

**POSSIBLE REVISION OF THE TOBACCO
PRODUCTS DIRECTIVE 2001/37/EC
PUBLIC CONSULTATION DOCUMENT
DG SANCO
2010**

1. SCOPE OF THE DIRECTIVE

1.1. Problem definition

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

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

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

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

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

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

1.2. Possible options

Option 1 - No change

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

Option 2 - Extend of the scope of the Directive

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

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

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

ESTOC Response
<p>Do you agree with the problem definition? If not, please provide explanations</p> <p>No.</p> <p>The problem definition does not include any information to support the contention that “the tobacco products market has increasingly diversified” since 2001. Instead, references are made to a variety of novel products, which do not meet the Directive’s definition of “tobacco products”.</p>
<p>In your view, which option addresses the problem most effectively?</p> <p>Option 1 – No Change</p>
<p>Do you recommend any additional option that would effectively address the problem?</p> <p>We think that the Directive should continue to cover only those products, which do contain tobacco. Our view is that non-tobacco nicotine products, which are being offered mainly by the pharmaceutical industry as alternatives to tobacco products should be properly regulated under other appropriate EU regulatory regimes, to the extent this is not already the case. Regulation of both tobacco products and non-tobacco nicotine products should be science-based, include appropriate product standards, allow EU tobacco consumers the option of choosing from a range of reduced risk (relative to combustible products) tobacco products such as snus and other Scandinavian smokeless tobacco products, and provide them with accurate information on the differing risks of different types of tobacco products.</p>
<p>Do you have any additional specific comments?</p> <p>Neither Option 1 nor Option 2 is optimal because of how the related proposals have been framed. Option 2 is contradictory as it starts by stating that “An extension of the scope of the Directive could be envisaged to include novel forms of oral tobacco” and ends by stating “Novel forms of tobacco would be banned similarly to snus.” We think that any proposal for an arbitrary and outright ban on novel forms of oral tobacco in the absence of prior scientific assessment of their product risks relative to the risks of cigarette smoking would be an unjustifiable and disproportionate action. We believe that there is sufficient scientific evidence available to support a lifting of the ban on snus, which is a substantially less hazardous product than cigarettes. Only robust scientific evidence should be used as a basis to justify an outright ban. And, in accordance with Article 36 of the Treaty on the Functioning of the European Union, “...prohibitions or restrictions shall not [,however,] constitute a means of arbitrary discrimination or a disguised restriction on trade between Member States.” The novelty of a product is not a valid argument to resort to the ultimate restriction of a ban for sale on the internal market.</p> <p>We would also like to point out that Swedish snus is not a novel products as it has been consumed in Scandinavia since the mid 1800.</p>

2. SMOKELESS TOBACCO PRODUCTS

2.1. Problem definition

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

All smokeless tobacco products are addictive and can cause cancer. They also increase the risk of death after a myocardial infarction and may have additional cardiovascular effects as stated in the Opinion of the Scientific Committee on Emerging and Newly Identified Health Risks (SCENIHR) of February 2008¹².

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

2.2. Possible options

Option 1 - No change

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

Option 2 - Lifting the ban on snus

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

Option 3 - Ban on all types of smokeless tobacco products

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

ESTOC Response

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

No.

The problem definition contains a very incomplete reflection of available evidence on the risk profile of smokeless tobacco products, and on the potential role which reduced risk (relative to combustible products) smokeless tobacco products could play in helping to reduce the public health impacts of tobacco use.

The current regulatory framework presents a contradiction whereby certain more hazardous chewing tobacco products (like gutkha) are permitted for sale while less hazardous snus products are banned.

The cite to the SCENIHR Opinion contained in the problem definition does not accurately reflect SCENIHR's statement that "*It appears* that the use of smokeless tobacco increases the risk of death after myocardial infarction but that it does not increase the risk of myocardial infarction" (pg 95, emphasis added). Nor does the problem definition reflect numerous other findings of SCENIHR contained in its Opinion, including:

"... marketed STP [smokeless tobacco products] vary considerably in form and content of

toxicants, including nicotine, and thereby in associated health effects which have been documented across countries” (pg 105).

Similar conclusions are also drawn in the WHO “TobReg” report on “The Scientific Basis of Tobacco Product Regulation” (2008)

Overall, snus use poses substantially lower health risks than cigarette smoking (pgs 114/115)

Reports suggest that in northern Sweden the “availability of snus and the way in which it has been used may have been beneficial to public health since the harm to health caused by any use of snus as a gateway into smoking may have been more than outweighed numerically by the numbers quitting snus from smoking” (pg 116)

The Swedish data “do not lend much support to the theory that smokeless tobacco (i.e. Swedish snus) is a gateway to future smoking. In the USA, the interpretation of two studies is divergent...” (pg 108)

Snus use is not a risk factor for oral cancer. (p. 113 & 120)

Observational data from Sweden indicate that “snus has been used more often than pharmaceutical nicotine products by some men as an aid to stop smoking ” (pg 110)

In the main markets where snus is traditionally consumed (Sweden and Norway), there has been a clear migration away from cigarette smoking not vice-versa. There is growing evidence that using snus can help some people quit smoking. Epidemiology studies (Furberg et al 2005) have shown that snus is being used as an aid to quitting smoking, particularly among Swedish men. Findings from a recent study from Norway (Lund et al 2010) show a similar smoking cessation phenomenon in Norway among the male smokers surveyed

SCENIHR’s conclusions included that “...for those who substitute smoking by STPs the benefits outweigh the risks” (pg 118).

The problem definition fails to address the implications of the current ban on sales of snus on the functioning of the internal market e.g. the adverse societal consequences of the ban which, in our view, are disproportionate when taking into account that the health risks associated with use of Swedish snus have been established as being substantially lower overall than those associated with cigarettes, which are permitted to be sold within the EU. The current situation denies 107 million smokers in the EU access to a non-combustible tobacco product such as snus as a potential alternative to their usual cigarettes - according to a study cited in the SCENIHR opinion, snus is “likely to be approximately 90% less harmful than smoking” (pg 115).

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

Option 2 - **Lifting the ban on snus**

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

Any future regulation of smokeless tobacco products should be science based with product standards of principal importance, as opposed to the criteria contained in the current Tobacco Products Directive, which is based on the intended use of tobacco products. The voluntary industry standard for manufacturing of snus based on the GothiaTek standard for snus, which was recently recognised by a WHO Study Group (WHO Study Group on Tobacco Product Regulation, WHO Technical Report Series 955, 2010), could serve as a basis for such smokeless tobacco product regulation.

For further reference see ESTOC’s regulatory proposal (www.estoc.org).

Do you have any additional specific comments?

Given the opinion of SCENIHR and many others that the use of snus is substantially less

hazardous than cigarette smoking, we think there is no scientific or other relevant justification for a continuing ban on the sale of snus. In our view, regulation of snus and other types of smokeless tobacco products should be: science-based; include appropriate product standards rather than the current focus on the intended use of the product; allow EU tobacco consumers the option of choosing from a range of reduced risk (relative to combustible products) tobacco products; and, provide them with accurate information on the differing risks of different types of tobacco products.

The voluntary industry standard for smokeless tobacco products based on the GothiaTek standard for snus, could serve as a basis for such smokeless tobacco product regulation (GothiaTek was recently recognised by a WHO Study Group in WHO Technical Report Series 955, 2010).

3. CONSUMER INFORMATION

3.1 Problem definition

Currently the use of pictorial warnings by Member States is limited. It does not cover all tobacco products and their visibility is limited. Currently, combined warnings shall cover not less than 40 % of the back side of the package¹³. Evidence shows that pictorial warnings if properly sized and well placed are an efficient measure to inform the public about the dangers of smoking, and they are particularly effective among vulnerable groups. The bigger the size of the picture warning, the more effective it is.

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

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

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

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

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

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

3.2. Possible options

Option 1 - No change

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

Option 2 - Improve consumer information

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

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

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

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

Option 3 - Introduce generic or plain packaging

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

ESTOC Response

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

No.

1. The assumption that larger graphic warnings will be more effective in informing the public on the health risks associated with tobacco products is arbitrary. The problem definition does not refer to any specific evidence in this respect and we are not aware of any. Current warnings on tobacco products' packaging are already conspicuous. Larger warnings would violate manufacturers' fundamental, protected rights to expression, information, and property.
2. So far, there is no sound evidence that plain packaging would achieve any intended public health objectives. On the contrary those packaging suggestions are far easier to counterfeit and would make enforcement against illicit trade even more difficult. Tobacco consumers are unlikely to be willing to pay a premium price for commoditized tobacco products that look the same as other – less-expensive – brands, which may lead to a switch in consumption to cheaper products, which in turn can be bought in larger quantities for the same price. There would also be significant legal hurdles to introducing this measure and it would represent a substantial burden on business.

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

Option 1
<p>Do you recommend any additional option that would effectively address the problem?</p> <p>Health warnings on tobacco products' packaging should be appropriate to each particular product category and should accurately reflect the associated health risks.</p> <p>We support EU tobacco consumers being given clear and accurate information on the relative risks of different tobacco products.</p>
<p>Do you have any additional specific comments?</p> <p>Health warnings occupying a very sizeable area are already required to be applied to the packaging of all tobacco products sold within the EU.</p>

4. Reporting and registration of ingredients

4.1. Problem definition

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

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

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

4.2. Possible options

Option 1 - No change

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

Option 2 - Establish a common compulsory reporting format

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

Option 3 - Introduce fees and sanctions

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

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

ESTOC Response
<p>Do you agree with the problem definition? If not, please provide explanations</p> <p>No.</p> <p>In relation to the disclosure of ingredients used in the manufacture of smokeless tobacco products, ESTOC members are not aware of any evidence that this is presenting any particular problems for manufacturers.</p>
<p>In your view, which option addresses the problem while supporting the objectives of the directive most effectively?</p> <p>Option 2</p>
<p>Do you recommend any additional option that would effectively address the problem?</p> <p>Allowing for protection of manufacturers' valuable brand recipes as well as third party suppliers' trade secrets and considering the aim to improve the functioning on the internal market, using the same standardized reporting format would be preferred that would cover all Member States.</p>
<p>Do you have any additional specific comments?</p> <p>No</p>

5. Regulation of ingredients

5.1. Problem definition

Attractive substances are added into tobacco products such as liquorice to increase the smoothness of the smoke and menthol to enable deeper inhalation. During the process of burning majority of additives form substances that are carcinogenic, mutagenic and/or toxic for reproduction.

There are no common conditions for the internal market ensuring a uniform high level of health protection. Some Member States allow a number of listed ingredients (so-called positive list) while some others have banned certain ingredients (so-called negative list). Some other Member States have both negative and positive lists. The existence of different positive lists in some Member States and negative lists in others lead to the authorisation of different ingredients used in the manufacturing of tobacco products. As a result substances that can be used in one Member State may not be used in another.

5. 2. Possible options

Option 1 - No Change

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

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

The Directive would lay down the basic criteria to be used by the Member States for restricting or prohibiting the use of certain ingredients in the manufacturing of tobacco

products. The criteria may be related to toxicity, the attractiveness and the addictiveness of a product when consumed (oral tobacco) or smoked (the combustion/inhalation effect). Member States would retain the right to have national bans according to national circumstances in so far as this would be deemed necessary and proportionate to protect public health.

Option 3 - Establish a common list of tobacco ingredients

The list would be based on the toxicity, the attractiveness and the addictiveness of a product when consumed (oral tobacco) or smoked (the combustion/inhalation effect).

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

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

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

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

ESTOC Response
<p>Do you agree with the problem definition? If not, please provide explanations</p> <p>No.</p> <p>The problem definition is based on the premise that ingredients are added to tobacco products to make them attractive. The recent SCENIHR opinion failed to draw firm conclusions on the role of ingredients in the attractiveness of tobacco products, finding that “Additives considered attractive may, in principle, lead to brand preference or a higher consumption of tobacco products but it remains difficult to distinguish the direct effects of these additives from indirect effects such as marketing towards specific groups”. SCENIHR also found that the methods currently used to assess the attractiveness of tobacco product ingredients are not adequate. Therefore, the problem definition is based on a faulty premise. (2010 cite)</p>
<p>In your view, which option addresses the problem most effectively?</p> <p>Option 1</p>
<p>Do you recommend any additional option that would effectively address the problem?</p> <p>Ingredients regulation for smokeless tobacco products should consider and reflect the scientific principles developed jointly by the WHO/FAO Codex Alimentarius Commission (CAC). It should be possible to amend or revise such regulation as new products and developments arise.</p> <p>[Although harmonised ingredients regulation is desirable in principle,] both Option 2 and Option 3 discuss the regulation of ingredients based on toxicity, attractiveness and addictiveness. For smokeless tobacco products, regulation of ingredients based on the scientific principles of the WHO/FAO CAC would take into consideration the potential toxicity of ingredients. However, according to both SCENIHR and RAND Europe there is no evidence currently to support ingredients regulation on the bases of attractiveness and addictiveness.</p>
<p>Do you have any additional specific comments?</p> <p>We disagree with the problem definition as it focuses only on cigarettes and not all tobacco products. Ingredients in snus do not make snus more "attractive" - some snus users prefer one flavour, some prefer others. Any standards should be based on science, not something as subjective as "attractiveness".</p>

6. Access to tobacco products

6.1. Problem definition

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

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

The UK has announced that it will prohibit the **display** of tobacco products in large shops from October 2011 and from all other places from October 2013 in England, Wales and Northern Ireland. In Finland it will be prohibited to display tobacco in points of sale as from the beginning of 2012. A similar ban has been announced by Ireland.

6.2. Possible changes

Option 1 - No change

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

Option 2 – Controlled supply and access

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

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

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

Option 3 – Ban

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

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

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

ESTOC Response

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

No.

There are legitimate concerns related to Internet sales, among others in connection with the supervising of the minimum purchasing age and collection of tax revenues. However, a ban on sales via one specific channel would distort competition between different economic operators. It can be questioned whether such an approach is compatible with the Commission's aspirations to strengthen the internal market.

In your view, which option addresses the problem most effectively? Option 1
Do you recommend any additional option that would effectively address the problem? No
Do you have any additional specific comments? The issues of enforcement of minimum purchasing age and the collection of tax revenues are common to many goods sold on the internet and are not specific to tobacco.