation successfully try to assess the contribution of European regulation in this field. We thus recommend establishing an up-to-date resource including the following:

- Key tobacco control measures at Member State level, such as:

- smoke-free legislation;
- excise duty rates;
- sales and advertising restrictions (vending machines, bans and limitations of PoS display and promotion, age limits for the purchase of tobacco products, etc.).

● An up-to-date resource on how Member States are currently implementing the 2001 Tobacco Products Directive, in particular in terms of their reporting requirements.

2. Outcomes

The intermediate effects of tobacco control policies are currently not well understood and documented, despite being central to achieving their ultimate objective: a healthier population. Such intermediate outcomes include for example:

- ease of youth access to tobacco products;
- number of spontaneous tobacco purchases;
- percentage of tobacco companies reporting data accurately and on time;
- consumer awareness of harmful health effects of tobacco products;
- types of tobacco products consumed.

3. Impact

Finally, monitoring and evaluation will need to take into account the final impacts that should be achieved. At the heart of such an assessment should be, without a doubt, prevalence and consumption information, but also a monitoring of tobacco-related health burden and associated costs.

In addition a good monitoring and evaluation framework would also keep track of the unintended impacts, which are primarily cost impacts on tobacco manufacturers and retailers.

4. Context

Finally, there is a need to understand better the economic context of tobacco product regulation. Very little information is currently available to DG SANCO on key indicators of the market. Such indicators include reliable data on the number of manufacturing businesses, number of retailers or employment in the sector. This impact assessment has had to rely substantially on self-reported costs from industry, given the lack of such cost data elsewhere. This has implications because self-reported data on costs from industry are more often than not overestimated and difficult to verify independently. Therefore developing independent expertise on the regulated industry sector will be essential to allow for an impartial assessment of the effects of current and future regulation.

13.1.3 Building a dashboard

The final stage involves prioritising and presenting indicators in a way that enables a quick but meaningful overview of how the tobacco product regulation contributes to achieving its objectives. To do so, we propose to adapt the idea of a management 'dashboard'.

Dashboards are executive information systems that present a small set of performance measures on a regular and structured basis to strategic decision makers in order to provide an overview of the organisation's performance, and thereby to identify areas of particular success or concern for more detailed examination. However, this dashboard will have a less operational perspective than management dashboards and will not need to be updated as often as a management tool (which often may be 'real time' as well). Instead, we envisage the dashboard as a more strategic tool that should be updated once or twice a year.

The key challenge of a dashboard lies in the selection of data sources and indicators. For this purpose, we suggest selecting a maximum of 16 to 20 sources and indicators. Criteria for the prioritisation of indicators and measurements should be systematic and pragmatic and should include the following:

- Does it cover a key causal chain?
- Does it cover an input, output, outcome or impact?
- Are the data being collected already?
- Are the data held by DG SANCO or its external partners?
- Will new data be collected?

The final step of the dashboard is to represent the indicators in a graphical interface. An example of a dashboard that structures information into inputs, outputs, outcomes and impacts may be found in Figure 13.3. The example looks at anti-smoking interventions at the local level in the UK.

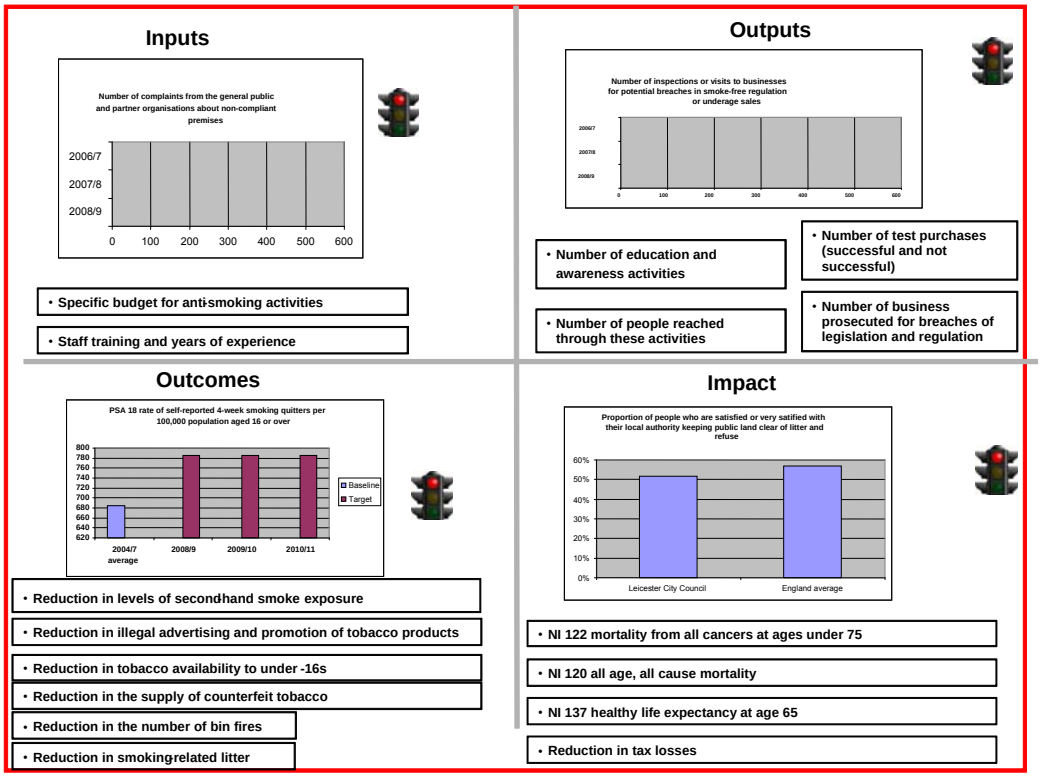


Figure 13.3: Example of a dashboard for local anti-smoking interventions in the UK

Source: RAND Europe

CHAPTER 14 Summary of stakeholder engagement

14.1 Introduction

As part of the development of this research, key stakeholders of tobacco product regulation were involved in an informal consultation exercise, preceding the formal consultation to be conducted by DG SANCO as the legislative proposal is developed. The key objective was to provide input into this research project at an early stage and to ensure that the project team could use the best information available. The engagement with stakeholders had two key components:

1. Discussion of an interim report.
2. Administrative burden measurement exercise with tobacco manufacturers and retailers.

In this chapter we briefly summarise the process of both these exercises.

14.2 Receiving comments on an interim report

At the end of October, RAND Europe produced an interim report summarising emerging results of the research project and outlining the next steps of the research. This report was presented to the Member States, the steering group and stakeholders on five different occasions, as summarised in Table 14.1.

Table 14.1: Stakeholder workshops

Date	Occasion	Participants
14 November 2009	Meeting with Inter Service Steering Group (ISSG)	Steering group members
30 November 2009	10th meeting of the Regulatory Committee established under Article 10 of the Tobacco Products Directive	Member States
3 December 2009	Workshop with European health stakeholders	European health stakeholders
4 December 2009	Workshop with European tobacco manufactures and retailer organisations	Tobacco industry and retail representatives
4 December 2009	Workshop with European organisations for the pharmaceutical industry	Representatives from pharmaceutical industry

In each session, RAND Europe presented a summary of research progress, and invited participants to comment on the suggested methodology, provide general comments and criticism, and highlight areas for improvement.

These workshops enabled stakeholders to give comments and criticisms on the interim report, which were recorded in the workshop write-ups and also could be submitted in writing until 18 January 2010. Table 14.2 provides an overview of the organisations that submitted written responses.

Table 14.2: Organisations that submitted written responses

Health NGOs	Tobacco manufacturers and retailers	Pharmaceutical industry	Member States
- Action on Smoking and Health (ASH) - CNCT (comite national contre tabagisme) - ECL (Association of European Cancer Leagues) - European Network for Smoking Prevention - European Respiratory Society (ERS) - Smoke Free Partnership	- CEDT(Confederacion Européenne des Détaillants en Tabac / European Conferation of Tobacco Retailers) - Confederation of European Community Cigarette Manufacturers (CECCM) - European Cigar Manufacturers Association (ECMA) - European Rolling Paper Association (ERPA) - European Smokeless Tobacco Council (ESTOC) - European Smoking Tobacco Association (ESTA) - European Tobacco Wholesalers Association (ETV) - Philip Morris International (PMI) - Swedish Match	- Association of the European Self-Medication Industry (AESGP)	- Bulgaria - Czech Republic - Greece - Germany - Italy - Lithuania - The Netherlands - Portugal - Romania - Slovakia - Slovenia

14.3 Collecting information about cost and administrative burden

The second component of stakeholder engagement concerned the collection of cost information from tobacco manufacturers and retailers to assess the current and future administrative burden of tobacco regulation. In collaboration with DG SANCO, RAND Europe identified and contacted a group of stakeholders for its administrative burden and compliance cost evidence collection exercise. The list of associations and companies conducted was created from the list of associations and companies taking part in the consultation process for RAND Europe's interim report; moreover, additional associations and companies were searched on the internet and contacted in areas where RAND Europe saw potential gaps in evidence. This was the case, for example, with tobacco retailers and vending machine operators.

RAND Europe interviewed a number of stakeholders, both tobacco manufacturers and retailers, in order to clarify its cost questionnaire (see Section 2.5 and Chapter 5). Then questionnaires were sent out to all associations contacted and all companies that indicated willingness to respond. Details of evidence collection may be found in Appendix C.

Table 14.3 List of companies and associations contacted throughout evidence collection

Contacted	Interviewed	Responded to questionnaire
	Tobacco manufacturers	
European Smoking Tobacco Association (ESTA)	Confederation of European Community Cigarette Manufacturers (CECCM)	Philip Morris International (PMI)
European Cigar Manufacturers Association (ECMA)	European Cigar Manufacturers Association (ECMA)	Imperial Tobacco Group (ITG)
Confederation of European Community Cigarette Manufacturers (CECCM)	European Smoking Tobacco Association (ESTA)	British American Tobacco (BAT)
European Smokeless Tobacco Council (ESTOC)	Philip Morris International (PMI)	Japan Tobacco International (JTI)
VdR Verband der deutschen Rauchtabakindustrie e.V. (German Smoking Tobacco Association)		J. Cortes Cigars
Philip Morris International (PMI)		Swedish Match Cigars
Imperial Tobacco Group (ITG)		Scandinavian Tobacco Group
Japan Tobacco International (JTI)		Dannemann
British American Tobacco (BAT)		Royal Agio Cigars
		Manufatture Sigaro Toscano
		Oettinger Davidoff Group
		Wörmann & Scholle
		Heupink & Bloemen Tabak
		Compania Canariense de Tabacos
		Poeschl Tabak
		Mac Baren
		Gryson
		Fiefler and Lundgren
	Tobacco retailers	
Tobacco Retailers Alliance	Confédération Européenne des Détaillants en Tabac (CEDT) (European Confederation of Tobacco Retailers)	Federazione Italiana Tabaccai
Interbranch organisation for the tobacco retail trade (NSO)		Bundesgremium der Tabaktrafikanten
Bundesverband Deutscher Tabakwaren-Großhändler und Automatenaufsteller (BDTA) (National Association of German Tobacco Wholsalers and Vending Machine Operators)		Unión De Asociaciones De Estanqueros De España
Bundesverband des Tabakwaren-Einzelhandels (BTWE) (National Association of Tobacco Retail)		Dutch Tobacco Retail Organisation
European Vending Association (EVA)		Europäischer Tabakwaren-Grosshandels-Verband (ETV)
Europäischer Tabakwaren-Grosshandels-Verband (ETV) (European Tobacco Wholesaler		

Association)
Confédération Européenne des Détaillants en Tabac (CEDT) (European Confederation of Tobacco Retailers)

Note: Some associations decided to respond to the questionnaire not as an association, but one by one per association member. Some international associations responded via their national associations. Therefore the list of companies and associations is broader than the list of companies and associations contacted.

CHAPTER 15 Conclusions

Rather than providing another summary of the results, which may be found at the beginning of this report and in Chapter 12, where the different options are compared, we should like to conclude this report by reflecting on some of the challenges involved in conducting this kind of impact assessment and on the limitation of the results and findings reported, as well as developing recommendations for future analysis.

15.1 Making best use of the evidence

Impact assessments have often been described as a tool to increase the use of evidence in policy making; therefore it may be valuable to reflect on the actual use of evidence in studies such as this one.

Given the broad range of topics the potential revision of the tobacco product legislation covers, ranging from the health effects of particular ingredients to the cost of labelling changes for tobacco manufacturers, this study presents a very wide range of evidence from a large array of sources. While researchers have made their best efforts to conduct balanced assessments of the evidence available, a study such as this one, limited by both time and resources, cannot feasibly present systematic evidence reviews for each topic area covered. Therefore the research team has chosen to produce rapid reviews of the data available – which are smaller in scale and less comprehensive than systematic evidence reviews – with a methodology based on that of systematic evidence reviews, as detailed in Chapter 2.

The second aspect that needs to be taken into account when reviewing the assessment of impacts described in this study is the accessibility and quality of the evidence, information and knowledge available. During the stakeholder consultation stage of this study, in which stakeholders were given the opportunity to comment on the interim report and findings, this study was criticised for using data sources that were deemed not sufficiently up to date – in particular data relating to prevalence rates as well as data on industry structures. However, as these are often the only comparable data sources with underlying time series, there is very little that can be done in a study like this to overcome the issue. Trying to compile our own data by merging data from different national data sources, as suggested by some stakeholders, would result in even wider ranging inaccuracies and would not be feasible in the scope of a study like this. At the same time, the authors are aware that some of the available data sources – in particular, for example, Eurostat's employment data – are of very poor quality in terms of comprehensiveness as well as reliability. This has been flagged up throughout the report as a key concern of the authors.

In this study, the research team was able to gather only additional primary data on one aspect: administrative burden and compliance costs. This was done through a consultation with the European tobacco manufacturers' and retailers' umbrella organisation and directly with some of the large cigarette manufacturers. The quality of any data collected in such a way is, however, doubtful as there was limited opportunity to verify and test the data provided and tobacco manufacturers coordinated their responses. This suggests that we will have witnessed at least some strategic responses from industry. A comparison of data provided by industry with other available data shows that self-reported cost data are substantially higher than other estimates, and therefore likely to overestimate the cost effects on industry.

15.2 Providing a balanced assessment under uncertainty

This leads us to another observation that it is important to make, concerning the challenges of providing a balanced assessment of costs and benefits if evidence, in particular quantitative, is not available equally for both the benefits and costs of a policy option. In this impact assessment we were able to provide a lot of 'hard' (i.e. quantitative) data on costs and administrative burden, but much less on the possible positive health impacts of additional regulation. This is due to a number of reasons.

First, the evidence of the health impacts of many new measures, such as large pictorial warnings and display bans, has so far relied on data gathered through small experimental set-ups or perception surveys, and there is very little evidence available that relates to changes in smoking behaviour in the wider population and overall prevalence rates. That type of evidence would have been the outcome of the type of study needed to make a quantitative assessment of the effect of the proposed measures. Secondly, assessing the future impacts of new and novel policy measures – such as plain packaging – that have not been previously implemented in other countries using 'hard' empirical evidence is impossible; such evidence is obviously unavailable and randomised controlled trials cannot be carried out in this field for obvious ethical reasons. In such cases, evidence has had to be extrapolated from evidence for other, similar measures. For example, evidence that packaging and pack designs detract from health warnings and incite young people to smoke may be used to assess the potential impact of plain packaging. A very narrow definition of what constitutes evidence might hinder regulatory innovation. Thirdly, public health interventions – and this holds particularly true for interventions related to tobacco use and smoking – are characterised by long-term health benefits and cost savings, while costs are incurred almost immediately by the regulated sector.

In this study we attempted to take these issues into account by summarising results in a multi-criteria decision-making framework rather than in a simple cost-benefit framework and by providing a scoring to assess the different costs and benefits. Nevertheless, this study is likely to overestimate the costs because of the issue of strategic reporting and it is likely to err on the conservative side with regard to the estimation of the health benefits of tobacco product regulation; the reader should be careful in interpreting the numbers detailed in this assessment.

15.3 Future analysis

Finally, this study showed that despite very clear evidence of the harmful effects of smoking and the subsequent costs for society, there is still substantial scope for improving the knowledge base for European tobacco control policies.

This first concerns a better understanding of the problem, in terms of having more recent, more comparable and more disaggregated prevalence and consumption data. This is essential for a thorough assessment of the positive impact of a policy on underage smoking. It should include ad-hoc efforts to gather data on issues that are perceived to be emerging, such as the use of electronic cigarettes and cross-border internet sales of tobacco products. More importantly, improvements in the policy-relevant knowledge – such as more up-to-date information about Member States' tobacco control policies and a better understanding of the effectiveness of specific tobacco control policy measures, as well as more information about the tobacco industry sector, which would allow DG SANCO to challenge some of the information provided by industry – are also crucial.

Defining further needs for research and analysis should, however, not detract from policy action in the field of tobacco control as the negative effects of tobacco consumption on citizens' health and societies as a whole are very well established. It is important to consider the potential health benefits to the general population that could be gained from stricter controls and measures.

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APPENDICES

Appendix A: Template for evidence review

This document should structure our research in the five key areas of change which are at the heart of the impact assessment.

1. Adjusting the **scope of the directive** by including further tobacco products and paraphernalia.
2. Changes to **the labelling requirements** for producers.
3. Introduction of **reporting and registration** requirements and market control fees.
4. Defining the **ingredients** of tobacco products.
5. Revising the **sales arrangements** for tobacco products.

In this stage we want to uncover the evidence that will later on allow an informed assessment of the impacts of the options.

Description of area of change against current regulation (2001/37/EC)

- Summary of the current requirements in the regulation.
- Summary of how the proposed options would change the regulation.

Implementation

- How is it implemented in the Member States? All Member States have to implement the minimum standards, but have some gone beyond the standards stipulated in Directive 2001/37/EC (e.g. are pictorial warning mandatory in some Member States)?

Problems

- Have problems been described with the current regulation?
- Description of the problems.

Benchmark/examples

- Has there been experience in this area of regulation in countries outside the EU? (e.g. US, Canada or New Zealand)

Evidence about the impact

- Is there evidence about the effectiveness of these measures in achieving their stated goals?

- What are the health impacts of regulation in this area (e.g. What is the health effect of pictorial warnings?)
- What are the economic impacts of regulation in this area (e.g. laboratory costs for analysis)?
- How varied will the impacts of the regulations be – will effects differ significantly by socioeconomic group, ethnicity, region of Europe, and so on?
- How do contextual factors influence impacts, what are they and can they be influenced in pursuit of the goals of the regulation?
- Are quantitative estimates of the impacts available? If not, can you describe them in qualitative terms?
- What are the methods used in other studies to assess the impact? How is the link between the measures and changes in smoking prevalence rates conceptualised?

Data

- What data sources are available to support the arguments made above?
- What are the key gaps in knowledge and data?

Sources

In searching for literature and evidence, we should focus on following categories:

1. Previous national impact assessments.
2. Reports by the EC and other international bodies, in particular WHO/FCTC.
3. Review and summary articles in academic journals.
4. Single academic studies only if there are no reviews and other forms of more systematic evidence.

Appendix B: Methodology for estimation of employment share and tax revenue impacts

RAND Europe's research approach

This chapter presents the findings of an econometric analysis into the impact of changes in smoking prevalence on employment and tax revenues. This analysis tests the hypothesis that the options have a statistical effect on employment and estimates the changes in tobacco tax revenue. We also aim to measure the extent of the relationship between prevalence and employment and tax revenue in order to forecast the potential impacts of a revision in the directive.

Specifically, we test the following hypotheses:

1. The options could reduce levels of employment across tobacco sectors (i.e. manufacturing, wholesale and retail).
2. The options could reduce levels of tobacco excise tax collected by governments.

In order to test these hypotheses we employ econometric analysis in which we estimate parameters of various models, the results of which indicate the degree of the relationship between prevalence and the economic outcomes of interest (employment and excise duty collection).

We then take our estimates of how measures of the options may affect prevalence (based on a review of the literature and calculations of administration costs) and apply these 'potential' prevalence rates to estimate 'potential' employment shares and excise duty collections.

The stages of the economic impact assessment are therefore as follows:

1. Identify theoretical underpinnings and empirical evidence for econometric model (for employment share).
2. Identify data with relevant variables across Member States and over time, and prepare data for estimation (including calculating costs incurred from administration burden).
3. With the prepared data, forecast consumption to 2027, estimate the employment model and calculate excise duty collection.

4. Estimate future changes in economic outcomes and excise duty collection for potential changes in prevalence due to options.

The four-stage approach, illustrated below in Figure B.1, demonstrates how we established an evidence base for our understanding of how to quantify the impacts of tobacco legislation on economic outcomes and how we approached providing quantitative estimates specific to the measures currently under review.

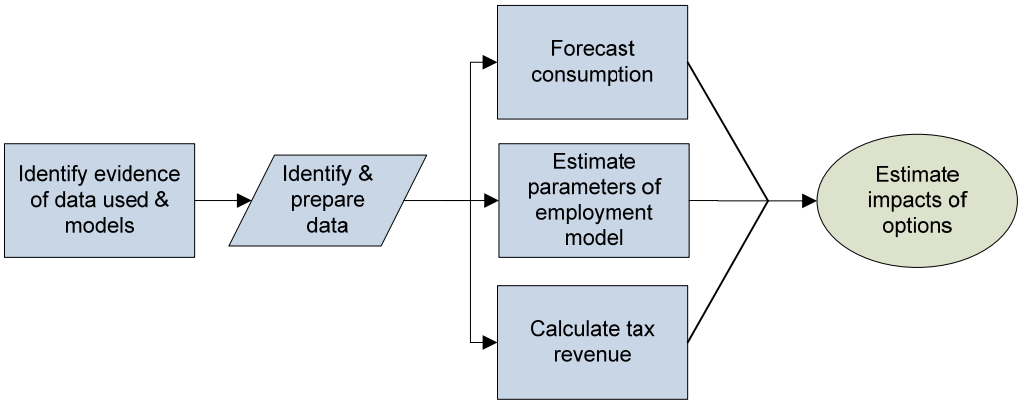

Figure B.1: Staged approach to estimating economic impacts of options

Employment share: the baseline

Dependent variable: tobacco employment as proportion of total employment, by sector

Although various activities may be deemed as being related to the tobacco market, tobacco industry and employment are generally defined as activities directly related to the production, distribution and retailing of tobacco leaf and tobacco products (World Bank, 2000:15; (Buck *et al.*, 1995). There are numerous direct activities involved with transforming tobacco crops into final products. The activities include preparing the land for farming, adding chemicals or additives to tobacco, storing cigarettes in warehouses and selling cigarette packets in retail shops. There are three main groups of activity into which direct employment fall (World Bank, 2000: 16; (Buck *et al.*, 1995)):

- Production sector: farming, leaf marketing and processing.
- Manufacturing sector: product manufacturing.
- Wholesale and retail sector: product wholesale and retail.

In order to perform quantitative analysis across countries and/or over time, there needs to be a common understanding of what constitutes a particular industrial activity and what does not (i.e. manufacturing in tobacco). The following table, Table B.1, briefly describes each of the activities deemed a direct tobacco activity (World Bank, 1999) and their respective NACE (Rev. 1.1) codes.

Table B.1: Tobacco supply activities

Activity	General description	Examples	NACE Rev. 1.1
Farming	All tobacco work on the farm	Land preparation	1.11 – Growing of cereals and other crops
		Delivery of cured tobacco to leaf processor	
Leaf marketing & processing	All activities after tobacco leaves farm and before ageing process	Leaf auctioning	1.11 – Growing of cereals and other crops
		Leaf warehousing	
		Leaf processing	
Product manufacturing	All aspects of production	Reordering	16 – Manufacture of tobacco products
		Blending	
		Leaf cutting	
		Delivery of packed tobacco to wholesaler	
Product wholesale & retail	All activities to deliver tobacco	Selling tobacco products to consumer	51.25 – Wholesale of unmanufactured tobacco
			51.35 – Wholesale of tobacco products
			52.26 – Retail sale of tobacco products

We use these codes to identify data that belong to a particular tobacco activity across Member States, thereby permitting us to perform quantitative analysis on harmonised data.

Theoretical foundations of the econometric model

The number of workers in the tobacco industry is not just an expression of willingness on the part of people to supply their labour to tobacco firms; it also reveals that firms are willing to hire individuals (Borjas, 2005). The demand for labour may be considered 'any decision made by an employer regarding the company's workers – their employment, their compensation, and their training' (Hamermesh, 1993). In keeping with the impact assessment literature of tobacco regulation, this impact assessment focuses on the influence the options may have on employment decisions, rather than on wages or training (World Bank, 2000; (Buck *et al.*, 1995).

In general, economists analyse (short run[73]) labour demand as functions of wages, where the demand for more workers increases as the wages decrease. Assuming firms are in a competitive market, the firms hire just enough workers to maximise their profits. They do not hire any more people because it becomes inefficient for all those workers to use the limited land and/or equipment, and the firms do not hire fewer workers because they could have earned more by hiring more people to work with the land and/or equipment. 'In other words, at the point where a firm maximises profit, the marginal gain from hiring an additional worker equals the cost of that hire, and it does not pay to further expand the firm because the value of hiring more workers is falling' (Borjas, 2005).

[73] Defined as a time span that is sufficiently brief for a firm not to be able to increase or reduce the size of its plant or purchase/sell physical equipment (Borjas, G., *Labour Economics*, New York, New York: McGraw-Hill Irwin, 2005..

While this is a useful skeletal framework, evidence suggests it is incomplete (Hamermesh, 1993). Firms operate in a dynamic market with uncertainty and shocks, so they make employment decisions based on more than current labour costs. Furthermore, there are institutional factors influencing a firm's ability to adjust levels of employment (such as labour contracts), so firms may adjust hours of work, for example, instead of terminating work contracts.

Regarding empirical research, there is general consensus that the notion of labour demand as purely a function of wage is incomplete (Card, 1987). For example, empirical research using business survey data in Germany finds that the decision to reduce the number of workers is primarily a function of exogenous changes in demand, and technological advances and then labour costs were of secondary (yet still significant) importance (Ross and Zimmermann, 1995). Therefore, firms make hiring decisions on the basis of their understanding of consumer demands and technological progress in their industry or market.

Description of variables used

In order to estimate the models, we utilise data from Eurostat, DG TAXUD data, WHO and OECD. These data sets are particularly useful for quantitative analysis of Member States because the data are relatively harmonised and are available for most of the EU countries over a number of years.

In order to compare the performance of Member State businesses over time, Eurostat provides harmonised data in the section named 'Structural Business Statistics' (SBS). Eurostat SBS provides information for Member States from 1997 onwards by industry sectors, identified by NACE code.

Independent variables

For the independent variables in the employment model, we identified the following in SBS that are consistent with the theoretical and empirical evidence provided earlier:

- Firm size: *number of firms in each size category*
- Labour cost: *average personnel cost per employee*
- Skilled labour: *apparent labour productivity* (*gross value added per person*)
- Technological progress: *capital investment.*

For the independent variable of interest in both models, the data for the consumption variable come from the OECD and WHO. This variable is used to understand how variation across countries over time, in terms of proportion of smokers, affects the number of persons employed in a sector of tobacco industry:

- Demand: *proportion of daily smokers in the population that is aged 15+.*

Dependent variable

For the dependent variable for tobacco employment, we use the following:

- Share of employees: *number of employees in a tobacco sector / total number of employees.*

These data are available from Eurostat. It is worth noting that we perform four separate analyses for each of the sectors: manufacturing (NACE code 16), wholesale of unmanufactured tobacco (NACE code 51.25), wholesale of manufactured tobacco (NACE code 51.35) and retail sales of tobacco products (NACE code 52.26).

Model and calculating the baseline scenario

As described earlier, we know that a number of other factors, besides consumption, affect tobacco employment, and we take this into account in our econometric analysis.

Some empirical evidence suggests labour demand (the number of workers) is a function of product demand, labour costs, skill of workers, technical progress and size of firms; the evidence found that uncertainty was not a statistically significant factor in labour demand (Ross and Zimmermann, 1995).

To understand the relationship between tobacco consumption and employment, we estimate the model for employment three times, each with data for the following sectors: 1) manufacturing; 2) wholesale of tobacco products; and 4) retail sales.

In order to identify the relationship between consumption and employment, we control for variables that also contribute to demand for workers in tobacco manufacturing, wholesale and retail sales. As indicated earlier, literature finds that these factors are firm size, labour costs, skilled labour and technological progress.

It is likely that the relationships between consumption and the economic outcomes are not linear. For example, we may find that as changes in consumption increase, the amount of the reduction in employment decreases (i.e. the marginal effect of consumption on employment increases at a decreasing rate). That is, there may have been large employment adjustments to the initial reduction in consumption; however, because of production efficiencies, there may be fewer and fewer adjustments to employment. As this element of the study is to consider the potential outcomes, not to identify the best fit model, we do not estimate several model specifications.

Taking values for the relationship between employment shares and various variables, including consumption, we forecast future employment shares with the forecasted consumption.

Relationship between employment shares and prevalence

We perform regression analysis to determine how changes in prevalence may change the level of employment in tobacco sectors. As we are investigating across countries over time (panel data), we perform the main techniques for panel data: fixed-effect and random-effect estimations.

As we should like to control for omitted variables that differ across countries, but are constant over time, the fixed effects regression is the most appropriate. It allows us to use the changes in the variables over time to estimate the effects of consumption on employment, and is generally the central technique applied for panel data analysis.

Findings

Manufacturing

Initial estimation with other variables finds a statistically insignificant relationship between manufacturing employment share and firm size, labour cost, skilled labour and capital

investment. The parsimonious model finds that an increase in prevalence would increase share of employment in manufacturing by 0.000145, which is an increase from the mean of 3.2 percent.

Table B.2: Variables for manufacturing employment

	Coefficient	t-value
Constant	0.000145	0.83
Smoking prevalence	0.000014	2.49
Year (1996 omitted)		
1997	0.000058	1.77
1998	–0.000020	–0.66
1999	–0.000086	–2.86
2000	–0.000105	–3.16
2001	–0.000105	–3.48
2002	–0.000115	–3.36
2003	–0.000135	–3.92
2004	–0.000157	–3.49
2005	–0.000150	–3.18
2006	–0.000154	–3.58
2007	–0.000220	–3.72

Wholesale of manufactured tobacco

Initial estimation with other variables finds a statistically insignificant relationship between wholesale of manufactured tobacco employment share and labour cost, skilled labour and capital investment. The parsimonious model finds that an increase in prevalence would reduce the share of employment in wholesale of manufactured tobacco by 0.00049, which is an decrease from the mean of 5.6 percent.

Table B.3: Variables for wholesale of manufactured tobacco employment

	Coefficient	t-value
Constant	0.00049	1.96
Smoking prevalence	–0.00001	–1.37
Firm size	0.00000	1.41
Year (1996 omitted)		
1997	–0.00001	–0.16
1998	–0.00002	–0.26
1999	–0.00001	–0.18
2000	–0.00001	–0.20
2001	–0.00001	–0.21
2002	–0.00002	–0.22
2003	–0.00001	–0.13
2004	0.00004	0.47
2005	–0.00005	–0.59

2006	–0.00008	–1.03
2007	–0.00006	–0.68

Retail in specialised tobacco

Initial estimation with other variables finds a statistically insignificant relationship between retail employment share and labour cost, skilled labour and capital investment. The parsimonious model finds that an increase in prevalence would increase the share of employment in retail by 0.00046, which is an increase from the mean of 6.6 percent.

Table B.4: Variables for retail employment

	Coefficient	t-value
Constant	0.00046	1.01
Smoking prevalence	0.00003	1.65
Productivity	–0.00001	–2.70
Investment	–0.00001	–5.04
Year (1996 omitted)		
1997	–0.00052	–2.45
1998	–0.00012	–0.82
1999	–0.00047	–3.37
2000	–0.00032	–2.11
2001	–0.00041	–2.93
2002	–0.00040	–2.67
2003	–0.00042	–2.97
2004	–0.00051	–3.32
2005	–0.00039	–2.41
2006	–0.00041	–2.66
2007	–0.00038	–2.03

Summary

Table B.5 summarises the changes in employment share due to changes in prevalence and change over time.

Table B.5: Summary of variables for employment

Sector	If prevalence decreases by 1 percent	Yearly trend
Share in manufacturing	Reduces by 3.2%	Falling by 0.00011 annually
Share in wholesale of manufactured tobacco	Increases by 5.6%	Falling by 0.00002 annually
Share in retail	Reduces by 6.6%	Falling by 0.00039 annually

Tobacco consumption excise duty collection: the baseline

Since 1995, it has been compulsory for Member States to provide the EC with detailed tax information. As in the case of employment analysis, in order to assess how the options may change tax revenue across countries, we need to have the same frame of reference (or same concept of what are moneys are received for taxation on tobacco) across all the countries. Table B.6 illustrates the category for which Member State governments provide the amount of tax revenue generated, or excise duties collected, in millions of national currency,[74] for the consumption of tobacco (the example is Belgium).

Table B.6: National classification of tobacco tax in the National Tax List, Belgium

Code	Tax name according to national classification (in one of national languages)	Tax name according to national classification (in one of national languages)	Tax name according to national classification (English)	Economic function	Alcohol, tobacco & environmental tax
D2122CC	Droits d'accise sur le tabac	Accijnzen op tabak	Excise duties on tobacco	C-Consumption tax	AT – alcohol, tobacco taxes

Baseline calculation of excise duty collection across the EU

According to DG TAXUD, 'Cigarettes are taxed by means of a specific and an ad-valorem excise duty. Specific excise duties are taxes on the quantities of cigarettes. Ad-valorem excises are a percentage applied to the price of the cigarettes. Consequently, for cheap cigarettes, the ad-valorem excise duty will be small' (DG TAXUD, 2006: 2).

Therefore Member States' revenue generated by taxing cigarettes includes a proportion from the number of cigarettes sold and a proportion from the price of cigarettes sold. To capture this, we calculate the impact the options would have on tax revenues through their effect on attractiveness (i.e. change in quantity sold) and on industry's costs (i.e. change in prices).

For the outcome of interest – tobacco excise duty collection – we use the following information provided by DG TAXUD:

- Tobacco tax revenue: *consumption excise duties.*

We then go on to calculate how the excise duties in future may change, based on future prevalence (using the forecast for consumption with OECD and WHO data) and based on the median annual change in excise duty collections from 2000 to 2007. That is, even when prevalence decreases, excise duty collections may increase because:

- not all excise duty rate increases are passed on to consumers (and thus prices change little); and/or
- even when excise duty changes are passed on to consumers, some consumers will continue to consume tobacco as before.

[74] Which we convert to euros.

Therefore, we also capture these potential relationship by allowing for excise duty collections to continue increasing by the median annual rate of change in excise duty collections; we then additionally adjust for changes in prevalence.

Change in the baseline: policy impact

There are generally two steps to get from the policy to the new employment outcomes:

1. How much does the policy change price?
2. How much does prevalence change for a change in price?

Through our review of the literature and data collection on the administrative burden, we are able to identify how much a policy may alter prices. We then use the literature on elasticities to calculate how much prevalence will change with the new prices; the meta-analysis suggests –0.3 to –0.5 and the World Bank suggests –0.43, so we use –0.5 in order to identify maximum impacts. Therefore our estimates should be considered overestimates.

We also use literature identifying changes in prevalence related to policy reducing the attractiveness of tobacco consumption. In this case, we add the price-induced effect to the attractiveness-induced effect. Again, this is to demonstrate maximum effect and thus makes the results overestimates of the impact.

With the new prevalence rates, we recalculate the employment shares and revenues.

We then demonstrate the impact of the policy by taking the 'change in baseline' values and subtracting from the 'baseline' figures. We present figures as either percentage change due to the policy (in the case of employment shares) or absolute difference (in the case of tax revenues).

Appendix C: Methodology for estimation of administrative burden and compliance costs

Questionnaires

To : Cigarette manufacturer

From : RAND Europe

Subject : Tobacco legislation impact assessment

Date : 7 January 2010

RAND Europe is currently conducting research to support the European Commission in assessing the possible impacts of potential changes to the Tobacco Products Directive (2001/37/EC). The first stages of this research showed a lack of evidence about the compliance costs and administrative burdens for manufacturers and retailers of tobacco products.

To fill this specific evidence gap, RAND Europe developed this questionnaire focusing on the analysis of costs, in particular the administrative burden and compliance costs that can be associated with the current and any potential future legislation. Thus there are no questions on wider impacts of regulations on, for example, consumer choice, property rights, or illicit tobacco trade. These issues are covered by other research phases and results are combined in the final report RAND Europe will deliver to the European Commission.

Your responses to the questions below would greatly help RAND Europe and the European Commission to understand the impacts of the current and future legislation.

If you have any further questions please contact Mihaly Fazekas (fazekas@rand.org) or Jan Tiessen (tiessen@rand.org) at RAND Europe at +44 (0) 1223 353 329. Please send us back the filled-in questionnaire by 1 February to the following email address: fazekas@rand.org.

1. Your company

In this section we would like to learn more about your company, which will allow us to later weigh your responses. Please give your responses regarding the whole company, considering all branches involved in tobacco manufacturing.

- How many different products with different package design (stock keeping units) did your company market in the EU in 2008 and 2009?
- How many packs/manufactured cigarettes did your company sell approximately in the EU in 2008 and 2009? Please list all the major product types.
- What was the volume of sales of these types of products in the EU in 2008 and 2009 (by weight/value)? Please list all the major product types.
- What was the approximate market share of your company in the EU-27 in 2008 and 2009, or if these data are not available, in your main European markets (Member States)?

2. Labelling requirements

In this section we want to learn more about the costs that tobacco manufacturers incur by labelling and packaging their products. We first ask some general questions about your labelling and packaging practice before asking how some of these costs would change with potential future legislation.

2.1 The costs of changing tobacco product labels

2.1.1 On a typical product, how often do you usually change the label/packaging per year or per longer time period if applicable? How many of these changes are due to (1) product repositioning, (2) regulations, (3) industry pack changes, and (4) other reasons? To what extent could these changes be synchronised?

2.1.2 How much time do you spend on collecting information to be put on a label in a typical case (e.g. warning texts, TNCO yields, picture warnings)? If there are no 'typical cases', could you identify different cases of collecting information and identify associated staff costs?

2.1.3 How much time does your staff spend on a redesign of a label in a typical case? If you involve external contractors, how much do you pay them in a typical case? If there are no 'typical cases', could you identify different types/cases of redesign and identify associated staff costs?

2.1.4 How often will printing and packaging equipment (such as embossing tools) be replaced? What are the costs implications of such a change (per change)?

2.2 Costs of labelling in the current directive

2.2.1 How much cost does your company incur by displaying the data on TNCO yields on cigarette packages per year? What are the key cost components;

please spell out the major types of in-house and outsourcing costs and the respective cost figures. Please don't take into account the initial costs of readjusting the production system.

2.2.2 How much cost does your company incur by displaying health warnings on cigarette packages per year? What are the key cost components? Please spell out the major types of in-house and outsourcing costs and the respective cost figures. Please don't take into account the initial costs of readjusting the production system.

2.2.3 How much of these costs arose before the introduction of the EU directive? Please spell out the major types of costs and the respective cost figures.

2.3 The effect of potential changes to the current legislation

In this section we would like to discuss the implications of potential future changes to the regulation; these can be discussed in qualitative terms as well, and do not have to be substantiated by cost estimates. We are aware that some companies might find it not appropriate to respond to these hypothetical questions, and that some of these questions might be difficult to respond to given the level that can be provided at this stage. If this is the case for you, please continue with section 3.

2.3.1 What would be the (cost) implication of displaying pictorial warnings on every cigarette package (following current voluntary scheme)?

2.3.2 Would these costs differ if 50 percent, 75 percent or 100 percent of both sides of the package would be covered by the pictorial warning? If so, why and how? What would be the impact on brand values at the company level?

2.3.3 If generic or 'plain packaging' on a mandatory basis for all tobacco manufacturers were introduced, what would be the (cost) implications? What would be the impact on brand values on the company level?

2.3.4 Please imagine the situation that TNCO quantitative labelling is replaced with qualitative information on contents and emissions and quit-lines. What would be the (cost) implication for your company?

2.3.5 Finally, please imagine legislation which would make it mandatory to introduce inserts with supplementary information, i.e. an additional piece of paper inserted to the package. What would be the (cost) implications for your company?

3. Testing tobacco products

The current Directive 2001/37/EC contains several requirements for industry to submit information to Member States and to report on the characteristics of tobacco

products. In this first set of questions we would like to learn more on the costs of testing the characteristics of tobacco products.

3.1 Testing the tar, nicotine and carbon monoxide (TNCO) yields

3.1.1 How frequently is TNCO measurement done in your company per year and stock keeping unit (SKU)?

3.1.2 What are the costs of testing TNCO yields of cigarettes in terms of costs of approved laboratories and in-house laboratory facilities? What other costs are incurred through testing?

3.1.3 How many working hours of the company's staff are spent on average on this process (per SKU)/total?

3.1.4 How much of these costs arose before the introduction of the EU directive?

3.1.5 Please imagine that the modified ISO method for TNCO yield measurement is introduced. What would be the cost implication of its introduction, in terms of:

- familiarising with the new measurement method (working hours)?
- purchase of new software or any equipment in order to carry out the new measurement method?
- other costs (e.g. laboratory costs)?

3.2 Ingredient testing

The EC directive obliges tobacco manufacturers to submit annually the toxicological data available to the manufacturer or importer regarding ingredients in burnt or unburnt form as appropriate, referring in particular to their effects on health and taking into account, inter alia, any addictive effects.

3.2.1 What is the overall cost per year of testing cigarette ingredients for your company in line with the EU directive? What are the key cost elements (staff costs, outsourcing, etc.)? If costs differ considerably from year to year, please give an average of the last few years.

3.2.2 How much of these costs arose before the introduction of the EU directive?

4. Reporting and relaying information

In this section we would like to discuss the costs your company might incur through reporting on your products and relaying information to Member States.

4.1 Reporting information

4.1.1 What costs (per year and per SKU) does your company incur from reporting on the TNCO yields of tobacco products (excluding the pack imprints)?

- How many working hours are spent on average on organising, processing and sending the required information?
- How frequently do you report this information?
- Other costs?

4.1.2 What costs (per year and per SKU) does your company incur from reporting on the **ingredients, and quantities thereof, used in the manufacture of tobacco products** by SKU?

- How many working hours are spent on average on organising, processing, and sending the required information?
- Other costs?

4.1.3 What costs (per year and per SKU) does your company incur from reporting on the **toxicological data available** about those ingredients per SKU?

- How many working hours are spent on average on organising, processing, and sending the required information?
- Other costs?

4.1.4 What costs (per year and per SKU) does your company incur from submitting annually a statement setting out the reasons for the inclusion of ingredients in tobacco products to indicate their function and category?

- How many working hours are spent on average on organising, processing, and sending the required information?
- Other costs?

4.2 Further issues of reporting

4.2.1 Please think about the possibility of **compulsory standardised reporting formats for product ingredients**, largely following the guidelines of the EC.

- How long would it take your company to familiarise itself with the new standardised reporting formats for product ingredients (working hours)?
- Would you have to buy new software for reporting in the standardised reporting formats? If yes, how much could it cost?

5. Additional issues

In this section we would like to discuss the implications of potential future changes to the regulation; these can be discussed in qualitative terms as well, and do not have to be substantiated by cost estimates. We are aware that some companies might find it not appropriate to respond to these hypothetical questions, and that some of these questions might be difficult to respond to given the level that can be provided at this stage.

5.1.1 Please consider the case when legislation defines a minimum package size for all cigarette products throughout the EU, e.g. 19 cigarettes per pack.

- What would be the consequences of such a regulation in terms of cost for your business?

- What elements of the production process do you have to change to comply with such a hypothetical regulation?
- What are the associated adjustment costs of each element in your business?
- At what stages of the production process is your business likely to incur on-going costs due to compliance?
- What are the associated costs per production stage?

5.1.2 Please consider the situation where the definition of ingredients is refined in order to include tobacco leaf.

- How long would it take your company to familiarise itself with the refined list of ingredients including tobacco leaf (working hours)?
- How long would it take your company to measure new ingredients each year (working hours)?
- Would you have to buy new software or any equipment in order to report according to the refined list of ingredients? If yes, how much could it cost?
- Would the new measurement method involve any form of outsourcing? If yes, how much could it cost?

5.1.3 Please consider the situation where the maximum limits for TNCO are continuously decreased.

- What elements of the production process do you have to change to comply with such a hypothetical regulation?
- What are the associated adjustment costs of each element in your business?
- At what stages of the production process is your business likely to incur on-going costs due to compliance?
- What are the associated costs per production stage?

To	:	Cigar manufacturer
From	:	RAND Europe
Subject	:	Tobacco legislation impact assessment
Date	:	7 January 2010

RAND Europe is currently conducting research to support the European Commission in assessing the possible impacts of potential changes to the Tobacco Products Directive (2001/37/EC). The first stages of this research showed a lack of evidence about the compliance costs and administrative burdens for manufacturers and retailers of tobacco products.

To fill this specific evidence gap, RAND Europe developed this questionnaire focusing on the analysis of costs, in particular the administrative burden and compliance costs that can be associated with the current and any potential future legislation. Thus there are no questions on wider impacts of regulations on, for example, consumer choice, property rights, or illicit tobacco trade. These issues are covered by other research phases and results are combined in the final impact assessment.

Your responses to the questions below would greatly help RAND Europe and the European Commission to understand the impacts of the current and future legislation.

If you have any further questions please contact Mihaly Fazekas (fazekas@rand.org) or Jan Tiessen (tiessen@rand.org) at RAND Europe at +44 (0) 1223 353 329. Please send us back the filled-in questionnaire by 1 February to the following email address: fazekas@rand.org.

6. Your company

In this section we would like to learn more about your company, which will allow us to later weigh your responses. Please give your responses regarding the whole company, considering all branches involved in tobacco manufacturing.

- How many different products with different package design (SKUs) did your company market in the EU in 2008 and 2009?
- How many tobacco or nicotine products did your company sell approximately in the EU in 2008 and 2009? Please list all the major product types.
- What was the volume of sales of these types of products in the EU in 2008 and 2009 (by weight/value)? Please list all the major product types.
- What was the approximate market share of your company in the EU-27 in 2008 and 2009, or if these data are not available, in your main European markets (Member States)?

7. Pack design requirements

In this section we want to learn more about the costs that tobacco manufacturers incur by labelling and packaging their products. We first ask some general questions about your labelling and packaging practice before asking how some of these costs would change with potential future legislation. If your company manufactures a large variety of differently packed products, please focus on the packaging of your two to three most important products.

7.1 The costs of changing tobacco product pack designs

7.1.1 For your two to three main products, how often do you usually change the label/packaging? How many of these changes are due to (1) product repositioning, (2) regulations, (3) industry pack changes, and (4) other reasons? To what extent could these changes be synchronised?

7.1.2 How much time do you spend on collecting information to be put on a label or package in a typical case (e.g. warning texts, picture warnings)?

7.1.3 How much time does your staff spend on a redesign of the package design in a typical case?

7.1.4 If you involve external contractors, how much do you pay them in a typical case?

7.1.5 How often will printing and packaging equipment be replaced? What are the cost implications of such a change (per change)?

7.2 Costs of package design in the current directive

7.2.1 How much cost does your company incur by displaying health warnings on product packages per year in the case of a typical product? Please don't take into account the initial costs of readjusting the production system. Please spell out the major types of in-house and outsourcing costs and the respective cost figures.

7.2.2 How much of these costs arose before the introduction of the EU directive? Please spell out the major types of costs and the respective cost figures.

7.3 The effect of potential changes to the current legislation

In this section we would like to discuss the implications of potential future changes to the regulation; these can be discussed in qualitative terms as well, and do not have to be substantiated by cost estimates. We are aware that some companies might find it not appropriate to respond to these hypothetical questions, and that some of these questions might be difficult to respond to given the level that can be provided at this stage. If this is the case for you, please continue with section 8.

7.3.1 What would be the (cost) implication of displaying pictorial warnings on every type of product package you are currently using (following the current voluntary scheme)?

7.3.2 Would these costs differ if 50 percent, 75 percent or 100 percent of both sides of the package were covered by the pictorial warning? If so, why and how? What would be the impact on brand values at the company level?

7.3.3 If generic or 'plain packaging' on a mandatory basis for all tobacco manufacturers were introduced, what would be the (cost) implications? What would be the impact on brand values on the company level?

7.3.4 Finally, please imagine legislation which would make it mandatory to introduce inserts with supplementary information, i.e. an additional piece of paper inserted to the package. What would be the (cost) implications for your company?

8. Testing tobacco products

The current Directive 2001/37/EC contains several requirements for industry to submit information to Member States and to report on the characteristics of tobacco products. In this first set of questions we would like to learn more on the costs of testing the characteristics of tobacco products.

8.1 Ingredient testing

The EC directive obliges tobacco manufacturers to submit annually the toxicological data available to the manufacturer or importer regarding these ingredients in burnt or unburnt form as appropriate, referring in particular to their effects on health and taking into account, inter alia, any addictive effects.

8.1.1 How many working hours are spent on average on this process?

8.1.2 How much of the costs would be incurred in the absence of the EC directive?

9. Reporting and relaying information

In this section we would like to discuss the costs your company might incur through reporting on your products and relaying information to Member States.

9.1 Reporting information

9.1.1 Does Member State regulation oblige tobacco manufacturers to measure and report on the TNCO content of non-cigarette tobacco and nicotine products (e.g. roll your own cigarette)?

- How many working hours are spent on average on organising, processing, and sending the required information?

- How frequently do you report this information?
- Other costs?

9.1.2 What costs (per year and per SKU) does your company incur from reporting on the **other tests performed as result of Member State regulation**, if there are any?

- How many working hours are spent on average on organising, processing, and sending the required information?
- How frequently do you report this information?
- Other costs?

9.1.3 What costs (per year and per SKU) does your company incur from reporting on the **ingredients, and quantities thereof, used in the manufacture of tobacco products** by brand name and type?

- How many working hours are spent on average on organising, processing, and sending the required information?
- Other costs?

9.1.4 What costs (per year and per stock keeping unit) does your company incur from reporting on the **toxicological data available** about those ingredients by brand name and type?

- How many working hours are spent on average on organising, processing, and sending the required information?
- Other costs?

9.1.5 What costs (per year and per SKU) does your company incur from submitting annually a statement setting out the reasons for the inclusion of ingredients in tobacco products to indicate their function and category?

- How many working hours are spent on average on organising, processing, and sending the required information?
- Other costs?

9.2 Further issues of reporting

9.2.1 Please think about the possibility of **compulsory standardised reporting formats for product ingredients**, largely following the guidelines of the European Commission.

- How long would it take your company to familiarise itself with the new standardised reporting formats for product ingredients (working hours)?
- Would you have to buy new software for reporting in the standardised reporting formats? If yes, how much could it cost?

10. Additional issues

In this section we would like to discuss the implications of potential future changes to the regulation; these can be discussed in qualitative terms as well, and do not have to

be substantiated by cost estimates. We are aware that some companies might find it not appropriate to respond to these hypothetical questions, and that some of these questions might be difficult to respond to given the level that can be provided at this stage.

10.1.1 Please consider the situation in which the definition of ingredients is refined in order to include tobacco leaf too.

- How long would it take your company to familiarise itself with the refined list of ingredients including tobacco leaf (working hours)?
- How long would it take your company to measure the new ingredient each year (working hours)?
- Would you have to buy new software or any equipment in order to report according to the refined list of ingredients? If yes, how much could it cost?
- Would the new measurement method involve any form of outsourcing? If yes, how much could it cost?

To	:	Tobacco manufacturer (European Smoking Tobacco Association)
From	:	RAND Europe
Subject	:	Tobacco legislation impact assessment
Date	:	7 January 2010

RAND Europe is currently conducting research to support the European Commission in assessing the possible impacts of potential changes to the Tobacco Products Directive (2001/37/EC). The first stages of this research showed a lack of evidence about the compliance costs and administrative burdens for manufacturers and retailers of tobacco products.

To fill this specific evidence gap, RAND Europe developed this questionnaire focusing on the analysis of costs, in particular the administrative burden and compliance costs that can be associated with the current and any potential future legislation. Thus there are no questions on wider impacts of regulations on, for example, consumer choice, property rights, or illicit tobacco trade. These issues are covered by other research phases and results are combined in the final impact assessment.

Your responses to the questions below would greatly help RAND Europe and the European Commission to understand the impacts of the current and future legislation.

If you have any further questions please contact Mihaly Fazekas (fazekas@rand.org) or Jan Tiessen (tiessen@rand.org) at RAND Europe at +44 (0) 1223 353 329. Please send us back the filled-in questionnaire by 1 February to the following email address: fazekas@rand.org.

11. Your company

In this section we would like to learn more about your company, which will allow us to later weigh your responses. Please give your responses regarding the whole company, considering all branches involved in tobacco manufacturing.

- How many different products with different package designs (stock keeping units / SKUs) did your company market in the EU in 2008 and 2009?
- What was the volume of sales of these types of products in the EU in 2008 and 2009 (by weight/value)? Please list all the major product types.
- What was the approximate market share of your company in the EU-27 in 2008 and 2009, or if these data are not available, in your main European markets (Member States)?

12. Labelling requirements

In this section we want to learn more about the costs that tobacco manufacturers incur by labelling and packaging their products. We first ask some general questions about your labelling and packaging practice before asking how some of these costs would change with

potential future legislation. If your company manufactures a large variety of differently packed products, please focus on the packaging of your two to three most important products.

12.1 The costs of changing tobacco product designs

12.1.1 For your two to three main products, how often do you usually change the label/packaging? How many of these changes are due to (1) product repositioning, (2) regulations, (3) industry pack changes, and (4) other reasons? To which extent could these changes be synchronised?

12.1.2 How much time do you spend on collecting information to be put on a label or package in a typical case and to familiarise yourself with the regulation (e.g. warning texts, picture warnings)? If there are no 'typical cases', could you identify different cases of collecting information and identify associated staff costs?

12.1.3 How much time does your staff spend on a redesign of a label or package in a typical case? If you involve external contractors, how much do you pay them in a typical case? If there are no 'typical cases', could you identify different types/cases of redesign and identify associated staff costs?

12.1.4 How often will printing and packaging equipment be replaced? What are the cost implications of such a change (per change)?

12.2 Costs of labelling in the current directive

12.2.1 How much cost does your company incur by displaying health warnings on a typical tobacco product (or your two to three most important products) per year and SKU? What are the key cost components? Please spell out the major types of in-house and outsourcing costs and the respective cost figures. Please don't take into account the initial costs of readjusting the production system.

12.2.2 How much of these costs arose before the introduction of the EU directive? Please spell out the major types of costs and the respective cost figures.

12.3 The effect of potential changes to the current legislation

In this section we would like to discuss the implications of potential future changes to the regulation; these can be discussed in qualitative terms as well, and do not have to be substantiated by cost estimates. We are aware that some companies might find it not appropriate to respond to these hypothetical questions, and that some of these questions might be difficult to respond to given the level that can be provided at this stage. If this is the case for you, please continue with section 13.

12.3.1 What would be the (cost) implication of displaying pictorial warnings on every type of product package you are currently using (following the current voluntary scheme)?

12.3.2 Would these costs differ if 50 percent, 75 percent or 100 percent of both sides of the package were covered by the pictorial warning? If so, why and how? What would be the impact on brand values at the company level?

12.3.3 If generic or 'plain packaging' on a mandatory basis for all tobacco manufacturers were introduced, what would be the (cost) implications? What would be the impact on brand values on the company level?

12.3.4 Finally, please imagine legislation which would make it mandatory to introduce inserts with supplementary information, i.e. an additional piece of paper inserted to the package. What would be the (cost) implications for your company?

13. Testing tobacco products

The current Directive 2001/37/EC contains several requirements for industry to submit information to Member States and to report on the characteristics of tobacco products. In this first set of questions we would like to learn more on the costs of testing the characteristics of tobacco products.

13.1 Ingredient testing

The EC directive obliges tobacco manufacturers to submit annually the toxicological data available to the manufacturer or importer regarding these ingredients in burnt or unburnt form as appropriate, referring in particular to their effects on health and taking into account, inter alia, any addictive effects.

13.1.1 How many working hours are spent on average on this process?

13.1.2 Does your company outsource these costs? If so, how much would it typically cost per ingredient?

13.1.3 How much of these costs arose before the introduction of the EU directive?

14. Reporting and relaying information

In this section we would now like to discuss the costs your company might incur through reporting on your products and relaying information to Member States.

14.1 Reporting information

14.1.1 What costs (per year and per SKU) does your company incur from reporting on the **ingredients, and quantities thereof, used in the manufacture of tobacco products** by SKU?

- How many working hours are spent on average on organising, processing, and sending the required information?
- Other costs?

14.1.2 What costs (per year and per SKU) does your company incur from reporting on the **toxicological data available** about those ingredients per SKU?

- How many working hours are spent on average on organising, processing, and sending the required information?
- Other costs?

14.1.3 What costs (per year and per SKU) does your company incur from submitting annually a statement setting out the reasons for the inclusion of ingredients in tobacco products to indicate their function and category?

- How many working hours are spent on average on organising, processing, and sending the required information?
- Other costs?

14.2 Further issues of reporting

14.2.1 Please think about the possibility of **compulsory standardised reporting formats for product ingredients**, largely following the guidelines of the European Commission.

- How long would it take your company to familiarise itself with the new standardised reporting formats for product ingredients (working hours)?
- Would you have to buy new software for reporting the standardised reporting formats? If yes, how much could it cost?

15. Additional issues

In this section we would like to discuss the implications of potential future changes to the regulation; these can be discussed in qualitative terms as well, and do not have to be substantiated by cost estimates. We are aware that some companies might find it not appropriate to respond to these hypothetical questions, and that some of these questions might be difficult to respond to given the level that can be provided at this stage.

15.1.1 Please consider the situation where the definition of ingredients is refined in order to include tobacco leaf too.

- How long would it take your company to familiarise itself with the refined list of ingredients including tobacco leaf (working hours)?

- How long would it take your company to measure the new ingredient each year (working hours)?
- Would you have to buy new software or any equipment in order to report according to the refined list of ingredients? If yes, how much could it cost?
- Would the new measurement method involve any form of outsourcing? If yes, how much could it cost?

To	:	Tobacco manufacturer (European Smokeless Tobacco Council)
From	:	RAND Europe
Subject	:	Tobacco legislation impact assessment
Date	:	7 January 2010

RAND Europe is currently conducting research to support the European Commission in assessing the possible impacts of potential changes to the Tobacco Products Directive (2001/37/EC). The first stages of this research showed a lack of evidence about the compliance costs and administrative burdens for manufacturers and retailers of tobacco products.

To fill this specific evidence gap, RAND Europe developed this questionnaire focusing on the analysis of costs, in particular the administrative burden and compliance costs that can be associated with the current and any potential future legislation. Thus there are no questions on wider impacts of regulations on, for example, consumer choice, property rights, or illicit tobacco trade. These issues are covered by other research phases and results are combined in the final report RAND Europe will deliver to the European Commission.

Your responses to the questions below would greatly help RAND Europe and the European Commission to understand the impacts of the current and future legislation.

If you have any further questions please contact Mihaly Fazekas (fazekas@rand.org) or Jan Tiessen (tiessen@rand.org) at RAND Europe at +44 (0) 1223 353 329. Please send us back the filled-in questionnaire by 1 February to the following email address: fazekas@rand.org.

16. Your company

In this section we would like to learn more about your company, which will allow us to later weigh your responses. Please give your responses regarding the whole company, considering all branches involved in tobacco manufacturing.

- How many different products with different package designs (stock keeping units / SKUs) did your company market in the EU in 2008 and 2009?
- What was the volume of sales of these types of products in the EU in 2008 and 2009 (by weight/value)? Please list all the major product types.
- What was the approximate market share of your company in the EU-27 in 2008 and 2009, or if these data are not available, in your main European markets (Member States)?

17. Labelling requirements

In this section we want to learn more about the costs that tobacco manufacturers incur by labelling and packaging their products. We first ask some general questions about your labelling and packaging practice before asking how some of these costs would change with

potential future legislation. If your company manufacturers a large variety of differently packed products, please focus on the packaging of your two to three most important products.

17.1 The costs of changing tobacco product designs

17.1.1 For your two to three main products, how often do you usually change the label/packaging? How many of these changes are due to (1) product repositioning, (2) regulations, (3) industry pack changes, and (4) other reasons? To what extent could these changes be synchronised?

17.1.2 How much time do you spend on collecting information to be put on a label or package in a typical case and to familiarise yourself with the regulation (e.g. warning texts, picture warnings)? If there are no 'typical cases', could you identify different cases of collecting information and identify associated staff costs?

17.1.3 How much time does your staff spend on a redesign of a label or package in a typical case? If you involve external contractors how much do you pay them in a typical case? If there are no 'typical cases', could you identify different types/cases of redesign and identify associated staff costs?

17.1.4 How often will printing and packaging equipment be replaced? What are the cost implications of such a change (per change)?

17.2 Costs of labelling in the current directive

17.2.1 How much cost does your company incur by displaying health warnings on a typical tobacco product (or your two to three most important products) per year and SKU? What are the key cost components? Please spell out the major types of in-house and outsourcing costs and the respective cost figures. Please don't take into account the initial costs of readjusting the production system.

17.2.2 How much of these costs arose before the introduction of the EU directive? Please spell out the major types of costs and the respective cost figures.

17.3 The effect of potential changes to the current legislation

In this section we would like to discuss the implications of potential future changes to the regulation; these can be discussed in qualitative terms as well, and do not have to be substantiated by cost estimates. We are aware that some companies might find it not appropriate to respond to these hypothetical questions, and that some of these questions might be difficult to respond to given the level that can be provided at this stage. If this is the case for you, please continue with section 18.

17.3.1 What would be the (cost) implication of displaying pictorial warnings on every type of product package you are currently using (following the current voluntary scheme)?

17.3.2 Would these costs differ if 50 percent, 75 percent or 100 percent of both sides of the package were covered by the pictorial warning? If so, why and how? What would be the impact on brand values at the company level?

17.3.3 If generic or 'plain packaging' on a mandatory basis for all tobacco manufacturers were introduced, what would be the (cost) implications? What would be the impact on brand values on the company level?

17.3.4 Finally, please imagine legislation which would make it mandatory to introduce inserts with supplementary information, i.e. an additional piece of paper inserted to the package. What would be the (cost) implications for your company?

18. Testing tobacco products

The current Directive 2001/37/EC contains several requirements for industry to submit information to Member States and to report on the characteristics of tobacco products. In this first set of questions we would like to learn more on the costs of testing the characteristics of tobacco products.

18.1 Ingredient testing

The EC directive obliges tobacco manufacturers to submit annually the toxicological data available to the manufacturer or importer regarding these ingredients in burnt or unburnt form as appropriate, referring in particular to their effects on health and taking into account, inter alia, any addictive effects.

18.1.1 How many working hours are spent on average on this process?

18.1.2 Does your company outsource these costs? If so, how much would it typically cost per ingredient?

18.1.3 How much of these costs arose before the introduction of the EU directive?

19. Reporting and relaying information

In this section we would like to discuss the costs your company might incur through reporting on your products and relaying information to Member States.

19.1 Reporting information

19.1.1 What costs (per year and per SKU) does your company incur from reporting on the **ingredients, and quantities thereof, used in the manufacture of tobacco products** by SKU?

- How many working hours are spent on average on organising, processing, and sending the required information?
- Other costs?

19.1.2 What costs (per year and per SKU) does your company incur from reporting on the **toxicological data available** about those ingredients per SKU?

- How many working hours are spent on average on organising, processing, and sending the required information?
- Other costs?

19.1.3 What costs (per year and per SKU) does your company incur from submitting annually a statement setting out the reasons for the inclusion of ingredients in tobacco products to indicate their function and category?

- How many working hours are spent on average on organising, processing, and sending the required information?
- Other costs?

19.2 Further issues of reporting

19.2.1 Please think about the possibility of **compulsory standardised reporting formats for product ingredients**, largely following the guidelines of the European Commission.

- How long would it take your company to familiarise itself with the new standardised reporting formats for product ingredients (working hours)?
- Would you have to buy new software for reporting in the standardised reporting formats? If yes, how much could it cost?

20. Additional issues

In this section we would like to discuss the implications of potential future changes to the regulation; these can be discussed in qualitative terms as well, and do not have to be substantiated by cost estimates. We are aware that some companies might find it not appropriate to respond to these hypothetical questions, and that some of these questions might be difficult to respond to given the level that can be provided at this stage.

20.1.1 Please consider the situation in which the definition of ingredients is refined in order to include tobacco leaf too.

- How long would it take your company to familiarise itself with the refined list of ingredients including tobacco leaf (working hours)?
- How long would it take your company to measure the new ingredient per each year (working hours)?

- Would you have to buy new software or any equipment in order to report according to the refined list of ingredients? If yes, how much could it cost?
- Would the new measurement method involve any form of outsourcing? If yes, how much could it cost?

To : Associations of tobacco retailers

From : RAND Europe

Subject : Tobacco legislation impact assessment

Date : 17. 11. 2009.

RAND Europe is currently conducting research to support the European Commission in assessing the possible impacts of potential changes to the Tobacco Products Directive (2001/37/EC). An essential part of this research is the analysis of costs, in particular the administrative burden and compliance costs that can be associated with the current and any potential future legislation. Your responses to the questions below would help RAND Europe and the European Commission understand thoroughly the economic, social (including health) and environmental impacts of legislation. If you have any further questions please contact Jan Tiessen at RAND Europe at +44 (0) 1223 227 595 or tiessen@rand.org.

21. Your organisation

In this section we would like to learn more about your organisation and the business sector you are representing.

21.1 Which and how many businesses are you or your members representing?

21.2 What is the average/median size of your member companies? [mostly small and medium enterprises, big companies, micro, local retailers?]

21.3 What percent of the sector does your organisation (in terms of member companies) cover?

22. Tobacco retailer sector in the EU

22.1 What is the current number of tobacco retailers within the European Union?

22.2 Do you have information about the size and structure of the sector?

23. Please imagine the situation in which legislation obliges tobacco retailers across the whole European Union to make vending machines inaccessible to minors

23.1 What elements of a typical tobacco retail business process will have to be changed to comply with such a hypothetical regulation?

23.2 How much is the associated adjustment cost per element per business?

23.3 Would a tobacco retail business face increased ongoing costs? If so, how much? Please specify the cost categories.

23.4 Could a tobacco retailer realise benefits from the legislation in terms of cost savings? Please specify.

24. Please imagine the situation in which legislation bans the use of vending machines

24.1 What elements of a typical tobacco retail business process will have to be changed to comply with such a hypothetical regulation?

24.2 How much is the associated adjustment cost per element per business?

24.3 Would a tobacco retail business face increased ongoing costs? If so, how much? Please specify the cost categories.

24.4 Could a tobacco retailer realise benefits from the legislation in terms of cost savings? Please specify.

25. Please imagine the situation in which legislation bans cross-border sales, notably via the internet, including the free distribution of product samples

25.1 What elements of a typical tobacco retail business process will have to be changed to comply with such a hypothetical regulation?

25.2 How much is the associated adjustment cost per element per business?

25.3 Would a tobacco retail business face increased ongoing costs? If so, how much? Please specify the cost categories.

25.4 Could a tobacco retailer realise benefits from the legislation in terms of cost savings? Please specify.

26. Please think of the situation in which promotion (e.g. billboards, discount banners) is banned at retail outlets in all EU countries

26.1 What elements of a typical tobacco retail business process will have to be changed to comply with such a hypothetical regulation?

26.2 How much is the associated adjustment cost per element per business?

26.3 Would a tobacco retail business face increased ongoing costs? If so, how much? Please specify the cost categories.

26.4 Could a tobacco retailer realise benefits from the legislation in terms of cost savings? Please specify.

27. Please think about the situation in which the display of products at retail outlets becomes restricted in all EU countries

27.1 What elements of a typical tobacco retail business process will have to be changed to comply with such a hypothetical regulation?

27.2 How much is the associated adjustment cost per element per business?

27.3 Would a tobacco retail business face increased ongoing costs? If so, how much? Please specify the cost categories.

27.4 Could a tobacco retailer realise benefits from the legislation in terms of cost savings? Please specify.

28. Please think about the situation in which the display of products at retail outlets becomes banned in all EU countries

28.1 What elements of a typical tobacco retail business process will have to be changed to comply with such a hypothetical regulation?

28.2 How much is the associated adjustment cost per element per business?
28.3 Would a tobacco retail business face increased ongoing costs? If so, how much? Please specify the cost categories.
28.4 Could a tobacco retailer realise benefits from the legislation in terms of cost savings? Please specify.

29. Please think about the situation where mandatory minimum package sizes are introduced in all EU Member States

29.1 What elements of a typical tobacco retail business process will have to be changed to comply with such a hypothetical regulation?
29.2 How much is the associated adjustment cost per element per business?
29.3 Would a tobacco retail business face increased ongoing costs? If so, how much? Please specify the cost categories.
29.4 Could a tobacco retailer realise benefits from the legislation in terms of cost savings? Please specify.

Appendix D: Environmental impacts

The consumption of tobacco products and in particular smoking of tobacco products has been shown to have a number of environmental impacts.

The effect on air quality

Reduction in tobacco consumption may improve air quality (reducing the effect of passive smoking) although studies in outdoors smoke-free environment to measure that effect are lacking. Cigarette smoke is a complex mixture of gases and particle matter that are emitted by burning tobacco products. Many of these substances have already been identified as toxic air pollutants (California Environmental Protection Agency, 2005). The effect of smoking bans on air quality indoors has been recognised scientifically (Goodman *et al.*, 2007) as a reduction of 83 percent to 93 percent in levels of particulate matter. 'Particulate matter' is the term used for a mixture of solid particles and liquid droplets found in the air. Particle pollution is made up of a number of components, including acids (such as nitrates and sulphates), organic chemicals, metals and soil or dust particles.

The effect of cigarette butt litter

In terms of quantity

Cigarette butts discarded by smokers outside buildings, in car parks and streets are an environmental issue in terms of quantity and toxicity – especially in rivers and beaches, whence they may be transported through rains and accumulate elsewhere. Smoking-related materials are one of the main types of marine debris (Jeftic *et al.*, 2009, Ocean Conservancy, 2008). Of the total debris count during the International Coastal Cleanup from 1989 to 2007, 27percent was related to smoking activities: cigarettes, cigarette filters, cigarettes lighters, cigar tips, tobacco packaging and wrappers. Cigarettes and cigarettes filters especially represent 25 percent of the total count of marine debris items, and also of the first marine debris counted in the Baltic Sea (37 percent), the Mediterranean Sea (29 percent) and the north-east Atlantic (16 percent). In 2008 cigarettes and cigarettes filters were found to represent 28 percent of the total count of the debris collected during the International Coastal Cleanup – that means around 3.2 million items.

In terms of degradation

Cigarette filters are mainly made with cellulose acetate. A plastic component, it is not biodegradable but photodegradable. Ultraviolet rays from the sun break the filters into

smaller pieces under certain environmental conditions. Studies disagree concerning the duration of this process, which has been determined to range from 18 months to 12 years. The source material never disappears but is diluted in water and soil (Novotny *et al.*, 2009).

Leachates

Cigarette butts may also cause harm to the environment because they contain some hazardous components – like tar and chemicals – which are found in cigarettes. These include nicotine, cadmium and arsenic. Cigarette filters are designed to absorb some of those components and limit their inhalation. However, once they come into contact with water the toxic chemicals leach out. Studies have established the acute toxicity of leachate from the remnant tobacco portion of a cigarette butt (Micevska *et al.*, 2006, Register, 2000). They show that the chemicals in cigarette butts are acutely toxic to a specific marine bacterium, to phytoplankton and to a small crustacean at concentrations higher than one cigarette filter in 0.40, 8 and 13 litres of water respectively. This toxicity persists for at least seven days. Many crustaceans are known to be more sensitive to a wide variety of pollutants than the crustacean used in the studies, which means that toxicity may occur at concentrations in the region of 100 times lower. The studies prove that the remnant tobacco in cigarette butts is a principal factor in determining the mortality, although the compounds in used cigarette filters also have a lethal effect. The components of new cigarette filters are toxic only at concentrations very much higher than used filters. It was determined that organic compounds caused the majority of the toxicity in the cigarette butt leachates. Among them, nicotine and ethylphenol were suspected to be the main toxicants.

Butts may be mistaken for food and be ingested by marine animal and birds. They have been found in the guts of whales, dolphins, sea birds and turtles. Once ingested, toxic chemicals may cause diseases or irritation (Marine Conservation Society, 2007).

Effects from tobacco production

Deforestation

Studies show that tobacco production participates in deforestation in developing countries (Africa, Asia and Latin America) where tobacco production is mainly located (80 percent) (Geist, 1998).[75] An estimated 200,000 hectares have been lost through tobacco farming each year from 1990 to 1995, amounting to 1.7 percent of global loss of forest cover and 4.6 percent of total national deforestation (Geist, 1998). In 1999 tobacco production was responsible for a important part of the annual total deforestation in the Republic of Korea (South Korea) (45 percent), Uruguay (51 percent), Bangladesh (31 percent), Malawi (26 percent), Jordan (25 percent), Pakistan (19 percent), China (18 percent), the Syrian Arab Republic (18 percent) and Zimbabwe (16 percent) (Mackay and Eriksen, 2002).

Tobacco manufacturing pollution

75 Tobacco is grown in 125 countries on over 4 million ha of land (less than 1percent of the world's agricultural land). The five main producers are China, Brazil, India, Turkey and the USA.

Tobacco manufacture is also considered a great souce of pollution. In 1995 the global tobacco industry produced an estimated 2.3 billion kilograms of manufacturing waste and 209 million kilograms of chemical waste (Novotny and Zhao, 1999).