

# Public consultation on SCENIHR preliminary report on "Health Effects of Smokeless Tobacco Products"

Please find below the questions posed by the Commission and the answers given by the Committee. These questions and answers are extracted from the SCENIHR preliminary report (see chapter 4). You are therefore encouraged to read the full text of the document available at:

[http://ec.europa.eu/health/ph\\_risk/committees/04\\_scenihr/docs/scenihr\\_o\\_009.pdf](http://ec.europa.eu/health/ph_risk/committees/04_scenihr/docs/scenihr_o_009.pdf)

DG SANCO has requested the Scientific Committee on Emerging and Newly Identified Health Risks (SCENIHR) to answer the following questions:

1. What are the adverse health effects of smokeless tobacco products?
2. What is the addiction potential of smokeless tobacco products?
3. Does the available data support the claim that smokeless tobacco may constitute a smoking cessation aid comparable to pharmaceutical nicotine replacement products?
4. What is the impact of smokeless tobacco use on subsequent initiation of smoking?
5. Is it possible to extrapolate the information on the patterns of smokeless tobacco use, smoking cessation and initiation from countries where oral tobacco is available to EU-countries where oral tobacco is not available?

In this opinion the smokeless tobacco products are defined according to the EC Tobacco Products Directive (2001/37/EC): "‘Tobacco for oral use’ means all products for oral use, except those intended to be smoked or chewed, made wholly or partly of tobacco, in powder or in particulate form or in any combination of those forms, particularly those presented in sachet portions or porous sachets, or in a form resembling a food product".

Synonyms for "tobacco for oral use" are moist snuff (called snus in Sweden) and oral tobacco.

The SCENIHR has the following answers to the questions:

## QUESTION 1

**What are the adverse health effects of smokeless tobacco products?**

In answering this question, it must be recognised that marketed smokeless tobacco products (STP) vary considerably in form and content of toxicants, including nicotine, and thereby in associated health effects, which have been documented across countries.

All STP contain nicotine, a potent addictive substance. The major group of carcinogens in STP includes non-volatile tobacco-specific nitrosamines (TSNA) and N-nitroamino acids. During the last two decades the levels of TSNA in snus have been considerably lowered. One recent study documented total TSNA levels in one brand of Swedish snus to be 2.0 microgram/gram product wet weight, whereas total TSNA levels in 6 American brands varied from 1.3 to 9.2 microgram/gram. Levels of TSNA in STP from other regions such as India and Africa are higher. Nevertheless, STP including moist snuff have higher levels of carcinogenic nitrosamines than any consumer product used orally. Some forms of STP contain polycyclic aromatic hydrocarbons depending on curing.

Aqueous and organic extracts of American and Swedish moist snuff and Indian chewing tobacco cause mutations and chromosomal damage in bacterial and mammalian cell cultures. Increased micronuclei formation in oral epithelial cells as evidence of chromosomal damage, has been associated with moist snuff use.

Use of American and Swedish moist snuff results in localised lesions in the oral epithelium, where the snuff is placed. These changes are reversible, whereas gingival retractions caused by moist snuff are not reversible. Moist snuff in portion-bag sachets gives less severe epithelial changes than snuff in loose form.

There is sufficient evidence that the use of a wide variety of STP causes cancer in humans. The pancreas has been identified as a main target organ in two Scandinavian cohort studies. Furthermore, several studies from the USA have provided additional support for a causal association between the use of smokeless tobacco and pancreatic cancer. There is no evidence that STP cause lung cancer.

Risks of oral cancer were strongly associated with the use of American snuff in one large case-control study; however, a detailed characterisation of the product was not given. Four studies in India and Pakistan and one study from Sudan have reported large increases in the risk for oral cancers related to the use of various STP. In Swedish studies, an increased risk of oral cancer has not been proven in snus users. In one study from Sweden among users of moist snuff, an increased overall risk of head and neck cancer was not detected. However, an increased risk of head and neck cancer has been found among the subgroup of never-smokers.

There are suggestions that nasal use of STP increases the risk for certain cancers, e.g. oral cancers.

Three large cohort studies show a statistically significant but weak effect on fatal myocardial infarction. In addition, animal experiments and human studies indicate that oral tobacco use has short-term effects resulting in an increase of blood pressure and heart rate. Whether long-term use increases the risk of hypertension is uncertain. These data indicate

a potential effect on the risk of cardiovascular disease.

The data on reproductive effects in relation to oral tobacco use during pregnancy are too sparse to allow conclusions. Nonetheless, studies of reproductive effects in female Swedish users of moist snuff indicated an increased risk for prematurity and pre-eclampsia. Other studies indicate that the use of STP during pregnancy is associated with reduced birth weight and reduction in gestational age.

Various studies suggest that diabetes and other components of the metabolic syndrome might be associated with the use of moist snuff, but these findings must be interpreted with caution, in particular because of study design limitations.

Based on the available evidence it is difficult to identify overall relative risk estimates for the various adverse health effects from oral tobacco products as a whole because the products and conditions of use (e.g. frequency, duration, mode of use, other lifestyle factors) vary widely.

In conclusion, all STP contain nicotine, a potent addictive substance. They also contain carcinogenic tobacco-specific nitrosamines, albeit at differing levels. STP are carcinogenic to humans and the pancreas has been identified as a main target organ in American and Scandinavian studies. All STP cause localised oral lesions and a high risk for development of oral cancer has been shown for various STP but has not been proven for Swedish moist snuff (snus). There is some 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 cannot be drawn.

Do you agree with the response given ? (optional)

- Agree
- Mostly agree
- Mostly disagree
- Disagree
- Uncertain

Please provide the technical/scientific evidence to improve the overall assessment (with complete references).  
*max. 7.000 characters with spaces included (approximately 1 page)* (optional)

References (optional)

## QUESTION 2

**What is the addiction potential of smokeless tobacco products?**

It is widely accepted that nicotine is the primary addictive constituent of tobacco, and there is a growing body of evidence that nicotine demonstrates the properties of a drug of abuse. All commercially successful tobacco products, regardless of delivery mechanism, deliver psychoactive levels of nicotine to users. Denicotinised tobacco products are typically not widely accepted by or palatable to chronic tobacco users and are of marginal commercial importance.

Smokeless tobacco contains and delivers quantities of nicotine comparable to those typically absorbed from cigarette smoking, although delivery of nicotine from STP lacks the high initial concentration that results from inhalation of tobacco smoke. Nicotine levels obtained from STP are generally higher than those typically obtained from nicotine replacement therapy.

The time course and symptoms of withdrawal from smokeless tobacco are generally similar to those of cigarette smokers. It seems also that symptoms of withdrawal are stronger with some brands of smokeless tobacco delivering higher levels of

nicotine compared to other brands with lower levels.

There is a lack of evidence from animal models for the addictive potential of STP, given the conceptual difficulty in developing an animal self-administration model of smokeless tobacco. There is also a lack of evidence relating to the effects of additives introduced to tobacco in the manufacturing process on the initiation of use of STP and subsequent dependence.

In conclusion, smokeless tobacco is addictive and withdrawal symptoms are similar to those seen in smokers.

Do you agree with the response given ? (optional)

- Agree
- Mostly agree
- Mostly disagree
- Disagree
- Uncertain

Please provide the technical/scientific evidence to improve the overall assessment (with complete references).  
*max. 7.000 characters with spaces included (approximately 1 page)* (optional)

References (optional)

### QUESTION 3

**Does the available data support the claim that smokeless tobacco may constitute a smoking cessation aid comparable to pharmaceutical nicotine replacement products?**

No randomized trial has been conducted on smokeless tobacco as an aid to smoking cessation and no randomized trial has compared smokeless tobacco to pharmaceutical nicotine replacement products in this respect.

A small number of studies have looked at the use of smokeless tobacco in relation to smoking habits and one of those also includes nicotine replacement products. The results of these studies are inconsistent. Due to this and methodological limitations no conclusions can be drawn.

Aggregate data on smokeless tobacco product use and cigarette smoking show that particularly in Swedish men, there is a clear trend over the last decade for smoking prevalence to decrease and for use of the oral tobacco snus to increase. It has been suggested that the greater decline in smoking prevalence in men compared to women in Sweden is explained by the availability of snus. However, the trend in smoking prevalence in males could also be due to successful non-smoking programs or other socio-cultural factors. Smoking prevalence in Norway has decreased at the same rates in men and women during the last decade, whereas a marked increase in snus use during this time period has only occurred in men. In general, aggregate data provide inadequate evidence to make any causal inference.

Due to insufficient evidence it is not possible to draw conclusions as to the relative effectiveness of smokeless tobacco as an aid to clinical smoking cessation in comparison with established therapies.

Do you agree with the response given ? (optional)

- Agree
- Mostly agree

- Mostly disagree
- Disagree
- Uncertain

Please provide the technical/scientific evidence to improve the overall assessment (with complete references).  
*max. 7.000 characters with spaces included (approximately 1 page) (optional)*

References (optional)

## QUESTION 4

**What is the impact of smokeless tobacco use on subsequent initiation of smoking?**

The association between smokeless tobacco use and cigarette smoking initiation is likely to be confounded by socio-demographic factors. In addition, across countries there are possible differences in risk for which the determinants are not fully understood. The associations observed may be due to an increased likelihood of all substance use (including STP and cigarettes) as part of a broader spectrum of risky and impulsive behaviours in adolescence. There is some evidence from the USA that smokeless tobacco use may lead to subsequent cigarette smoking. The Swedish data, with its prospective and long-term follow-up do not support the hypothesis that smokeless tobacco (i.e. Swedish snus) is a gateway to future smoking. The marked social, cultural and product differences between North America and Europe suggest caution in translating findings across countries, also within Europe.

Do you agree with the response given ? (optional)

- Agree
- Mostly agree
- Mostly disagree
- Disagree
- Uncertain

Please provide the technical/scientific evidence to improve the overall assessment (with complete references).  
*max. 7.000 characters with spaces included (approximately 1 page) (optional)*

References (optional)

## QUESTION 5

**Is it possible to extrapolate the information on the patterns of smokeless tobacco use, smoking cessation and initiation from countries where oral tobacco is available to EU-countries where oral tobacco is not available?**

The only smokeless tobacco product, as defined in the Tobacco Products Directive (2001/37/EC) (i.e. ‘tobacco for oral use’ means all products for oral use, except those intended to be smoked or chewed, made wholly or partly of tobacco, in powder or in particulate form or in any combination of those forms, particularly those presented in sachet portions or porous sachets, or in a form resembling a food product) that is available in some European countries, but not all, is the oral tobacco snus, which is available in Sweden but not allowed to be sold in other EU-countries. As discussed in the answer to Question 3, the smoking prevalence in Swedish men has declined over the last decade while the use of snus has increased during the same period. However, while smoking prevalence has decreased also in Swedish women during this period, the prevalence of snus use in women has increased to a smaller degree than in men. In Norway, smoking cessation rates are similar in both genders, however, increased prevalence of smokeless tobacco use is observed only in men. In California both the prevalence of smoking and smokeless tobacco use have decreased concurrently. These data imply that the association between patterns of smokeless tobacco use and smoking cessation differ from one population to the other and are affected by cultural and societal factors. As was also discussed in the answer to Question 3, available scientific data are inadequate to determine if there is any causal relation between the trends in smoking prevalence and prevalence of use of STP.

In conclusion, it is not possible to extrapolate future patterns of tobacco use across countries. In particular, it is not possible to extrapolate the trends in prevalence of smoking and use of oral tobacco if it were made available in an EU-country where it is now unavailable due to societal and cultural differences.

Do you agree with the response given ? (optional)

- Agree
- Mostly agree
- Mostly disagree
- Disagree
- Uncertain

Please provide the technical/scientific evidence to improve the overall assessment (with complete references).  
*max. 7.000 characters with spaces included (approximately 1 page)* (optional)

References (optional)

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