



// CED WG ORAL HEALTH

CED RESPONSE TO THE PUBLIC CONSULTATION ON A POSSIBLE REVISION OF THE TOBACCO PRODUCTS DIRECTIVE 2001/37/EC

1. SCOPE OF THE DIRECTIVE

Q. 1) Do you agree with the problem definition?

A. 1) Yes.

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

A. 2) Option 2- Extend the scope of the Directive.

Q. 3) Do you recommend any additional option that would effectively address the problem? (Optional)

A. 3) No.

Q. 4) Do you have any additional specific comments?

A. 4) All tobacco products are hazardous to health – there is no safe level of usage. Therefore we recommend that the scope of the Directive includes the regulation of any new smoked tobacco products (such as low emission or nicotine-free cigarettes), while the prohibition of any novel forms of oral tobacco, including snus, should be maintained.

Herbal cigarettes are also harmful because it is the combustion and inhalation of smoke that causes most of the harm from smoking. Therefore, herbal cigarettes should be included in the scope of the Tobacco Products Directive and should also be subject to health warnings requirements.

Finally, all forms of nicotine based products (that is, products containing nicotine but which are not tobacco products, such as electronic cigarettes, nicotine gel, drinks, and sweets) are often marketed as alternatives to cigarettes and in some cases as an aid to quitting smoking. Therefore, they should only be sold as quitting aids and comply with specific safety and quality requirements under the same regulatory framework as pharmaceutical products rather than under the scope of the Tobacco products Directive. That includes evidence-based studies of the effectiveness of these products.

Special attention should be paid to specific protection of young people and women.

2. SMOKELESS TOBACCO PRODUCTS

Q. 1) Is the problem definition correct? If not, please provide your comments and supporting evidence.

A. 1) Yes.

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

A. 2) Option 1 - No change.

Q. 3) Do you recommend any additional option that would effectively address the problem? (Optional)

A. 3) No.

Q. 4) Do you have any additional specific comments?

A. 4) The ban on snus should remain. Research suggests that the use of snus in Sweden is less hazardous than cigarettes with the risk of developing most forms of cancer. It should be noted that 40% of snus users continued to smoke tobacco¹, there is evidence of an increased risk of cardiovascular disease². Removing the ban on snus would bring a new hazardous product to the market. The removal of the ban on the use of snus may encourage the dual use consumption of snus and cigarettes and discourage the cessation of tobacco consumption, losing the associated health gains.

There is evidence that the use of snus is shown to produce pathological changes in the oral mucosa: dysplasia and a suggested increase in oral and pharyngeal carcinoma^{3 4}. The use of other smokeless products should be regulated. These are particularly used by the ethnic minority populations. A total ban on these products may make it more difficult to interface in terms of health education with this section of the population. There is also a risk that an illegal market for products of this type may be created. These issues will have a negative impact on the delivery of oral and general health.

3. CONSUMER INFORMATION

Q. 1) Do you agree with the problem definition?

A. 1) Yes.

Q. 2) In your view, which option addresses the problem most effectively? (more than one option can be chosen)

A. 2) Option 2a – 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 2d – Health warnings would be placed on water pipes.

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

A. 3) No.

4. REPORTING AND REGISTRATION OF INGREDIENTS

Q. 1) Do you agree with the problem definition?

A. 1) Yes.

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

A. 2) 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.

It is unsatisfactory to have different formats and reporting mechanisms. A reporting system can only be effective if the same reporting mechanisms are used.

¹ Broadstock M. Systematic review of the health effects of modified smokeless tobacco products. New Zealand Health Technology Assessment. Christchurch School of Medicine and Health Sciences. NZHTA Report 2007, Volume 10 Number 1.

² Piano MR, Benowitz NL, FitzGerald GA *et al*. Impact of smokeless tobacco products on cardiovascular disease: Implications for policy, prevention, and treatment. A policy statement from the American Heart Association. *Circulation*, 2010; DOI: 10.1161/CIR.0b013e3181f432c3.

³ Schwart JL, Brunnemann KD, Adami AJ *et al* *Journal of Oral Medicine*.39(6):453-9, 2010 July.

⁴ Rooscaar A, Johansson AL, Sandborgh-Englund G. *International Journal of Cancer*.123(1):168-73, 2008 July 1.

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

A. 3) No.

5. REGULATION OF INGREDIENTS

Q. 1) Do you agree with the problem definition?

A. 1) Yes.

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

A. 2) Option 3b – Establish a negative common list of tobacco ingredients.

We support the adoption of a negative common list of tobacco ingredients. Tobacco products are highly toxic and addictive, and their content (main substances and additives) should be closely regulated. Tobacco smoke is a complex mixture of more than 4,800 substances, of which 90 are carcinogens or suspected to cause cancer^{5,6,7,8,9}. In addition, nicotine and co-carcinogens promote cancer development.

Tobacco smoke contains many toxic substances. During inhalation, poisonous gases, volatile substances and also some small particles will be very quickly absorbed. The tobacco industry, in the production of its tobacco products uses 600 additives that increase the addictive potential and also facilitates the initial use of tobacco. When the cigarettes are smoked at high temperatures, new and sometimes toxic or carcinogenic substances¹⁰ are produced from the additive ingredients.

The prohibition of ingredients such as sugars and sweeteners, flavouring substances, spices and herbs, in cigarettes and cigarette-like tobacco products is necessary. The prohibition of ingredients as vitamins, ingredients associated with energy and vitality (e.g. caffeine), and ingredients with colouring properties (e.g. pink cigarette paper) should also be banned. Tobacco manufacturers and importers should report sales volume information by brand. This information is essential to help governments ensure that product regulation is effective.

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

A. 3) No.

6. ACCESS TO TOBACCO PRODUCTS

Q. 1) Do you agree with the problem definition?

A. 1) Yes.

⁵ Baker RR (1999) Smoke chemistry. In: Davis DL, Nielsen MT: Tobacco. Production, chemistry and technology. Blackwell Science, Paris, 398–409

⁶ California Environmental Protection Agency (2005) Proposed identification of environmental tobacco smoke as a toxic air contaminant – June 2005. California Environmental Protection Agency, Office of Environmental Health Hazard Assessment, http://www.oehha.ca.gov/air/environmental_tobacco/2005etsfinal.html

⁷ Hecht SS (2003) Tobacco carcinogens, their biomarkers and tobacco-induced cancer. *Nat Rev Cancer*, 3, 733–744

⁸ International Agency for Research on Cancer (2004) Tobacco smoke and involuntary smoking. IARC Monographs on the evaluation of the carcinogenic risks to humans, Vol. 83. International Agency for Research on Cancer, World Health Organization, Lyon

⁹ Smith CJ, Perfetti TA, Garg R et al. (2004) Percutaneous penetration enhancers in cigarette mainstream smoke. *Food Chem Toxicol*, 42, 9–15

⁹ International Agency for Research on Cancer (2008) IARC Monographs Volumes 1–99, overall evaluations of carcinogenicity to humans, last update 28.04.08. <http://monographs.iarc.fr/ENG/Classification/crthallist.php>

¹⁰ Deutsches Krebsforschungszentrum (2005) Erhöhte Gesundheitsgefährdung durch Zusatzstoffe in Tabakerzeugnissen – Konsequenzen für die Produktregulation. Deutsches Krebsforschungszentrum, Heidelberg

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

A. 2) 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 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.

We do not think that option 3a would be effective. A total ban on cross-border sales over the Internet would result in an increase in the black economy as already currently present in many Member States.

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

A. 3) No.