



EUROPEAN SMOKELESS TOBACCO COUNCIL

**PROPOSED REGULATION OF  
SMOKELESS TOBACCO PRODUCTS WITHIN THE  
EUROPEAN UNION**

ESTOC  
Scientific Committee  
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# PROPOSED REGULATION OF SMOKELESS TOBACCO PRODUCTS WITHIN THE EU

## PART 1

### Executive Summary

Smokeless tobacco products are by definition not smoked but are used orally or inhaled through the nose. There is a multitude of products, which fall into four main categories: snus, moist snuff, chewing tobacco and nasal snuff.

Currently within the EU, Directive 2001/37/EC on the Manufacture, Presentation and Sale of Tobacco Products bans marketing and sales of snus and moist snuff; chewing tobacco and nasal snuff are permitted.

Because of the differences in product formulation and manufacturing techniques, the levels of potentially hazardous undesired constituents that smokeless tobacco products contain may vary considerably. It is therefore proposed that future regulation of smokeless tobacco products should be science-based with product quality characteristics of principle importance. This is in contrast to the current Directive, which is based only on the intended use of the product.

A comprehensive document detailing the proposed future regulation of smokeless tobacco products is presented. The regulation addresses consumer protection and has food regulation as one of the guiding principles. This is in line with the fact that, in Sweden, snus and chewing tobacco are currently regulated under the Swedish Food Act. The regulation includes requirements for:

**Nicotine and pH.** Nicotine is the main pharmacologically active principle in tobacco products. Reporting requirements are proposed for the level of nicotine in the finished product. In addition, as pH influences the bioavailability of nicotine in the finished product, reporting requirements are proposed for the pH value of the finished product.

**Undesired constituents.** These are potentially hazardous compounds present in the tobacco raw material and finished products. Limits, as well as annual reporting requirements, are proposed for:

- TSNA (Tobacco-Specific Nitrosamines)
- NDMA (nitrosodimethylamine - also present in food)

- B(a)P (Benzo(a)pyrene - also present in food)
- Lead (also present in food)
- Cadmium (also present in food)
- Aflatoxins (also present in food)

Reporting requirements are proposed for arsenic, nickel, chromium and nitrate.

**Ingredients.** Ingredients used in smokeless tobacco products can be separated into food items, chemically defined flavour substances, oils of botanical origin and additives that perform certain technological functions in the product. We propose that food items are permitted for use and that the EU-wide positive list of chemically defined flavouring substances permitted for use on foods should also be applied to smokeless tobacco products. Oils and extracts of botanical origin should be permitted, unless they are prohibited for use in the German Tobacco Ordinance or in food regulation. Only EU authorised food additives should be accepted for use in smokeless tobacco products.

**Non-tobacco materials.** Such materials used in the manufacture of smokeless tobacco products, e.g. inert sachet (sometimes also called pouch) fabrics, should have reporting requirements.

**Packaging materials.** Such materials used for smokeless tobacco products should be permitted for use with food.

**Labelling.** We propose that the warning label required in the EU Directive 2001/37/EC article 5.4 is retained. In addition, each smokeless tobacco unit shall display information on best before date and a declaration of ingredients according to EU food labelling requirements.

**Consumer information.** Manufacturers are willing to provide information to consumers about their products. Should the EU or national authorities determine that information relating to products be made available to consumers, this information should be provided in a meaningful way to consumers, while at the same time taking due account of manufacturers valuable brand recipes.

**Ingredients reporting.** As required in the EU Directive 2001/37/EC, this must include appropriate trade secret protection measures.

How the current EU Directive 2001/37/EC could be adapted to reflect these proposed regulations for smokeless tobacco, is described in Part 2 of this document.

## **1. PROPOSED REGULATION OF SMOKELESS TOBACCO PRODUCTS WITHIN THE EU**

Smokeless tobacco products by definition are not smoked. They are used orally or inhaled through the nose. Smokeless tobacco products include snus, moist snuff, chewing tobacco and nasal snuff.

- Snus is composed of finely ground or cut tobacco in loose or sachet form and is used orally. Snus is uniquely manufactured using a tobacco heat treatment process resembling pasteurisation.
- Moist snuff is composed of finely ground or cut tobacco in loose or sachet form and is used orally. It is commonly manufactured by fermentation.
- Chewing tobacco is composed of strands of spun tobacco, compressed leaves of tobacco or grated tobacco particles and is used orally. It is manufactured either from fermented or unfermented tobacco.
- Nasal snuff is composed of finely ground tobacco and is inhaled through the nose. It is manufactured by fermentation or the mixing of the ingredients.

Currently within the EU, Directive 2001/37/EC on the Manufacture, Presentation and Sale of Tobacco Products bans marketing and sales of snus and moist snuff; chewing tobacco and nasal snuff are permitted. Sweden gained an exemption from this ban when entering the EU in 1995 as the country has a long tradition of snus usage. It should also be added that some member states ban all smokeless tobacco products.

Today there are a multitude of smokeless tobacco products available for sale in most EU Member States. Because of differences in product formulation and manufacturing techniques, the levels of potentially toxic constituents that these contain may vary considerably. It is therefore proposed that future regulation of smokeless tobacco products should be science-based with product quality characteristics of principle importance, as opposed to the current Directive, which is based on the intended use of the product.

Regulation for food could be one of the guiding principles when considering smokeless tobacco products, since these products are consumed and partly ingested in the mouth or in the nose. This means that the emphasis is, just as with food regulation, on consumer protection. This also means that like food, smokeless tobacco products should meet high hygiene standards. This approach is in line with the current regulations pertaining to the manufacture of snus and chewing tobacco in Sweden.

A science-based regulation should cover all smokeless tobacco products and have requirements for:

- a) Nicotine
- b) Constituents (e.g. nitrosamines)
- c) Pesticide residues
- d) Ingredients
- e) Non-tobacco materials
- f) Packaging materials
- g) Labelling
- h) Consumer information
- i) Reporting/Surveillance

It is important to distinguish between undesired constituents (potentially hazardous compounds derived from the tobacco raw material), pesticides originating from application to the tobacco during growth and post-harvest storage and ingredients, which are selected and added to the tobacco by the tobacco manufacturer. Non-tobacco materials such as sachet (sometimes called pouch) fabrics are also selected by the tobacco manufacturer and should also be regulated.

The definitions used in this document concur with those used for food and differ from the definition formulated by the WHO SACTob group, where “Ingredients include all product components, materials used to manufacture those components, residual substances from agricultural practices, storage and processing, and substances that can migrate from the packaging into the product.” In the latter definition ingredients are included with chemical components of the finished product and comprise compounds of widely different origin. We prefer to handle potentially hazardous compounds mainly derived from the tobacco raw material as undesired constituents and compounds added by the manufacturer as ingredients. Pesticide residues, which originate from handling at the farm or storage level, and contaminants from packaging material would be dealt with as separate categories.

### **(a) Nicotine**

Nicotine is the main pharmacologically active component in tobacco and in smokeless tobacco products. It is present in varying amounts and the exposure of nicotine from a smokeless tobacco product is dependent not only on the nicotine content and the pH of the product but also on the particle size, texture, physical appearance and geometry of the product as well as the mode of use and consumer behaviour.

We suggest that reporting requirements are introduced for nicotine and pH for smokeless tobacco products and that international standards (e.g. ISO) are developed for these measurements as a priority. Until such international standards are developed, the industry is conducting appropriate method validation studies (proficiency testing) of nonstandard methods. In addition, standards for measurement of the extraction of nicotine from smokeless tobacco products should be developed for future reporting. Similarly, standards for measurement of the nicotine intake from smokeless tobacco products should be developed and the actual intake assessed for future reporting.

### **(b) Constituents**

All smokeless tobacco products contain undesired constituents that have been cited as being potentially hazardous. They include compounds that are formed in the tobacco leaf during growth, curing or post-curing processing and compounds that are taken up by the tobacco plant from the soil or fertilizers.

We propose that limits should be set for six constituents present in smokeless tobacco products typically cited and toxicologically relevant and that the actual levels of these are reported annually (listed in Table 1). Supporting information surrounding the selection of these undesired constituents and their limits is given in Annex 2. In order to achieve this, as with nicotine and pH, internationally recognised standardised analytical methods should be defined and established. As the limits in Table 1 relate to the dry weight of the tobacco, a standardised method for the determination of water should also be established. Each analytical method for different types of smokeless tobacco will need to be validated as an international standard (e.g. through ISO). As with nicotine and pH measurements, until such international standards are developed the industry is conducting appropriate method validation studies (proficiency testing).

Epidemiology indicates that the levels of these undesired constituents found in Swedish snus are correlated with the lowest risk to health relative to other forms of tobacco use including some other forms of smokeless tobacco. By setting these limits we seek to ensure that all smokeless tobacco products available within the EU match the lower risk profile of snus. Products with level(s) of undesired constituent(s) that exceed these limits, should not be permitted for sale after an appropriate period of time for compliance. A compliance period is required because by tradition certain smokeless tobacco products are manufactured using raw materials such as fire-cured tobacco that may have elevated levels of benzo(a)pyrene (B(a)P). Other smokeless tobacco products are produced using manufacturing processes that may increase the levels of TSNA, for instance uncontrolled fermentation.

There are EU-wide limits of lead, cadmium and aflatoxins in food, and since June 2006 there is a limit of aflatoxins in snus and chewing tobacco in the Swedish Food Act.

**Table 1.** Proposed limits for constituents in smokeless tobacco products

<b>Constituent</b>	<b>Limit (dry weight basis)</b>
TSNA (tobacco-specific nitrosamines)	10 mg/kg
NDMA (nitrosodimethylamine)	10 µg/kg
B(a)P (benzo(a)pyrene)	20 µg/kg
Lead	2 mg/kg
Cadmium	2 mg/kg
	<b>Limit (fresh weight basis)</b>
Aflatoxin B1,B2,G1,G2 (sum of)	0.005 mg/kg

Reporting requirements are suggested for other toxicologically relevant constituents such as the trace elements arsenic, chromium, and nickel. As with other crops these are taken up by the tobacco plant from the soil and fertilizer. Reporting requirements are also suggested for nitrate, which derive from soil and fertilizers.

### **(c) Pesticide residues**

Currently, there is no EU-wide regulation of pesticide residues in tobacco products.

Council regulation 396/2005 sets maximum residue levels (MRLs) for plant protection product (PPPs) residues on food and feedstuffs. We believe that comparable and appropriate levels could be extracted for smokeless tobacco and suggest that, as a first step, Standards should be developed for further discussion with the Commission.

### **(d) Ingredients**

As currently in Sweden, food regulation should be a guiding principle for regulating ingredients added to smokeless tobacco products. Using the terminology for food ingredients, the ingredients used in smokeless tobacco products can be separated into:

- i. food items, e.g. fruit juices
- ii. chemically defined flavouring substances, e.g. benzaldehyde
- iii. oils and extracts of botanical origin, e.g. geranium oil

- iv. additives (substances added intentionally to foodstuffs to perform certain technological functions, for example to colour, sweeten or preserve) e.g. glycerol.

The reporting requirements of the EU Directive 2001/37/EC on the Manufacture, Presentation and Sale of Tobacco Products should be retained (see below). Taking into account the types of ingredients used on smokeless tobacco products, it is proposed that :

- Food items are permitted for use.
- The EU-wide positive list of chemically defined flavouring substances permitted for use on foods should also be applied to smokeless tobacco products.
- Oils and extracts of botanical origin should be permitted, unless they are prohibited for use in the German Tobacco Ordinance or in food regulation (see Table 2). Proven hazardous ingredients such as areca nuts present in certain types of smokeless tobacco products should also be banned.
- Only EU authorised food additives should be accepted for use in smokeless tobacco products.

**Table 2.** Ingredients prohibited for use in tobacco products according to the German Tobacco Ordinance.

Agaric acid	Bitter almond oil with free or bound cyanides
Birch tar oil	Juniper tar oil
Sassafras oil	Coumarin
Camphor oil	Thujone
Safrole	Camphor wood
Stipules of bitter-sweet	Mint of Penny-royal
Polypody root	Quillaia bark
Qassia	Rue
Tansy	Sassafras leaves
Sassafras wood	Melilot
Sassafras bark	Deertongue leaves
Tonka beans	Woodruff

**(e) Non-tobacco materials**

Non-tobacco materials for smokeless tobacco products comprise e.g. inert sachet fabrics. These materials should be of food grade standard and reporting requirements are proposed.

**(f) Packaging materials**

Only packaging permitted for food materials must be used for smokeless tobacco products.

**(g) Labelling**

The warning label required in the EU Directive 2001/37/EC on the Manufacture Presentation and Sale of Tobacco Products article 5.4 is retained. In addition, it is proposed in line with Swedish smokeless tobacco regulation that each consumer package shall be labelled with a best-before date and shall have a declaration of ingredients in accordance with Food labelling regulation. Ingredients that are used in the manufacture of each product shall be listed in descending order of weight, with flavourings listed as a group.

**(h) Consumer information**

Manufacturers are fully prepared to provide information to consumers about their products. However, it is important for consumers to understand that the intake of nicotine and constituents from the product is dependent on factors such as product texture, size and formulation, as well as consumption pattern. Should EU and national authorities determine that information relating to product be made available to consumers, this information should be provided in a meaningful way e.g. on a per piece, per pinch, per sachet basis.

**(i) Reporting/Surveillance**

Reporting is a means of providing information to member states and thereby facilitating surveillance by relevant authorities. EU Directive 2001/37/EC on the Manufacture, Presentation and Sale of Tobacco Products requires tobacco manufacturers or importers to submit to Member States an annual report on all ingredients, their function, and quantities thereof, used in the manufacture of those tobacco products by brand name and type. Such a reporting system must allow for full regulatory disclosure but with appropriate trade secret protection. Disclosure models might evolve from ongoing discussions with DG SANCO and national authorities. It should also be noted that due to the nature of smokeless tobacco products, some of the required testing detailed in a document (SANCO/C6/ES D 2006: Draft Harmonised Reporting Format for the Submission of Tobacco Products' Ingredients Information to National Authorities) e.g. data in burned form, is not relevant.

To facilitate surveillance and to increase transparency, we propose that a comprehensive reporting system comprising not only ingredients but also nicotine levels, pH values and levels of undesired constituents, as detailed above, is introduced.

N.B.

If this proposed regulation is adopted, Part 2 shows the EU Directive 2001/37/EC on the Manufacture, Presentation and Sale of Tobacco Products could be amended accordingly.

## REFERENCES

EC No 466/2001 COMMISSION REGULATION (EC) No 466/2001 of 8 March 2001 setting maximum levels for certain contaminants in foodstuffs.

Hoffmann, D., Djordjevic, M.V., Brunnemann K.D., J. Smoking-Related Dis. 1991:2; pp 165-172, 1991.

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(<http://www.inchem.org/pages/jmpr.html>)

Rodu , B., Jansson, C. Crit. Rev. Oral Biol. Med. 2004:15; pp 252-263.

SANCO/C6/ES D (2006) Harmonised Reporting Format for the Submission of Tobacco Products' Ingredients Information Draft to National Authorities. Letter in response from ESTOC dated July 20, 2006

## **Appendix 1.**

### **CURRENT REGULATION OF SMOKELESS TOBACCO PRODUCTS**

#### **1. EU (EU Directive 2001/37/EC on the Manufacture, Presentation and Sale of Tobacco Products )**

##### **Definition**

EU Directive 2001/37/EC on the Manufacture, Presentation and Sale of Tobacco Products defines smokeless tobacco as follows: "Smokeless tobacco products" means products for the purposes of sniffing, sucking and chewing inas much as they are, even partly, made of tobacco, whether genetically modified or not.

##### **Ban**

Article 8 deals with Tobacco for oral use and states: "Member States shall prohibit the placing on the market of tobacco for oral use, without prejudice to Article 151 of the Act of Accession of Austria, Finland and Sweden."

The EU Directive 2001/37/EC on the Manufacture, Presentation and Sale of Tobacco Products hence retains the ban on sale of smokeless tobacco products intended to be sucked that was enacted in Directive 92/41/EEC, which amended Directive 89/622/EEC. Article 151 of the Act of Accession of Austria, Finland and Sweden grants Sweden a derogation from the ban.

##### **Warning label**

Article 5.4 states that "Tobacco products for oral use, where their marketing is permitted under Article 8, and smokeless tobacco products shall carry the following warning: "This tobacco product can damage your health and is addictive."

##### **Reporting – ingredients**

Article 6 deals with further product information, and in particular, reporting of ingredients. The requirements laid down are applicable to smokeless tobacco products. The only exception is that toxicological data for ingredients in burnt form is not relevant for smokeless tobacco products.

##### **Others**

No requirements for yields, constituents and pesticide residues are included in the EU Directive 2001/37/EC on the Manufacture, Presentation and Sale of Tobacco Products.

## **2. Sweden (Food Act 1971)**

Since 1971 chewing tobacco and snus are included in the Swedish Food Act - the rationale being that these tobacco products are consumed in the mouth and are partly ingested.

As stated in the Swedish Food Act (SFS 1971:511, translation from Swedish):  
“Food-stuffs are defined as foods, beverages, stimulants or other products that are intended to be consumed by humans with the exception of products that are regulated by the Medical Products Act (1962:701)”.

As a consequence, only additives and flavour ingredients permitted for food are allowed for snus and chewing tobacco. Also, the hygienic conditions during manufacture and storage are subjected to regular inspection by food authorities.

## **3. Germany (Tobacco Ordinance 1977, RHmV 1994)**

Chewing tobacco (“Kautabak”) and snuff (“Schnupftabak”) are regulated in the Tobacco Ordinance (Tabakverordnung) of 1977. The Tobacco Ordinance includes positive lists for flavour ingredients as well as for additives to be used in chewing tobacco and snuff. The regulation also contains a list of prohibited flavour ingredients, which are banned in all tobacco products. The German Tobacco Ordinance has also been adopted in other countries, e.g. Austria and the Czech Republic.

Mandatory and recommended limits for a number of residues of agrochemical agents in tobacco products are set in the “Rückstands-Höchstmengenverordnung –RHmV of 1994.

## Appendix 2.

### INFORMATION ABOUT THE CONSTITUENTS, FOR WHICH LIMITS HAVE BEEN PROPOSED

#### TSNA (Tobacco-Specific Nitrosamines)

- TSNA include four compounds, two of which are classified by IARC as Group 1, carcinogenic to humans.
- TSNA are formed in tobacco during curing (drying), storage and fermentation via a reaction of microbially generated nitrite and tobacco alkaloids.
- The levels in tobacco products vary considerably due to curing and processing conditions. Ranges from below 0.1 – 1200 mg/kg have recently been reported for smokeless tobacco products purchased in Sweden and the USA (Rodu et al. 2004)
- TSNA are the most frequently discussed of the controversial constituents in tobacco.

#### NDMA (N-nitrosodimethylamine)

- NDMA is a marker for volatile N-nitrosamines. It is classified by IARC as a Group 2A, probably carcinogenic to humans.
- NDMA occurs in food stuffs such as bacon, beer and whisky and is not specific to tobacco.
- The levels in tobacco products vary considerably due to curing and processing conditions. Levels from 0.1 – 265 microg/kg (dry weight) have been reported (Hoffmann et al. 1991)
- The levels of NDMA in 18 groups of Swedish foodstuffs range between 0.1-2.3 microg/kg (fresh weight) (National Food Administration; [www.slv.se](http://www.slv.se)).
- There is no EU harmonized limit for NDMA in foodstuffs. In the USA, there are limits, 5-10 microg/kg, for malt and malt-containing drinks.

#### B(a)P (Benzo(a)pyrene)

- B(a)P is a marker for polycyclic aromatic hydrocarbons. It is classified by IARC as Group 1, carcinogenic to humans.
- B(a)P is not specific to tobacco and is formed on incomplete combustion of organic material. It is found in fried and smoked food stuffs.
- The levels in tobacco products vary with the in-going tobaccos from <0.1 – 90.5 microg/kg (dry weight) (Hoffmann et al 1987).
- The levels in foodstuffs vary considerably, from not detected to 212 microg/kg in Swedish foodstuffs (fresh weight) (National Food Administration 8/98).

- There is no general EU regulation for BaP in foodstuffs, but limits have been set on the concentrations in smoke flavours and in certain foodstuffs.

## **Lead**

- Lead is a trace metal. It is classified by IARC as a Group 2B compound, possibly carcinogenic to humans.
- Lead is a contaminant, taken up by the tobacco plant from the soil, fertilizer or environment.
- Lead is found in vegetables and fruits and is not specific to tobacco.
- The levels in smokeless tobacco products vary with the in-going tobacco from 0.27-2.96 mg/kg (dry weight) (Hoffmann et al 1987).
- The levels in eight groups of Swedish foodstuffs varied between 0.003-0.12 mg/kg (fresh weight) during the years 1993-2002 (National Food Administration; www.slv.se).
- EU harmonized limits are set for the concentration of lead in foodstuffs (EC No 466/2001). The limits vary dependent on the type of foodstuff from 0.02-1.5 mg/kg (fresh weight).
- A limit of 3 mg/kg is set for snus and chewing tobacco (fresh weight) in the Swedish Food Act (LIVSFS 2004:7)

## **Cadmium**

- Cadmium is a trace metal. It is classified by IARC as a Group 1 carcinogen, carcinogenic to humans.
- Cadmium is a contaminant, taken up by the tobacco plant from the soil, fertilizer or environment.
- Cadmium is found in cereals, vegetables and fruits and is not specific to tobacco.
- The levels in smokeless tobacco products vary with the in-going tobacco from 0.45-1.58 mg/kg (dry weight) (Hoffmann et al 1987).
- The levels in Swedish foodstuffs vary between <0.001-0.051 mg/kg but levels as high as 36 mg/kg (fresh weight) have been reported for liver and kidney (National Food Administration; www.slv.se).
- EU harmonized limits have been set for the content of cadmium in foodstuffs (EC No 466/2001). The limits vary, for most foodstuffs they range between 0.05-0.2 mg/kg (fresh weight). Shellfish, liver and kidney have limits between 0.5-1.0 mg/kg.

## **Aflatoxin**

- Naturally occurring mixtures of aflatoxins (Cas No 1402-68-2) is classified by IARC in Group 1, carcinogenic to humans.

- According to the Commission Regulation (EC) No 466/2001 setting maximum levels for certain contaminants in foodstuffs, aflatoxins have the following permissible threshold values in different foodstuffs.
  - Unprocessed and processed groundnuts, nuts and dried fruit:
    - Aflatoxin B1 (2-8 µg/kg), Aflatoxin B1+B2+G1+G2 (4-15 µg/kg)
  - Unprocessed and processed cereals (buckwheat included):
    - Aflatoxin B1 (2 µg/kg ) Aflatoxin B1+B2+G1+G2 (4 µg/kg)
  - Unprocessed maize:
    - Aflatoxin B1 (5 µg/kg) Aflatoxin B1+B2+G1+G2 (10 µg/kg)
  - Spices (capsium, pepper, nutmeg, ginger and tumeric):
    - Aflatoxin B1 (5 µg/kg ) Aflatoxin B1+B2+G1+G2 (10 µg/kg)
  - Baby food and cereal containing foodstuffs for infants and babys:
    - Aflatoxin B1 (0.1 µg/kg )
  - Diet foodstuffs for special medical purpose:
    - Aflatoxin B1 (0.10 µg/kg)
  - All other kinds of foodstuffs which are not included above
    - Aflatoxin B1+B2+G1+G2 (5 µg/kg )