Comment on the
Consultation on the possible Revision of the Tobacco Products Directive 2001/37/EC
by Norway and Iceland

1. EXECUTIVE SUMMARY

The revision of the Tobacco Products Directive 2001/37/EC is a good opportunity to introduce more comprehensive tobacco product legislation in Europe. The measures under consideration are all important, but Norway and Iceland would like to stress that some measures should have higher priority than others, taking into account their health impact. Highest priority should be given to: increasing the size of the health warnings and introducing mandatory pictorial warnings, plain packaging for all tobacco products, a display ban, as well as banning cross border sale via the Internet. It is in our view also important to extend the ban on snus to all types of smokeless tobacco.

2. INTRODUCTION

Directive 2001/37/EC is part of the EEA Agreement and has been implemented at national level in Norway and Iceland. Any amendments to or revision of the Directive is therefore of equal importance to Norway and Iceland as to the EU Member States as they are bound by the same rules and obligations. In addition, Norway and Iceland welcome the EU’s efforts to improve the tobacco product legislation bearing in mind that the protection of public health should be in the forefront of tobacco products control related measures.

3. GENERAL COMMENTS

In Norway around 6,700 deaths each year are caused by smoking related illness. In addition, approximately 350-550 persons die from passive smoking each year. Among women aged between 40 and 70 smoking was responsible for 26% of deaths, and the comparable figure for men was 40%.

In 2009, the smoking prevalence in Norway was 21% daily smokers and 9% occasional smokers (16-74 years old). Among young people (16-24 years old), 17% smoked daily and 14% occasionally. There is virtually no difference between men and women when it comes to smoking.
In recent years, the Norwegian health authorities have become concerned about the increasing use of smokeless tobacco, especially among young men. In 2009, 21% of men aged 16-24, used snus daily and 12% occasionally, which gives a total of 33% users of snus among young men. In 1985 there were only 3% daily users of snus and 6% occasional users in this age group, a total of 9%. Among women aged 16-24, 7% used snus daily in 2009 and 11% occasionally. Marketing strategies from the tobacco industry clearly indicate that women and young people are their new target group.

As Norway, together with Sweden, is the only EEA country that allows the sale of snus, Norway has a special interest in the subject of how to regulate this product. In Norway’s experience, the current Tobacco Products Directive is hindering the implementation of effective public health measures, such as sufficient health warnings.

4. SPECIFIC COMMENTS

Questions posed in the Public Consultation Document

Norway and Iceland have the following responses to the questions set forth in the Public Consultation Document.

4.1. Scope of the Directive

Question 1
Norway and Iceland agree with the problem definition. It is however paramount to the effectiveness of such possible regulation that the legislative definition of new products containing tobacco and/or nicotine not be too specific but remain general/comprehensive so as to cover all future forms of such products.

Question 2
Option 2 to extend the scope of the Directive, is in our view the most effective option to deal with the issues of novel tobacco and/or nicotine products.

The Directive should cover novel products that contain tobacco and/or nicotine, herbal cigarettes and other combustion products that entail health risks, products such as the electronic cigarette with the no-nicotine cartridges, and other novel cigarette and cigarette like products. However, the regulation should not just cover cigarette-like products (i.e. herbal cigarettes), but all tobacco-like products (i.e. herbal snus). Tobacco-like products, should they not be covered by the Directive, can be used to undermine the provisions of the Directive (and the Tobacco Advertising Directive). Special effort must be taken in drafting the scope of the Directive, so as to capture all relevant products, insofar as they are not covered by existing legislation.

It is important to take note of the recent report from the WHO Study Group on Tobacco Product Regulation¹ which remarks, inter alia, that Electronic Nicotine Delivery Devices (ENDS) have not been established to be safe. The safety and extent of nicotine uptake has not been established, there is no scientific evidence to validate the manufacturers’ claim that the

products are safe and effective in smoking cessation, and that delivery to the lungs might be dangerous, independent of the effects of nicotine.

In view of protecting public health, once the above-mentioned products are included in the scope of the Directive, it must also be considered to what extent the other provisions of the Directive should apply to these products and which information on contents and emissions should be reported to the authorities in connection with ENDS (with and without nicotine), herbal cigarettes, and other novel tobacco and/or nicotine products. Health warnings should be required for the novel products, but must be specially tailored for each product. The advertising ban should also apply to these products.

4.2. Smokeless tobacco products

**Question 1**
It is the view of Norway and Iceland that the problem definition is correct.

**Question 2**
Option 3, a ban on all types of smokeless tobacco products, is clearly the best option. This would provide a more comprehensive ban than under today's regulation and would keep other types of smokeless tobacco off the market. There is already a great diversity of tobacco products on the market, and to protect public health still further, this option should be introduced.

Cigarette producers are experiencing diminishing sales in developed parts of the world due to improved tobacco control measures, and they are now launching into the business of smokeless tobacco in order to keep old customers and target new groups. The development of many new snus products containing a variety of taste additives, such as chocolate, and pink design boxes, clearly demonstrate that the industry's interest is not mainly to market snus as a smoking cessation aid, but to maintain nicotine dependence in the population. Snus should not be considered either as a rational substitute for cigarettes or as a cessation aid. There is no sound scientific evidence that snus is effective as a smoking cessation product. Countries with substantial comprehensive tobacco control programs, have demonstrated that a lower prevalence of smoking than in Sweden, for example, can be achieved without snus on their markets. There is therefore no reason to allow the introduction of a new tobacco product with serious health effects on the European market. Smokers in Europe are better served by the implementation of the broad tobacco control strategy of the FCTC.

The FCTC draft report on oral tobacco presented at the 4th Conference of the parties in November 2010, states in section 16 that: "It is important to emphasize that all forms of smokeless tobacco have an adverse impact on health and that smokeless tobacco products should not be promoted as a harm-reduction product."

It has been suggested by some that snus could be used as a method in smoking cessation because it is less harmful than smoking tobacco. This is sometimes being referred to as the Scandinavian strategy. However, this approach is not in accordance with Norwegian tobacco policy for the following reasons:
1. There are no published randomised clinical trials of long term efficacy of using snus in smoking cessation. In the absence of evidence it is not possible to draw reliable conclusions as to the relative effectiveness of smokeless tobacco as an aid to clinical smoking cessation in comparison with either placebo or other established therapies.

2. Although snus is less harmful than smoking tobacco, it causes cancer in several organ systems and also increases the risk of vascular disease. Thus, it is very difficult from an ethical point of view to advocate the replacement of one form of a harmful product by another form of the same product, although the latter may be less harmful.

3. From Norway’s experience, we also know how difficult it is from a public health communication point of view, to advocate non-use of snus among young people and at the same time advocate the use of the same product as a smoking cessation tool for another group (nicotine addicts).

The Scandinavian health authorities\(^2\) are in agreement concerning their position on snus as a harm reduction product. In 2009 they published an article entitled “Snus does not save lives: quitting smoking does!” in Tobacco Control\(^3\). In the article it is emphasized that: “rather than promoting the use of Scandinavian moist snuff, we would like to see a major increase in preventive efforts. Countries that have seriously invested in such initiatives, such as Canada and Australia, have also achieved excellent results, thus demonstrating that snus is not a prerequisite for reduced smoking”.

**Question 3**

As the Commission rightfully states in the consultation paper, new scientific evidence (SCENIHR and IARC) has concluded that snus is carcinogenic. In our view, this evidence should also be reflected in the smokeless tobacco health warnings.

### 4.3. Consumer information

**Introduction/general remarks**

**Pictorial warnings**

Norway has introduced legislation on mandatory pictorial warnings, entering into effect on 1 July 2011 for cigarettes, and 1 January 2012 for all other tobacco products, except smokeless tobacco.

**Tobacco packaging as an advertising tool**

The development in Europe and the rest of the world has shown an explosive increase of innovative packaging targeting in particular young people and women. It is therefore important to introduce measures to counteract the advertising impact of tobacco product packaging.

\(^{2}\) Swedish National Board of Health and Welfare, Danish National Board of Health, Norwegian Directorate for Health, Finnish National Public Health Institute, and Public Health Institute of Iceland

In 2002, the Norwegian Directorate for Health commissioned a report on effective measures to reduce smoking among adolescents. In the report, one of the conclusions is that mandating neutral tobacco packaging is one of several effective tobacco control measures for this target group. A report from the Norwegian Institute for Alcohol and Drugs Research (2008)\(^5\) contains a review of literature available on the impact of tobacco advertising on purchasing behaviour and tobacco consumption. It contains an assessment, inter alia, of the effect of tobacco product packaging as a much used and effective channel for tobacco advertising. This report is currently being updated and a new version will be published in 2011.

**Question 1**
Norway and Iceland agree with the problem definition.

**Question 2**
Norway and Iceland are of the opinion that **option 3**, introduction of generic packaging, would address the problem most effectively. Introducing mandatory generic packaging would be the most effective option for maximising the effect of consumer information and minimising tobacco product packaging as an advertising tool. The size and shape of the package should also be regulated. This would also be in line with the FCTC guidelines for article 11. The guidelines state:

> "Plain packaging
> 46. Parties should consider adopting measures to restrict or prohibit the use of logos, colours, brand images or promotional information on packaging other than brand names and product names displayed in a standard colour and font style (plain packaging). This may increase the noticeability and effectiveness of health warnings and messages, prevent the package from detracting attention from them, and address industry package design techniques that may suggest that some products are less harmful than others."

In addition, option 2a (mandatory picture warnings) and 2b (levels of tar, nicotine and carbon monoxide to be replaced by general information on harmful substances) should also be included in the revision, since introducing generic packaging would reduce the advertising value of the packaging but not completely optimise consumer information on health effects of tobacco use.

**Option 2a**
Picture warnings should be mandatory in the EU. They should also be considerably larger than they are today, and on both sides of the pack towards the top of the pack. The FCTC Article 11 guidelines recommend the use of picture warnings and large warnings:

\(^4\) En gjennomgang av forskningslitteraturen om tiltak for å redusere røyking blant ungdom (A review of research literature on measures to reduce smoking among adolescents), IS-1037, Lund and Risedal, 2002.

\(^5\) Kunnskapsgrunnlag for forslaget om et forbud mot synlig oppstilling av tobakksvare (Knowledge base relating to the bill proposing a ban on visible display of tobacco products), Lund and Risedal, SIRUS skrifter nr.1/2008. The report is only in Norwegian, but an English summary can be found here: [http://www.sirus.no/Knowledge+base+relating+to+the+bill+proposing+a+bann+on+visible+displays+of+tobacco+products_E2x322-8_Bp77BFv3TR9D6C1KXynwJVP.jpg](http://www.sirus.no/Knowledge+base+relating+to+the+bill+proposing+a+bann+on+visible+displays+of+tobacco+products_E2x322-8_Bp77BFv3TR9D6C1KXynwJVP.jpg)
“Article 11.1(b)(v) of the Convention specifies that health warnings and messages on tobacco product packaging and labelling may be in the form of or include pictures or pictograms. Evidence shows that health warnings and messages that contain both pictures and text are far more effective than those that are text-only. They also have the added benefit of potentially reaching people with low levels of literacy and those who cannot read the language(s) in which the text of the health warning or message is written. Parties should mandate culturally appropriate pictures or pictograms, in full colour, in their packaging and labelling requirements. Parties should consider the use of pictorial health warnings on both principal display areas (or on all main faces if there are more than two) of the tobacco products packaging.

15. Evidence shows that, when compared with text-only health warnings and messages, those with pictures:
- are more likely to be noticed;
- are rated more effective by tobacco users;
- are more likely to remain salient over time;
- better communicate the health risks of tobacco use;
- provoke more thought about the health risks of tobacco use and about cessation;
- increase motivation and intention to quit; and
- are associated with more attempts to quit.

16. Pictorial health warnings and messages may also disrupt the impact of brand imagery on packaging and decrease the overall attractiveness of the package...”

In the 2009 report “Australia: The healthiest country by 2020”, the technical report on tobacco presents evidence for introducing generic packaging. If the Directive is not amended in such a way as to include provisions on mandatory generic packaging, it should at least be clarified that member states wishing to introduce this measure in order to fulfil the FCTC, are free to regulate on this.

Option 2b
It is important to utilise tobacco packaging to give consumers useful and truthful information about health and tobacco use. Tar, nicotine and other smoke emission yields do not give valid estimates of human exposure, and are often misleading to consumers. They should therefore be banned and the European legislation should be brought in line with the FCTC Article 11 guidelines, which state the following concerning constituent warnings on tobacco packages:

“Parties should not require quantitative or qualitative statements on tobacco product packaging and labelling about tobacco constituents and emissions that might imply that one brand is less harmful than another, such as the tar, nicotine and carbon monoxide figures or statements such as “these cigarettes contain reduced levels of nitrosamines” and further: “Parties should prohibit the display of figures for emission yields (such as tar, nicotine and carbon monoxide) on packaging and labelling, including when used as part of a brand name or trademark. Tar, nicotine and other smoke emission yields derived from smoking-machine testing do not provide valid estimates of human exposure. In addition, there is no conclusive epidemiological or

scientific evidence that cigarettes with lower machine-generated smoke yields are less harmful than cigarettes with higher smoke emission yields. The marketing of cigarettes with stated tar and nicotine yields has resulted in the mistaken belief that those cigarettes are less harmful."

Option 2d could be considered, but we do not think that it is a priority measure. If health warnings were to be introduced on water pipes, warnings would also have to be introduced on "regular" pipes, and other smoking equipment. In addition there would be the problem of mandating health warnings that are non-removable on such equipment and surfaces.

Option 2c concerning inserts could be considered, but should not be a priority measure.

Additional comment from Norway
Norway is exempted from the EU ban on smokeless tobacco. Norway is however bound by the other provisions in the Tobacco Products Directive, including the provisions on health warnings.

Several organisations and institutions have contacted the Norwegian Ministry of Health with requests that the health warnings on smokeless tobacco should be re-introduced with warnings of smokeless tobacco being carcinogenic. Such warnings were removed in Norway in 2003 as a result of Directive 2001/37/EC, implemented in Norwegian legislation through the EEA Agreement. Hence, smokeless tobacco sold in Norway today only bears the following warning, cf. Article 5 subsection 4: "This tobacco product can damage your health and is addictive."

In the light of new evidence from SCENIHR and IARC\(^7\) on health effects of smokeless tobacco products, the Norwegian Minister of Health wrote to the EU Commissioner for Health in 2008 and 2010 to encourage an amendment of the Directive on this point. Also a 2005 report from the Swedish National Institute of Public Health\(^8\) concluded that smokeless tobacco is carcinogenic.

The use of snus has increased dramatically in Norway in recent years, especially among young people. Among 16-24 years olds, 33% of boys and 18% of girls in Norway, now use snus. And the trend is that the use of snus is still increasing.

Norway’s problem is that the toolbox for implementing effective preventative measures against snus use, is more limited than when it comes to cigarettes: For instance, health warnings on snus to inform the population about the fact that smokeless tobacco is carcinogenic cannot be used. Nor can pictorial warnings on smokeless tobacco be introduced, as has been done for all other types of tobacco products. The hindrance for these measures is that the Tobacco Products Directive imposes exhaustive rules on health warnings, and that the health warnings on smokeless tobacco are outdated and misleading.

Norway would therefore strongly urge for the amendment of the Directive so that the health warnings on smokeless tobacco reflect the scientific evidence that smokeless tobacco is

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\(^8\) Hälsoerik och svensk snus (The health risks of Swedish moist snuff), Swedish National Institute of Public Health in collaboration with Karolinska institutet, 2005.
carcinogenic. Norway would also request that the Directive be amended so that there is an opening for the use of pictorial warnings on smokeless tobacco.

4.4. Reporting and registration of ingredients

Question 1
Norway and Iceland agree with the problem definition.

Question 2
Norway has had some issues with collecting and analysing tobacco industry ingredient data. This is due partly to the amount of data being collected yearly and partly because of the resources required to monitor compliance with the reporting regulations. Norway has been part of the EMTOC project and is now working on the legal amendments that will be necessary in order to use the EMTOC system.

Norway has been using the harmonised reporting format over the last couple of years, and would welcome it if the reporting format would be made compulsory for all ingredients reporting, i.e. option 2. By introducing a mandatory reporting format, disclosure of tobacco ingredients data to the public would also be easier to achieve. However, option 2 should be combined with option 3, the introduction of fees and sanctions in order to finance data collection and analysis and disclosure.

4.5. Regulation of ingredients

Question 1
Norway and Iceland agree with the problem definition.

Question 2
From the perspective of public health, there is no justification for permitting the use of ingredients, such as flavouring agents, which help make tobacco products attractive.

Norway and Iceland would favour option 3b, establish a negative common list of tobacco ingredients, provided that the list would not be exhaustive. It is necessary to give member states the right to go further based on national circumstances and public health needs. The list should apply to all tobacco products. In Norway, the problem of additives used to increase attractiveness is today mainly present when it comes to snus products.

Such regulation would be in line with the FCTC Article 9 guidelines, which recommends parties to ban or restrict ingredients used to increase palatability, ingredients that have colouring properties, ingredients used to create the impression that products have health benefits and ingredients associated with energy and vitality.

4.6. Access to tobacco products

Norwegian display ban
On 1 January 2010, a ban on the visible display of tobacco products and smoking devices at points of sale came into effect in Norway. Section 5 of the Norwegian Tobacco Control Act states:
§ 5. Prohibition against the visible display of tobacco products and smoking devices
The visible display of tobacco products and smoking devices at retail outlets is forbidden. The same applies to imitations of such products and to token cards which give the customer access to acquire tobacco products or smoking devices from vending machines.

The prohibition in the first paragraph does not apply to dedicated tobacco boutiques. At the retail outlets it is allowed to provide neutral information regarding the price and which tobacco products are for sale at the premises. The same applies to smoking devices.

The Ministry can through regulations provide for rules on the implementation and supplementing of these provisions and provide exemptions from such.

It is allowed to provide neutral information regarding price, tobacco products and smoking devices which are for sale at the premises, for instance verbally or by having a list at the cash register which only contains the name and price of the products. In the same manner as before the introduction of the display ban, the said list cannot give any indication of trademarks or logos.

An exception has been made for dedicated tobacconist shops, see Section 5 third paragraph. These are businesses which mainly sell tobacco products and smoking devices. At such points of sale it is therefore allowed to display tobacco products and smoking devices inside the premises of the shop. The rationale for this exception is that such retail outlets are primarily used by customers who, already before they enter the premises, have an intention to purchase tobacco products. Even for dedicated tobacconist shops, there is a ban against window exhibitions and against other forms of display of tobacco products which are visible from outside the shop.

The main purpose of the display ban is to reduce the amount of smokers and snus users in the population in general and amongst children and young people especially. The ban shall contribute to the protection of children and youngsters against the harmful health effects of tobacco use. In addition, a prohibition against visible displays could contribute to making it easier for those persons trying to quit or who have quit smoking tobacco.

Regarding children and young people’s exposure to advertising and other impressions created by tobacco products and tobacco use, The Norwegian Knowledge Centre for the Health Services concludes in the report “Smoking prevention measures amongst children and young people” that there is a correlation between an early exposure to the tobacco industry’s marketing in the form of advertising and future smoking among young people in the ages of 8 to 17 years old. Studies have also shown that young people are influenced by how common smoking is, and that young people who overestimate how many people smoke also have a greater risk of starting to smoke. Accessibility to points of sale for tobacco products, the conspicuous placement of tobacco products at the cash registers and sale of tobacco products together with other common every day products can contribute to an impression in children and youngsters that tobacco use is more extended and less dangerous than it is in reality.

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The Norwegian Institute for Alcohol and Drug Research (SIRUS) indicates in the report "Knowledge Basis for the proposal of a prohibition against the visible display of tobacco Products"\(^{10}\) that the tobacco industry has invested considerable resources in developing package designs which shall communicate a message to current consumers and potential customers, and that the packet as an advertising medium has acquired a greater significance after the introduction of the ban against tobacco advertising. SIRUS concludes in the report that there is reason to assume that tobacco products displays work as a purchase influencing factor along the same dimensions as ordinary advertising. It is however difficult to estimate whether the strength of the purchase influencing factor is greater or weaker than in ordinary advertising and to what degree the health warnings on packets have an impact on the advertising effect.

Iceland, Ireland, England, Finland, Thailand and parts of Canada and Australia have introduced various degrees of bans on displaying tobacco products at points of sale. The Norwegian and Icelandic bans are the two most comprehensive bans.

**Question 1**

Norway and Iceland agree with the problem definition.

**Question 2**

Norway and Iceland recommend the introduction of **Option 3**. All three alternatives, 3a, 3b and 3c, should be included in the legislation.

**Option 3a**

A ban on cross-border advertising is covered by the FCTC article 13. The guidelines to article 13 state the need for a comprehensive ban on cross-border advertising. The guidelines also specifically recommend that the most effective way to stop cross-border advertising is to ban tobacco sales on the internet:

18. Internet sales of tobacco inherently involve advertising and promotion as defined in the Convention. The problem is not only limited to advertising and promotion but also includes sales to minors, tax evasion and illicit trade.

19. The most direct way of avoiding tobacco advertising or promotion on the Internet is to ban tobacco sales on the Internet. The ban should apply not only to entities that sell the products but also to others, including credit card companies that facilitate payment and postal or delivery services for the products.

20. To the extent that Internet sales are not yet banned, restrictions should be imposed, allowing only textual listing of products with prices, with no pictures or promotion features (e.g. any references to low prices).

21. Given the covert nature of tobacco advertising and promotion on the Internet and the difficulty of identifying and reaching wrongdoers, special domestic resources are needed to make these measures operational. Measures recommended in decision FCTC/COP3(14) to eliminate cross-border tobacco advertising, promotion and sponsorship, in particular identifying contact points and dealing with notifications

\(^{10}\) Kunnskapsgrunnlag for forslaget om et forbud mot synlig oppstilling av tobakkvarer (Knowledge base relating to the bill proposing a ban on visible display of tobacco products), Lund and Rise, SIRUS skrifter nr.1/2008. The report is only in Norwegian, but an English summary can be found here: [http://www.sirus.no/Knowledge+base+relating+to+the+bill+proposing+a+bann+on+visible+displays+of+tobacco+products.E2x322-8_Bp77BFv3TR9D6cJ1K3ymwJVIPL28nMhPLZB9M4lY6ShRzQO_4ps](http://www.sirus.no/Knowledge+base+relating+to+the+bill+proposing+a+bann+on+visible+displays+of+tobacco+products.E2x322-8_Bp77BFv3TR9D6cJ1K3ymwJVIPL28nMhPLZB9M4lY6ShRzQO_4ps)
from other Parties, would help to ensure that domestic enforcement efforts are not undermined.

**Recommendation**

*Internet sales of tobacco should be banned as they inherently involve tobacco advertising and promotion."

**Option 3b**

Self-serviced vending machines are banned under Norwegian law. This is in line with the FCTC Article 13 guidelines, which state:

"14. Vending machines should be banned because they constitute by their very presence a means of advertising or promotion under the terms of the Convention."

**Option 3c**

The introduction of a display ban in the EU would be a big step towards eliminating tobacco product advertisement in society. Based on the Norwegian (and Icelandic) experiences, we strongly recommend that a display ban is included in the upcoming revision of the Directive. This would also be in line with the FCTC Article 13 guidelines, which state:

Under the FCTC Article 13 (2), parties are obliged to introduce a general advertising ban. In the FCTC Article 13 guidelines, a ban against the display of tobacco products is referred to in the following manner:

"12. Display of tobacco products at points of sale in itself constitutes advertising and promotion. Display of products is a key means of promoting tobacco products and tobacco use, including by stimulating impulse purchases of tobacco products, giving the impression that tobacco use is socially acceptable and making it harder for tobacco users to quit. Young people are particularly vulnerable to the promotional effects of product display.

13. To ensure that points of sale of tobacco products do not have any promotional elements, Parties should introduce a total ban on any display and on the visibility of tobacco products at points of sale, including fixed retail outlets and street vendors. Only the textual listing of products and their prices, without any promotional elements, would be allowed. As for all aspects of Article 13 of the Convention, the ban should also apply in ferries, airplanes, ports and airports.

...

**Recommendation**

*Display and visibility of tobacco products at points of sale constitutes advertising and promotion and should therefore be banned..."

In Council Recommendation 2003/54/EC Member States are recommended to remove the advertising effect which the visibility of tobacco products represents.