

Proposed revision to the Tobacco Products Directive

A critique of the scientific reasoning supporting the proposed measures relating to oral tobacco

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Introduction

Disclosure: both authors have worked in the field of tobacco control over many years and have consistently argued for harm reduction strategies based on promotion of low risk alternatives to cigarettes, including oral tobacco ('snus'). Both authors have no competing interests and are interested only in securing the best public health outcome from European measures to regulate tobacco and nicotine products.

The proposed revision of the Tobacco Products Directive. On 19 December 2012, the European Commission published its proposal for a revision to the 2001 Tobacco Products Directive³. The proposal was published as a package including an explanatory memorandum with draft directive⁴ and impact assessment⁵. The impact assessment sets out the Commission's options analysis and rationale for the proposed measures. In the impact assessment, the Commission provides its rationale for the ban on oral tobacco ('snus') and other restrictions on smokeless tobacco. For oral tobacco, the proposed directive has the following effect: defines oral tobacco as tobacco that is consumed orally but not inhaled or chewed; maintains a ban on oral tobacco outside Sweden but does not ban other smoked or smokeless tobacco; bans 'characterising flavours' in all smokeless tobacco; controls the use of additives; and sets standards for labelling and warning consumers. This document provides an evidence-based critique of the scientific reasoning used in the impact assessment to justify the Commission's preferred policy and legislative options for oral tobacco.

Executive summary

The purpose of the proposed directive is to improve the functioning of the internal market in tobacco and nicotine products, whilst securing a high level of health protection. While some measures in the proposal are likely to support this purpose, the proposed regulatory framework for smokeless tobacco products would be sharply counterproductive. We show that the scientific reasoning in the impact assessment has pervasive errors of fact and interpretation, selective use of evidence, important omissions, and poor conceptual framing. Legislation based on flawed scientific foundations will harm the health of Europeans, impede the development of the internal market and open the directive to legal challenge.

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³ [2001/37/EC](#)

⁴ [COM\(2012\) 788 final](#)

⁵ [SWD\(2012\) 452 final](#)

Summary of the critique of the impact assessment

The case for the Commission's preferred options rests on several arguments set out in the Impact Assessment:

- Harmful and addictive nature of oral tobacco use
- Inconclusive effectiveness on whether oral tobacco is effective in smoking cessation
- Risks of initiation, through creation of a 'gateway' into smoking or tobacco use
- Risks of 'dual use', through which oral tobacco will maintain smoking where users might otherwise quit tobacco use completely
- The use of characterising flavours to make the product more attractive
- Application of the precautionary principle to justify a ban where there is uncertainty about the science

The analysis that forms the body of this document shows the Commission's scientific reasoning to be fundamentally flawed. The Commission's case has failed to articulate the most important characteristics of oral tobacco, which are summarised here and developed through the detailed critique later in this analysis.

- **Health risks of snus are low.** The impact assessment seeks to establish that oral tobacco is associated with various diseases, but mostly without quantifying risk or harm. No-one argues that snus is perfectly safe, but *how unsafe* is important. What should matter to a regulator or legislator is the following: (1) that the *excess risk* of prolonged snus use compared to being a non-tobacco user is small and comparable with other lifestyle risks; (2) that the *relative risk* compared to smoking, for which it is a viable alternative, is very low, and thus presents opportunities for harm reduction and health benefits – and these are strongly evident in Sweden.
- **Relative risk compared to smoking is very low.** The relative risk of use of oral tobacco in the form of Swedish snus is *at least* 90% less than cigarette smoking and at the low end of the spectrum of risk arising from smokeless tobacco products. It is the least hazardous form of tobacco available, yet most severely regulated.
- **Health benefits from harm reduction are significant.** Oral tobacco can substitute for cigarette use and provide a substantial health benefit for those who switch. The *health benefit* arising from 'harm reduction' is unambiguously clear in Sweden, which has by far the lowest rates of smoking and smoking related disease in Europe. It takes particularly perverse reasoning to argue that the product that has created Europe's best tobacco-related *health outcomes* should be deliberately denied elsewhere. This has happened largely through the action of consumers and a competitive market for a much safer alternative to cigarettes, yet the ban on snus has the supposed purpose of improving the functioning of the internal market.
- **No significant gateway effects have been found.** Weight of evidence suggests that where oral tobacco is in widespread use it does not cause initiation, create new smokers or show any significant gateway effects. Its effect is to reduce smoking and to act as an exit not entrance.
- **Oral tobacco is an effective aid to smoking cessation.** That oral tobacco has been widely used as a smoking cessation aid and has been more effective than NRT.

- **Oral tobacco marginalises rather than encourages smoking.** A tiny fraction of users in Sweden use both snus and cigarettes. By reducing the visibility of smoking at home and in public, smokeless tobacco supports ‘denormalisation’ of smoking, not continued smoking.
- **Making snus relatively less attractive than cigarettes is dangerous.** Characterising flavours are integral to the viability of oral tobacco as a product category and as an alternative to smoking, but only a marginal part of the cigarette market. Making snus relatively less attractive by banning characterising flavours may cause users to return to smoking or never switch to snus from smoking – and so cause more harm.
- **Proper application of the precautionary principle would mean lifting the ban.** The Commission’s own guidelines on the precautionary principle have not been followed, and this principle cannot be used to justify the ban on the grounds that snus is harmful and addictive. Application of the precautionary principle also requires assessment of the *unintended costs and risks of the ban itself* – and, on the available evidence, the estimated impact of denying smokers safer alternatives would be substantial.

Legal importance of sound scientific foundations for the proposed directive

The quality of scientific reasoning in these documents is important. This is not just because European citizens naturally hope and expect that laws are based on sound science, but because law-makers are constrained by various principles written into the governing treaties of the European Union⁶, which may be violated if the underlying scientific case is flawed. These principles include: proper legal base; proportionality; subsidiarity; non-discrimination; free movement of goods facilitated by the approximation of laws, with the aim of a high level of health protection; and obligations to consult and to give reasons for measures. The draft directive does, at face value, conflict with several of these principles where it concerns oral tobacco:

- impedes free movement of goods and competition between tobacco products by banning sales of oral tobacco outside Sweden;
- restricts competition by regulating product characteristics, for example by banning characterising flavours, and adversely affects the competitive balance between smoking and smokeless tobacco;
- imposes the most severe restriction, a ban, on the least risky products, so appears disproportionate;
- treats similar products with discriminatory differences in regulation - some forms of smokeless tobacco are allowed and lightly regulated but others are banned, depending on whether the product is sucked or chewed once in the mouth.

It is conceivable that these apparent breaches of basic principle may be acceptable, *but only if there is robust science-based health protection justification*. This critique shows the scientific justification is wholly inadequate and the justification for the ban on snus used in the 2003-4 case before the European Court of Justice⁷ would not be sustainable now, given the available evidence and quality of scientific reasoning in the impact assessment.

⁶ Primarily the Treaty on the European Union and Treaty on the Functioning of the European Union

⁷ Case C-210-03 Judgment of the Court (Grand Chamber) of 14 December 2004. The Queen, on the application of: Swedish Match AB and Swedish Match UK Ltd v Secretary of State for Health.

What should be done?

Mainstream scientific opinion does not support the European Commission's case. The report of the SCENIHR committee (2008) for the Commission provides no basis for a ban and substantial evidence to justify replacing a ban with regulation of ingredients. The WHO Study Group on Tobacco Regulation (WHO TobReg 2009), Royal College of Physicians (2007), European Monitoring Centre for Drugs and Drug Addiction (2010) all argue for ingredients regulation for common standards for product toxicity for all smokeless tobacco. Fifteen eminent scientists and experts wrote to Commissioner Dalli in May 2011 to argue this case (Axell T. *et al*, 2011). These views have not been faithfully represented in the impact assessment, but they support the regulatory option rejected by the Commission (option 1). There are many options for setting a regulatory standard for smokeless tobacco which would both protect health and improve functioning of the internal market. The obvious, proportional and non-discriminatory way to establish a single market in smokeless tobacco products is to regulate the toxicity of the products. This is exactly the proposal of the WHO Study Group on Tobacco Regulation (WHO TobReg 2009)

3. Report on setting regulatory limits for carcinogens in smokeless tobacco

3.9 Recommendations

- All products that deliver nicotine for human consumption should be regulated
- Smokeless tobacco products should be regulated by controlling the contents of the products
- The metric for measuring toxicants in smokeless tobacco should be the amount per gram of dry weight of tobacco
- Initially, upper limits should be set for two nitrosamines N-nitrosornicotine (NNN) and 4-(methylnitrosamino)-1-(3-pyridyl)-1-butanone (NNK), and one polycyclic aromatic hydrocarbon, benzo[a]pyrene
- The combined concentration of NNN plus NNK in smokeless tobacco should be limited to 2 µg/g dry weight of tobacco
- The concentration of benzo[a]pyrene in smokeless tobacco should be limited to 5 ng/g dry weight of tobacco.
- Regulation of the distribution and sale of smokeless tobacco products should include a requirement for affixation of the date by which the product must be sold or returned to the manufacturer and a requirement for refrigeration of the product before sale in order to limit the increase in the concentration of nitrosamines that occurs over time of storage.

Other regulatory standards could be set for nitrites, heavy elements (cadmium, lead, arsenic, nickel, chromium) and pesticide residues – these are included in the voluntary Gothiatek standard, in use in Sweden (Rutqvist L *et al* 2011).

Conclusion

There has been ample opportunity for the Commission to develop policy and legislation based on sound science, and thereby to produce good legislation that is beneficial to the health of European Union citizens will not be struck down when tested in the courts. This critique suggests that science has been misused to justify a predetermined policy, rather than the policy developed on the basis of sound science.

The impact assessment as it relates to oral tobacco: an evidence based critique

The substantive part of this document takes statements made in the impact assessment (IA) and provides comment based on best available scientific understanding. The critique covers the evidence related to the following:

1. Health risk and harm
2. Cessation, initiation and dual use – changes in tobacco use status
3. Ban on characterising flavours and consequences of make oral tobacco relatively less attractive
4. Application of the precautionary principle

1. Critique of evidence on health risks and harm

The presence of toxins and addictive agents in oral tobacco is only a concern to the extent that it causes health risks.

1.1. Poor and unquantified framing of risk

IA Statement (p.64) “In terms of health, all STP tobacco products contain nicotine and are addictive. They also contain carcinogenic substances, including tobacco specific N-nitrosamines (TSNA) and polycyclic aromatic hydrocarbons (PAH). The Scientific Committee on Emerging and Newly Identified Health Risks (SCENIHR) concluded, in its opinion on 6 February 2008, that STP in all its forms can cause cancer (with the pancreas as a main target organ) and are addictive.²⁵⁸ The International Agency for Research on Cancer (IARC) has also classified smokeless tobacco as “carcinogenic to humans”.²⁵⁹ A study on smokeless tobacco and cancer from 2008 concludes that the cancer risk of smokeless tobacco users is probably lower than that of smokers but higher than that of non-tobacco users.²⁶⁰ Studies show that STP are less hazardous to health than FMC²⁵⁷ and even option 1 would prevent STP with increased toxicity or addictiveness to enter the market.”

Comment: It is true that both TSNA and BaP (a human carcinogen included in the group of PAH) are present in snus, but it is important to distinguish between *cancer hazards* and *cancer risks*. *Cancer hazards* are agents that are capable to cause cancer under certain circumstances. *Cancer risks* are estimates of the carcinogenic effects expected from exposures to cancer hazards. This means that a cancer hazard can pose very low cancer risks at current exposure levels. In fact, a recent risk evaluation has indicated that the current levels of TSNA in Swedish snus are two orders of magnitude too low to be a risk factor for cancer (Nilsson, 2011).

PAH in snus products originate from air pollution and are present in trace amounts. *The levels are actually lower than those found in many foodstuffs.*

1.2. Overlooking the potential to reduce risks from the most toxic smokeless tobaccos through regulation

IA Statement (p.64): “There are many forms of smokeless tobacco products, which differ considerably in their composition and toxic potential. Some chewing tobacco products, in particular some products used by the South Asian community in the UK, according to a recent study, contain a wide range of toxic substances, such as tobacco-specific nitrosamines (TNSA) chromium, nickel and lead.²⁶¹ During the last two decades, the level of tobacco-specific

nitrosamines (TNSA), the major group of carcinogens in smokeless tobacco, has been considerably lowered in some STP, including Swedish oral tobacco (snus).²⁶² This means that the adverse health effects of snus might differ from other non-combustible tobacco products. However, it does not mean that snus or any other oral tobacco product is safe or harmless. Products with lower levels of carcinogenic tobacco-specific nitrosamines (TNSA) have also been on the market for too short time for any convincing support in favour of the presence or absence of a lower cancer risk. The WHO Study Group on Tobacco Product Regulation concludes in its report from 2009 that existing evidence has not established that lowering TSNA or PAH levels in smokeless tobacco will lower cancer risks.²⁶³”

Comment: It is now generally recognised that there is a *risk continuum* among tobacco products. This continuum is referred to by WHO in the report “The scientific basis of tobacco product regulation (2008)” where it is stated that “cigarette smoke is the most hazardous form of nicotine intake, and medicinal nicotine the least hazardous. Among smokeless tobacco products on the market, products with low levels of nitrosamines, such as Swedish snus, are considerably less hazardous than cigarettes, while the risks associated with some products used in Africa and India approach those of smoking.”

Snus is not safe and harmless. The important issue from a public health aspect is the *relative risk* of snus use compared to cigarette smoking and compared to other common lifestyle or consumption-related risks. The SCENIHR Report contains a section (3.8) on smokeless tobacco, public health, and the harm reduction argument, which was not addressed in the abstract or executive summary. One conclusion from this section is: “Overall therefore, in relation to the risks of the above major smoking-related diseases, and with the exception of use in pregnancy, STP are clearly less hazardous, and in relation to respiratory and cardiovascular disease substantially less hazardous, than cigarette smoking.” A study using a modified Delphi approach to estimate the relative hazard of snus concluded that the product was likely to be approximately 90% less harmful than smoking (Levy et al. 2004). Snus use is hence associated with substantially lower health risks than cigarette smoking.

The Impact Assessment Report chooses not to cite the complete passage from the WHO Report (2009), which reads “While existing evidence has not established that lowering TSNA or PAH levels in smokeless tobacco products will lower cancer risks, it is difficult to justify allowing high levels of known carcinogenic constituents in a product that is known to cause cancer, when lower levels are readily achievable with existing technology. As they do for other consumer products, regulators should lower the concentrations of carcinogens present in smokeless tobacco by limiting the concentrations that can be present in products that are marketed.” The WHO TobReg group hence calls for “product regulation having the aim to reduce toxicity.” This is not attempted in either the current or proposed Tobacco Products Directive. In contrast the largest Swedish manufacturer of snus has voluntarily adopted the limits proposed by WHO for TSNA and BaP in their products.

1.3. Selective use of evidence exaggerates the risk of pancreatic cancer

IA Statement (p. 64-65): “The link between STPs and pancreatic cancer has been discussed by the research community in recent years. Based on a number of case-control and cohort studies, the two authoritative international research groups SCENIHR and IARC have concluded that there is

sufficient evidence that STPs cause pancreatic cancer in humans.²⁶⁴ A recent case-control study suggests, however, that there is no significant association between pancreatic cancer and smokeless tobacco.²⁶⁵ The discrepant results of this study with other case-control studies have been questioned by a number of researchers calling for a cautious interpretation in view of existing strong cohort data supporting an association between STP and risk of pancreatic cancer.²⁶⁶”

Comment: The Impact Assessment Report is *selective* in the use of scientific data. The outcome from the two Nordic cohort studies is actually inconsistent and neither study adjusts for alcohol use and history of diabetes, which are known risk factors and may confound the results (Boffetta et al. 2005, Luo et al. 2007). This is pointed out by the authors of the recent case-control study mentioned above, who noted that “*the apparent inconsistency between their findings and those from Nordic cohorts may be due to the absence of adjustment of estimates in the Nordic studies for most of the covariates allowed for in their analyses*” (Bertuccio et al. 2011). Two meta-analyses (i.e. a statistical combining of data or risk estimates from separate but similar epidemiological studies, leading to a single quantitative summary, a risk number for the pooled results) reported an increased risk of pancreatic cancer for snus users or subgroups of snus users, while a third meta-analysis did not find an association between snus use and cancer of the pancreas (Sponsiello-Wang et al. 2008, Lee et al. 2009a, 2009b. 2011). Of particular interest is the fact that the incidence of pancreatic cancer is low among Swedish men compared to that among men in other member states, despite the fact that 20% of Swedish men are snus users.

1.4. Selective use of evidence exaggerates the risk of oral cancer

IA Statement (p.65): “Risk of oral cancer have been found for various smokeless tobacco products, including some of the chewing tobacco products (e.g. areca nut and betel quid) used by ethnic minorities in the UK.²⁶⁷ There are also suggestions that nasal tobacco increases the risk of certain cancers, e.g. oral cancers.²⁶⁸ The risk for oral cancer is less clear as regards Swedish oral tobacco (snus).²⁶⁹”

Comment: A summary of the evidence strongly suggests that use of Swedish snus does not increase the risk of oral cancer, a conclusion now strengthened by results from *three meta-analyses* (Boffetta et al. 2008, Weitkunat et al. 2007, Lee and Hamling 2009a). *Also, compared to men in other European countries the incidence of oral cancer is low among Swedish men.*

1.5. Selective use of evidence to exaggerate the risk of oesophageal cancer and omission of the most important data on lung cancer

IA Statement (p.65): “SCENIHR concluded in 2008 that published studies support a causal role of STP in the etiology of oesophageal cancer.²⁷⁰ According to IARC, there is now sufficient evidence that there is a causal association between smokeless tobacco and oesophageal cancer.²⁷¹”

Comment: The evidence that the use of Swedish snus causes oesophageal cancer is *contradictory*. Three out of four studies found no effect, while the fourth did observe an elevated risk for one specific type of oesophageal cancer (Lewin et al. 1998, Lagergren et al. 2000, Boffetta et al. 2005 and Zendejdel et al. 2008). *Two meta-analyses have been performed; one reported an increased risk, while the second concluded that there was no real indication of an effect for snus in Scandinavia* (Boffetta et al. 2008 and Lee et al. 2009a, 2009b).

It should also be recognised that snus use is not associated with lung cancer, which is by far the largest cause of tobacco-related cancer mortality. Consistent with this is the fact that the incidence of lung cancer among Swedish men is the lowest among men in the EU-member states. There is no significant discussion of the most important cancer associated with tobacco use in the assessment to support oral tobacco policy.

1.6. Selective use of evidence to exaggerate the risk of heart disease

IA Statement (p.65): “In addition, there is evidence for an increased risk of fatal myocardial infarction among STP users.²⁷² Hansson concluded in a study from February 2012 that current snus users had a higher probability of dying from acute myocardial infarction (AMI) as compared to non-users, and that this increase may be explained in confounding factors, although a small increased risk of sudden death from AMI among snus users cannot be ruled out.²⁷³”

Comment: The conclusion from Hansson’s study (2012) is that “there is no or a very low increased risk of fatal myocardial infarction among snus users”. For clarity, it should be pointed out that the incidence in myocardial infarction in total is not increased among snus users.

1.7 Significant omission of the diseases not caused by oral tobacco

Though it is probably the most important feature of oral tobacco, the IA does not adequately distinguish between the diseases risks of smokeless tobacco and smoking.

IA statement (p.22): The role of tobacco in the society. Tobacco is a legal product on the EU’s internal market, but is no ordinary commodity in the sense that it is the largest avoidable health threat in the EU, responsible for almost 700,000 deaths in the EU each year (see Annex 5). Moreover, millions of people in the EU suffer from one or more of the six main disease categories associated with smoking: 1) Bronchitis and other lower respiratory infections, 2) Chronic obstructive pulmonary diseases, 3) Stroke, heart attacks, arterial obstructions (especially in the legs) and other cardiovascular diseases, 4) Asthma, 5) Lung cancers and 6) Other cancers, such as pancreas, oesophagus, and stomach. Studies show that around 50% of smokers die prematurely and if they do so they die on average 14 years earlier. In addition, smokers have more life years that are characterised by serious disease.

Comment: Though the paragraph is headed ‘the role of tobacco in society’ the discussion relates to the disease impact of *smoking*. Oral tobacco does not cause (1), (2), (4) & (5) in the statement above. To the extent it causes (3) and (6), the risks are significantly lower than for smoking (see discussion above in 1.3-1.6 above). In the case of (6) the absolute risks are low in comparison to the major cancer risk – lung cancer. All of these conclusions are supported in depth by the advice of SCENIHR (2008). However, the IA attempts to make as much of the residual health impacts as possible, and simply ignores the significant reductions in risk - even though these explain why Sweden has the lowest rates of smoking-related disease in Europe. Though a figure of 14 years of lost life is given for smoking, no figure is given for oral tobacco users. In Gartner et al (2007) a central estimate of around 6 months (0.48 years) was made.

1.8. Risks to pregnant women are acknowledged but do not contribute to the case for a ban

IA Statement (p.65): “Some data also indicate that STP use is associated with several pregnancy complications, including pre-term birth, intrauterine growth restriction, placenta abruption and still birth.²⁷⁴”

Comment: Pregnant women are advised to avoid many forms of consumption – including smoking, alcohol and unpasteurised dairy products. Snus and other nicotine-containing products should not be used by pregnant women, and NRT is a better option for those unable or unwilling to quit nicotine during pregnancy.

1.9. Unquantified risk statements are of less regulatory significance than risk relative to smoking

IA Statement (p.66): “In conclusion, despite differences in composition and carcinogenic potential, there is scientific evidence that all STPs are addictive and harmful to health. As shown above, some of the epidemiological data are questioned by studies (partly sponsored by the industry) inconsistent but this does not put into question the overall conclusion. In any event it justifies the application of the precautionary principle, i.e. it justifies not allowing market entry of products, which are addictive and harmful.²⁷⁵”

Comment: The relevant conclusion is that snus, although addictive and not completely safe, is considerably less harmful than cigarette smoking (90% or more) and not particularly harmful in absolute terms compared to other lifestyle risks. Use of unquantified statements about harm does not provide a credible basis for regulation. Relative evaluations – compared to other lifestyle/consumption risks and, especially, relative to smoking are much more relevant. This poor framing of risk has the consequence that a much less harmful product is banned and at least ten times more hazardous cigarettes remain the only option for those EU citizens who have chosen to use tobacco. The precautionary principle in this case has been misapplied and most likely resulted in an increase in harm (see discussion on the precautionary principle below).

2. Critique of evidence on cessation, initiation and dual use

2.1 Understatement of the role of snus as a smoking cessation aid and positive experience in countries where snus is used

IA Statement (p.66-67): “In terms of substitution, some studies suggest that oral tobacco (snus) can play a role in smoking cessation²⁷⁶ or that oral tobacco users are more likely to quit smoking than users of medicinal smoking cessation products.²⁷⁷ Most of the studies are based on observational data, which makes it difficult to draw reliable conclusions as to the relative effectiveness of smokeless tobacco in smoking cessation.²⁷⁸ On the other hand, a randomised controlled trial showed that use of STP in cessation did not have any long-term efficacy.²⁷⁹ Swedish Match recently sponsored two clinical trials comparing the effectiveness between oral tobacco (snus) and placebo products in smoking cessation in Serbia and the US.²⁸⁰ The studies suggest that smokers using Swedish snus were 2-3 times more likely to quit smoking than those using placebo-products. However, the studies took place over a relatively short time (24 and 28 weeks) and it is impossible to say whether the relatively few people quitting smoking in these

studies would have done so also without oral tobacco or also, or even more, with the assistance of NRT.²⁸¹ In this context it should also be considered that 2/3-3/4 of smokers quit un-aided.²⁸²

Comment: It is concluded in section (3.7.2.3) of the SCENIHR Report that “*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. The data are consistent in demonstrating that these male snus users are more likely to quit smoking than non-users. In these uncontrolled, retrospective studies, results on par with those achieved with nicotine replacement products and above, are quoted. A side effect, however, is that 60% or more smoking abstainers become chronic snus users*”.

Since then additional studies from Sweden have corroborated these findings (e.g. Rutqvist, 2012). Moreover, several studies from Norway are consistent with the findings from Sweden that snus has, for many years, been the most widely used method for smoking cessation among men. The effects are better for snus than for NRT (Lund et al. 2010, Scheffel et al. 2012). The fact that most snus-users in Sweden and Norway are former smokers, shows that snus has long-term effects as an informal quit smoking aid (e.g. Ramström et al. 2006, Gilljam et al. 2003, Stenbeck et al. 2009, Lund et al. 2010, 2012). It should also be emphasized that most smoking cessation occurs outside of clinical settings so results from observational studies may even be more relevant than clinical studies.

The Impact Assessment Report uses the article by Barrett et al (2011)²⁷⁷ to cast doubt about the acceptability of snus as cessation aid in a snus-naïve society, but it neglects to give references to other scientific reports, where snus is accepted and preferred over nicotine gum (e.g. Caldwell et al. (2009)).

It is true that the study by Tønnesen et al. (2008) showed no long-term efficacy, but neither did *counselling*, which is one of the few options offered to smokers in Europe. It should also be noted that *NRTs have very low long-term efficacy (ca 7%, when combined with counselling)* (Hughes et al. 2003).

It is also true that the randomized clinical studies on snus took place over a relatively short time, but other objections raised against these studies are irrelevant. Use of placebo-controls in clinical studies simply adjusts for such random effects.

A rough calculation shows that there are as many as 100-130 million smokers in the EU, who cannot quit on their own. Since smoking is a complex addictive behaviour, smokers react differently and would ideally need a wide range of aids to select from. For Swedish (and Norwegian) men, snus has been a viable and successful option for many years. It is obvious, however, that the smokers in the rest of the EU are left with very few efficient aids.

2.2 Understatement of the contribution of snus to low smoking prevalence in Sweden and Norway

IA Statement (p.67): “Sweden's low smoking prevalence in combination with the availability of oral tobacco (snus) is sometimes referred to as an indication of snus as an effective cessation method and there are some data indicating that snus has been used by Swedish smokers as an alternative to smoking.²⁸³ On the other hand, SCENIHR concluded in 2008 that the overall smoking

prevalence in Norway, as well as in young Norwegians, had decreased at the same rates in men and women during the last decade, whereas a marked increase in oral tobacco (snus) use during this time period has only occurred in young men.²⁸⁴ In California, both the prevalence of smoking and smokeless tobacco use have decreased concurrently.²⁸⁵ Some countries which have invested heavily in preventive measures have also managed to reduce smoking rates without the availability of STP.²⁸⁶ These data imply that the association between patterns of STP tobacco use and smoking cessation differs between populations and is likely to be affected by cultural, societal and other factors. In this context, SCENIHR has concluded that it is not possible to extrapolate the trends in prevalence of smoking and use of oral tobacco from countries where oral tobacco is available to EU-countries where oral tobacco is not currently available.²⁸⁷ This is highly relevant, as the sale of the product cannot be limited to people who wish to stop smoking, unless the product is a medicinal product available only on prescription.”

Comment: It is true that there are cultural differences among nations but also that *consumers’ knowledge about the differing health effects among tobacco products is almost non-existing* (Wikmans et al. 2010, Lund et al. 2011, Lund 2012, Borland et al. 2011a, 2011b). This will affect smokers’ willingness to use STP products. Correct information should be a human right.

In the case of Sweden the prevalence of adult smoking is 13%, while the EU average is 28% and the closest member state is 23% (Eurobarometer 2012). In Norway, the adult smoking rate was 16% in 2012, i.e. well under the EU average. Among young people (16-24 years of age) the smoking rate was only 7%, while snus was used by 19% in this age group.

2.3 Assertion without credible evidence that snus use will increase smoking, whereas evidence suggests it decreases smoking

IA Statement p.67-68): “Option 1 is also expected to result in uptake of STP use among individuals (including among young people) who would otherwise not have used tobacco. A survey undertaken by the Swedish National Institute of Public Health reveals that four out of ten oral tobacco (snus) users started using tobacco with oral tobacco.²⁸⁸ In Norway, recruitment of oral tobacco (snus) users among young people, including recruitment of those with no previous experience of smoking, is increasing.²⁸⁹ Results from cross-sectional studies from Norway show that over 40% of young people (16-20 years old) of daily snus users had no previous smoking experience.²⁹⁰ Considering the current marketing strategies described under the problem identification (e.g. STP with distinctive tastes) and the obvious interest of the industry to recruit new users, a non-negligible uptake rate is expected under option 1. Smoke-free environment also play an important role in this respect.

Comment: It is concluded in the SCENIHR Report (Section 3.7.1.1.) that “*The Swedish data, with its prospective and long-term follow-up do not lend much support to the theory that smokeless tobacco (i.e. Swedish snus) is a gateway to future smoking.*” This is also true for male youths, and it seems that early snus use prevents later uptake of cigarette smoking. Thus, studies from Sweden show that young people, who start with snus are less likely to take up smoking and the few snus-starters who take up smoking are more likely than average to quit eventually (Galanti et al. 2001, 2008)

Data from Norway shows that the prevalence of smoking is decreasing, whereas the prevalence of snus use is going up. This is valid both for young men and women. It cannot be excluded that some of the young snus users, who have characteristics similar to those of tobacco-free young people, would otherwise have stayed tobacco-free. Others have properties characteristic of smokers, which would indicate that they would have started smoking if snus was not available (Larsen et al. 2012). In addition, the fact that some 70% of the young snus users have used or are using cigarettes indicates that snus users are often recruited from smokers (Lund 2012).

2.4 Conjecture without evidence about new smokeless tobacco products with no acknowledgement of their role as an alternative to smoking and means to quit

IA Statement (p.68): “Although there is currently limited evidence regarding novel STP, which are yet to be marketed to consumers, there may also be a risk of uptake of these products among new users and smokers who would otherwise have quit smoking altogether. Despite the claim that these products are reduced risk products, they are addictive and harmful to health. As BAT states on their web site: *“Cigarette smoking is a cause of serious and fatal diseases and the only way to avoid the health risks associated with tobacco products is to not use them.”*²⁹¹”

Comment: Even if the target is to achieve a tobacco free society, it is important that current users have viable means to stop smoking, reduce harm and eventually to quit. A ban on oral tobacco means that a sizable number of current smokers in the EU are left with very few efficient options and many will die prematurely from a smoking-related disease. With an EU average for smoking of 28% the target 0% is far off.

Snus is at least 90% less harmful (probably 95-98% less harmful) than cigarettes and novel STP are anticipated to have similar characteristics. It has been estimated that *“for net harm to occur 14-25 ex-smokers would have to start using snus to offset the health gain from every smoker who switched to snus rather than continuing to smoke. Likewise, 14-25 people who have never smoked would need to start using snus to offset the health gain from every new tobacco user who used snus rather than smoking (Gartner et al. 2007).”* It is obvious that allowing use of snus or similar products as an alternative tobacco product would not only be a health gain on an individual but also on a population level. The low incidence of lung cancer among Swedish men is an obvious piece of evidence, but the significance of this highly relevant fact is not recognised in the assessment.

2.5. Overlooking more recent studies confirming snus does not function as a gateway

IA Statement (p.68): “There is also uncertainty as regards STPs' potential as a "gateway" to future smoking. Evidence from the US indicates that oral tobacco use may lead to subsequent FMC smoking, while some Swedish data do not support this hypothesis.²⁹² The SCENIHR opinion of February 2008 suggests caution in translating these data.²⁹³”

Comment: The conclusion that it is more common among Swedish smokers to switch to snus use than for snus users to switch to smoking have been strengthened by new studies (Furberg et al. 2008, Stenbeck et al. 2009). Also, studies from Norway demonstrate that snus use is not a gateway to smoking (Lund et al. 2010).

2.6. Exaggerating the scale and consequences of 'dual use' and excluding significant evidence

IA Statement (p.68): "Moreover, there is a risk of "dual use". One study of snus as a cessation method found that 20% of unsuccessful quitters continued to use snus on a daily basis (dual use).²⁹⁴ A recent Norwegian study has also found that around 30% of daily snus users were smoking at least occasionally.²⁹⁵ Oral tobacco (snus) use in early adolescence has also been associated with increased risk of taking up occasional smoking in addition to snus in late adolescence.²⁹⁶ There is also a risk that consumers taking up STP will become chronic users.²⁹⁷"

Comment: New research from Sweden and Norway has shown that the increase snus use has not increased dual use of snus and cigarettes. It is also well established that the cigarette consumption is lower among dual users than among those who only smoke (i.e. reduction of harm). Data from Sweden shows that daily smokers, who start using snus, are more likely to quit daily smoking than non-snus users. Almost half of those who have switched from cigarettes to snus eventually quit snus. Only 1.7% of men and 0.2% of women pursue daily dual use. (Ramström et al.). This demonstrates that smokers' uptake of snus does not interfere with their incentives to quit smoking.

New results from Norway show that among dual users with daily intake of snus a majority reported that the purpose of their snus use was to quit smoking. It has been speculated that dual use represents a transition stage away from cigarettes (Lund et al. 2012).

It is true that snus use at the age of 16 was associated with an increased risk of taking up occasional smoking at the age of 19 among Norwegian boys. It is not mentioned in the Impact Assessment Report, however, that use of snus only at the age of 16 was not associated with increased odds of smoking only at the age of 19 (Grötvedt et al. 2012).

In their literature review on dual use, Frost-Pineda K et al. (2010) report: "*These data suggest that there are not any unique health risks associated with dual use of smokeless tobacco products and cigarettes, which are not anticipated or observed from cigarette smoking alone. Furthermore, studies show that dual users smoke fewer cigarettes than exclusive smokers, and studies of tobacco use patterns over time (tobacco use trajectory data) indicate that dual users are more likely than exclusive cigarette smokers to cease smoking*". They conclude: "*Overall, the concern about dual use appears to be contradicted by the evidence in the literature that dual use of smokeless tobacco and cigarettes may result in reduction in smoking-related harm as smoking intensity is decreased and smoking cessation increases*"

2.7. Showing no evidence that snus undermines tobacco control policies and failing to acknowledge its role in denormalising smoking

IA Statement (p.68): "Finally, there is a risk under option 1 that lifting the ban on oral tobacco could have a negative impact on overall tobacco control policies. Norway has in its response to the public consultation on the TPD pointed to difficulties from a communication point of view of advocating non-use of oral tobacco (snus) among young people and at the same time advocating the use of the same product as a smoking cessation tool for another group.²⁹⁸ The same is true for other types of STP, including novel non-combustible products. In addition, the introduction of oral tobacco could potentially weaken cessation policies, in particular as it would allow people to keep

up their nicotine addiction in situations where smoking is not allowed (e.g. smoke-free environments) and subsequently resume smoking.

Comment: The communication dilemma mentioned above is understandable but not insurmountable if health professionals and communicators are prepared to be clear and honest about the continuum of risk in tobacco products. It should be noted in this context that a number recent studies conducted in several countries have addressed consumers' knowledge about the health risks of snus and of smokeless tobacco products in general. The results show that *knowledge about the health effects is low and misconceptions are common among smokers in the countries studied. Even among health personnel knowledge is low* (Lund et al. 2011). This is an ethical problem, since it is a basic right to have good information to make informed choices about health effects of STP and cigarettes. It should also be understood that snus in Sweden contributes to the low visibility of smoking resulting from only 13% smoking prevalence (Eurobarometer 2012) and so supports 'denormalisation' of smoking in public places and in the home. This may explain why both smoking and snus prevalence is low among women. Whatever the effect on tobacco control policies the low prevalence of smoking found in Sweden and Norway is the intended outcome of tobacco control – which is, on this measure, much less successful where oral tobacco is not permitted in Europe, where average smoking prevalence (28%) is more than double that of Sweden (Eurobarometer 2012).

2.8 Concluding there is no clear evidence that snus assists smoking cessation or reduces smoking prevalence despite significance evidence to the contrary

IA Statement (p.69): "Summarising the findings on oral tobacco, it is not possible at this stage to draw the conclusions that oral tobacco is an effective smoking cessation aid in the long term. Any impacts therefore on smoking-related diseases remain uncertain under option 1. On the other hand, it is likely that new oral tobacco users would be recruited under option 1 who would otherwise not have used tobacco (entry gate) and current smokers who would otherwise have quit using tobacco altogether might switch to oral tobacco or use both products (dual use). This would lead to increased adverse health effects (see section 2.2.1). In this light, it appears difficult to reconcile lifting the ban with the precautionary principle.

Comment: Available data are consistent in showing that snus is and, for many years, has been an efficient long-term smoking cessation aid for smokers in Sweden and Norway. It cannot be excluded that some new oral tobacco users may be recruited. Studies both from Sweden and Norway show that young people who take up snus are less likely to begin smoking. Because snus use is associated significantly less harmful effects than smoking (at least 90%) there will be a net gain in health benefits both for the individual and on a population level.

A most recent review studied cancer and cardiovascular disease risk in current snus users who formerly smoked (switchers) with that of never snus users who continued to smoke (continuers) or of never smokers who quit smoking (quitters). Although there are some weaknesses in the study, the results were consistent in showing that *"switching from cigarettes to snus is associated with a clearly lower risk of cardiovascular disease and cancer than is continuing to smoke. The risk in switchers is no different from that in smokers who quit smoking. These findings are consistent with other evidence that adverse health effects of snus are at most minimal* (Lee 2013)."

It is evident therefore that not lifting the ban on snus will deprive many smokers of a less harmful alternative to cigarettes and is not consistent with the precautionary principle (see further discussion below).

3. Critique of evidence for ban on characterising flavours

The Commission proposal would ban characterising flavours in all tobacco products (Article 6.1), including oral tobacco.

3.1. Asserts that marketing strategies are aimed at recruiting young people without evidence

IA Statement (p.23) “As indicated in the market description (section 2.1.1), the main manufacturer of oral tobacco (snus) increased its portfolio from 22 to 180 brands between 2002 and 2008.¹⁰³ New market strategies target consumers outside the distinctive population groups who traditionally used these products, including young people. For example, there are STP available which are especially developed for modern taste or a younger generation. STP with characterising flavours (including chewing tobacco with tropical or bergamot flavours, nasal tobacco with peanut butter or cheese and bacon flavour and oral tobacco with elderflower and rhubarb taste) are put on the market and nasal tobacco has recently been promoted at youth parties throughout Germany”.

Comment. No evidence is provided to show that this brand diversification has increased tobacco initiation or smoking prevalence or is targeted at younger people or non-smokers – it is asserted. In fact, smoking prevalence in Sweden fell over this period from 18 to 13%, while snus use stayed approximately level at 11-12%⁸. It is important to recall that snus is used as a gateway exit from smoking and as an alternative to cigarettes. As a result, Sweden now has the lowest smoking prevalence, 13% in the EU by far (Eurobarometer 2012). This suggests that any marketing strategy is making snus relatively more attractive to smokers, and so supporting switching, reducing smoking and causing a health benefit. The IA makes no credible assessment of the scale of the impact of banning characterising flavours in oral tobacco or what the likely health outcome could be, *even though it could be strongly detrimental*. These two themes – scale and health outcome – are discussed below.

3.2. Does not adequately estimate the impact of a ban on characterising flavours on the market for oral tobacco

Comment: scale of impact. Characterising flavours are a marginal segment of the cigarette market – 4.6% of sales in 2010 were menthol flavoured (Matrix 2012), and other flavours are not significant (<0.5% in any country), so less than 5% of the cigarette market would be included in a ban on characterising flavours. However, almost all oral tobacco in Sweden is sold with an artificial smoke aroma and around 70% with other flavours such as juniper or bergamot etc. Taking the definition literally, this could remove up to 70% of the snus products as currently formulated from the market. Commissioner Borg has suggested that the impact would be relatively small: “*prohibiting characterising flavours in snus would mean also only hitting 10% of the entire production of snus which relies on the characterising flavours themselves*” (statement at European Parliament ENVI

⁸ Statistics from SCB (2002) and Swedish Public Health Institute (2008)

committee public hearing, 25 February 2013). This appears to be based on a statement made by an investment firm about impact on Swedish Match's overall profitability following a ban on characterising flavours, and was published before the proposed directive was published. It is opaque and far from an adequate assessment of impact.

3.3. Does not recognise or assess the potential for additional harm if oral tobacco is made relatively less attractive than cigarettes

Comment: health outcome arising from market impact. If a snus product is withdrawn, the user is faced with several options: give up using snus altogether; switch to a different snus product; or switch to a different tobacco or nicotine product, including switching cigarettes. Potential snus users face similar pathways: if snus becomes less attractive, they may not switch to snus and continue to smoke; switch to a different snus product; or quit smoking and nicotine completely. The important point is that several of these switches make the health impact considerably worse. It may be impossible to know what the real-world switching behaviour would be in advance, but the 'downside' harm of increased smoking is far greater than the 'upside' benefit of a switch from snus to non-tobacco use. If smoking is 10-20 times more risky than snus use, then for 'risk/use equilibrium' (Kozlowsky LT et al. 2001) in which total population harm was unchanged, 10-20 users would need to quit tobacco completely for each user that switched back to smoking or remained a smoker rather than switching to snus. No attempt has been made in the impact assessment to comprehend or grapple with these issues. But given that Sweden has the lowest rate of smoking in the EU by far, there should be real concern about an ill-considered intervention in the regulation of the product that accounts in large part for this public health success.

4. Critique of application of the precautionary principle

The Impact Assessment relies on the 'precautionary principle' to make the case to retain the ban and in support of the rejection of option 1 in the options appraisal. This option, which does in fact have a solid basis in science, would replace the ban with stricter regulation of labelling and ingredients.

4.1 Misapplication of the precautionary principle and fails to apply the Commission's own guidelines

IA Statement (p75) "Lifting the ban on oral tobacco (option 1) would have adverse health effects. It could also attract new tobacco users who would otherwise not have taken up tobacco consumption. Moreover, it would have a negative health impact on smokers who would otherwise have quit smoking, but who continue to use both FMC/RYO and STP (dual use) and for smokers taking up STP use who would otherwise have quit using tobacco altogether. For individuals replacing FMC/RYO with STP completely, the health effects would be positive. Considering the uncertainty in relation to substitution, an overall negative outcome under option 1 cannot be excluded. Therefore, this option raises doubts in terms of coherence with the precautionary principle."

Comment: the precautionary principle does not justify this reasoning. The Commission's own guidance on the precautionary principle (CEC 2000) is much more sophisticated.

Where action is deemed necessary, measures based on the precautionary principle should be, inter alia: proportional to the chosen level of protection; non-discriminatory in their application;

consistent with similar measures already taken; based on an examination of the potential benefits and costs of action or lack of action (including, where appropriate and feasible, an economic cost/benefit analysis); subject to review, in the light of new scientific data, and capable of assigning responsibility for producing the scientific evidence necessary for a more comprehensive risk assessment.

Application of these principles suggests at least two significant failings in the Commission's argument. First, the ban is disproportionate and discriminatory, given that other smokeless tobaccos are not banned and cigarettes, the most hazardous of all forms of tobacco, remain by far the dominant market leader – tobacco users are free to start smoking with cigarettes and switch from low risk snus to smoking. As the earlier sections of this critique have shown, there is no credible evidence supporting the various hypotheses raised to justify retaining the ban on a precautionary basis. These hypotheses include: that it may prevent quitting (in fact oral tobacco supports cessation and helps smokers reduce risk); that it may lead to smoking initiation (there is no evidence for this, and smoking prevalence is much lower in countries where oral tobacco is widely available); that 'dual use' may be a problem (it is insignificant and may reduce consumption of cigarettes or be part of a transition). In those situations where people use snus who would otherwise have quit completely, their risk is quite small (at least 90% less than smoking), so measures to protect against this outcome should be proportionate to the risk. The precautionary principle does not provide *carte blanche* to take excessive action based on any hypothesis, no matter how tenuous and poorly supported by evidence.

Second, the risks to health associated with not allowing oral tobacco on the market have not been considered and weighed into the decision-making, but the Commission's guidance require a symmetrical assessment of the costs of acting and not acting. The available evidence strongly suggests there have been *significant health benefits* from the use of oral tobacco in Sweden and Norway, at both individual level and population level. Properly applied, the precautionary principle would more realistically justify lifting the ban because of the high risk to health arising from extra smoking if smokers are denied low risk alternative nicotine products, combined with relatively low risks associated with any additional use of oral tobacco. The ban is a more reckless option from a health perspective, *and therefore it is the preferred option – the ban – that should be challenged on precautionary grounds.*

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