

## Letter from experts in tobacco science and policy regarding the European Union snus prohibition

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Dear Mr Timmermans

### Lifting the unjustified European Union ban on oral tobacco or “snus” in the light of ongoing legal action

Given your professional mandate and your personal commitment to better regulation in the European Union, we write to draw your attention to one of the worst examples of EU regulation ever made. This is the ban on oral tobacco, known as “snus”, as implemented in the revised Tobacco Products Directive, 2014/40/EU. This measure harms the health of EU citizens, protects the cigarette trade and violates key principles of the treaties and the EU objectives for better regulation<sup>1</sup>.

- *decision-making is open and transparent*
- *citizens and stakeholders can contribute throughout the policy and law-making process*
- *EU actions are based on evidence and understanding of the impacts*
- *regulatory burdens on businesses, citizens or public administrations are kept to a minimum*

We write as public health scientists and experts to reaffirm our view that the prohibition of snus in 27 member states of the European Union is unprincipled and lacks any credible scientific basis. The current challenge to the legality of this prohibition (European Court of Justice case C-151/17<sup>2</sup>) brought by a producer (Swedish Match) and a consumer group (New Nicotine Alliance) provides a timely opportunity to reassess this policy and implement genuinely better regulation. That would mean lifting the prohibition of snus and regulating this form of smokeless tobacco no differently to the other forms of smokeless tobacco that are already permitted in the European Union.

This is not the first time we have raised these concerns. Many of us are authors of one or more letters to key decision-makers: to the European Commission in May 2011<sup>3</sup>, to the Government of Sweden and European Council in February 2013<sup>4</sup>, to the European Parliament in September 2013<sup>5</sup> and to UK government in October 2013<sup>6</sup> arguing that the European Union prohibition of snus is unjustified and damaging and should be lifted. A detailed critique of the proposal was provided to the Commission and widely shared in March 2013<sup>7</sup>. These letters and critique are [attached](#).

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<sup>1</sup> European Commission, Better Regulation: why and how. Accessed 23 May 2017 [\[link\]](#)

<sup>2</sup> Court of Justice of the European Union, Case C-151/17 24 March 2017 [\[link\]](#)

<sup>3</sup> Letter to Commissioner Dall: Advancement of the scientific basis for the EU TPD, May 2011 [\[link\]](#)

<sup>4</sup> Letter to Maria Larsson, Minister for Health, Government of Sweden 15 February 2013 [\[link\]](#) copied to Working Party on Public Health - Health Attachés, Brussels on 15 February 2013 [\[link\]](#)

<sup>5</sup> Letter to Martin Schulz, President of the European Parliament, copied to MEPs 23 September 2013 [\[link\]](#)

<sup>6</sup> Letter to Rt. Hon. Jeremy Hunt MP, Secretary of State for Health (UK/England), 7 October 2013. [\[link\]](#)

<sup>7</sup> Bates CD, Ramström L. Proposed revision to the Tobacco Products Directive: a critique of the scientific reasoning supporting the proposed measures relating to oral tobacco , 18 March 2013 [\[link\]](#) and Covering letter to Commissioner Borg 18 March 2013 [\[link\]](#)

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This prohibition was first introduced in 1992 (Directive 92/41/EEC) then reaffirmed in the Tobacco Products Directive of 2001 (2001/37/EC). Regrettably, the 2012 Commission proposal for a further revision of the directive<sup>8</sup> retained the snus prohibition and the Community legislature included the ban in the revised Tobacco Products Directive 2014/40/EU of 3 April 2014 as Article 17<sup>9</sup>. Whatever justification may have prompted the original prohibition in 1992, there was no basis for extending it in 2014 and there is no basis for continuing to defend it in 2017. We are concerned that the European Union is dogmatically clinging to a decision made more than 25 years ago that no longer has any evidential foundations and now clearly violates important European Union principles.

### **Failure to assess evidence or to understand impacts**

The main reason for lifting the ban is that availability of snus to EU citizens could significantly reduce the burden of tobacco-related disease and premature death, as it has in Sweden. The use of snus carries a very small fraction of the risk to health compared to cigarette smoking<sup>10 11</sup> and, where available, snus has displaced smoking leading to significant population health improvements, even if there are minor residual risks<sup>12</sup>. This is the concept of 'harm reduction'. For people who cannot or do not wish to stop using tobacco or nicotine, they should be able to access safer products. Where it is available in Scandinavia, snus is the primary reason why smoking rates, especially among men, are low<sup>13</sup> and the burden of smoking-related disease is also correspondingly low<sup>14</sup>.

According to Eurobarometer, the effect is large. Sweden has by far the lowest rate of smoking in the European Union (11% compared to the EU average of 26% in 2015)<sup>15</sup> and in Northern parts of Sweden, smoking has almost been completely displaced by snus use<sup>16</sup>. For daily smoking the data are even more striking<sup>17</sup>. However, the policy of European Union is deliberately to prevent any prospect of the full or partial replication of this public health success in the other 27 member states.

Norway has also benefitted from reduced smoking rates<sup>18</sup> by remaining outside the European Union and securing an exemption from the snus ban in its European Economic Area agreement. However, when Finland joined the EU, the rate of decline in smoking slowed and it has been estimated that Finland has a materially higher smoking rate as a result, and hence higher rates of disease than

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<sup>8</sup> European Commission. Revision of the Tobacco Products Directive. 19 December 2012. [\[link\]](#)

<sup>9</sup> Tobacco Products Directive, 2014/40/EU 3 April 2014 [\[link\]](#)

<sup>10</sup> Lee PN. Summary of the epidemiological evidence relating snus to health. *Regul Toxicol Pharmacol*. 2011;59(2). [\[link\]](#)

<sup>11</sup> Lee PN. Epidemiological evidence relating snus to health - an updated review based on recent publications. *Harm Reduct J*. England; 2013;10(1):36. [\[link\]](#) "I concluded that snus use is clearly much safer than smoking, and that any effects of snus use on the risk of cancer or [circulatory disease], if they exist, are probably no more than 1% of that of smoking".

<sup>12</sup> Ramström L, Borland R, Wikmans T. Patterns of Smoking and Snus Use in Sweden: Implications for Public Health. *Int J Environ Res Public Health*. Multidisciplinary Digital Publishing Institute (MDPI); 2016 Nov 9;13(11). [\[link\]](#)

<sup>13</sup> Foulds J, Ramstrom L, Burke M, Fagerström K. Effect of smokeless tobacco (snus) on smoking and public health in Sweden. *Tob Control*. 2003 Dec;12(4):349–59. [\[link\]](#)

<sup>14</sup> Ramström L, Wikmans T. Mortality attributable to tobacco among men in Sweden and other European countries: an analysis of data in a WHO report. *Tob Induc Dis*. 2014 Jan;12(1):14. [\[link\]](#)

<sup>15</sup> European Commission. Eurobarometer Survey 429: Attitudes of Europeans towards Tobacco and Electronic Cigarettes. 2015. [\[link\]](#)

<sup>16</sup> Stegmayr B, Eliasson M, Rodu B. The decline of smoking in northern Sweden. *Scand J Public Health*. 2005 Jan;33(4):321–4; 243. [\[link\]](#)

<sup>17</sup> Eurostat. Proportion of daily smokers of cigarettes, by sex and age, 2014 (% persons aged 15 and over) March 2017 [\[link\]](#). Sweden has male daily smoking of 7.5% (EU28 = 21.9%) and female daily smoking of 9.8%, (EU-28 = 15.1%)

<sup>18</sup> Lund I, Lund KE. How has the availability of snus influenced cigarette smoking in Norway? *Int J Environ Res Public Health*. 2014 Nov 13;11(11):11705–17. [\[link\]](#)

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would otherwise have been the case: “*In the post-ban period, smoking was 3.47 percentage points higher in Finland relative to what it would have been in the absence of the ban*”.<sup>19</sup>

Through wholly inadequate assessment of evidence and impacts, the European Union has imposed arbitrary regulation that appears to be *adding* to the avoidable burden of disease and premature death in the EU through its ban on snus.

### **Violation of key European Union principles and better regulation objectives**

The prohibition of snus fails to meet several key principles of European Union policymaking:

- *The prohibition of snus is disproportionate.* The alternative regulatory strategy of setting standards (e.g. for contaminants or manufacturing practice) is far superior and recommended by WHO’s scientific expert panel<sup>20</sup>. WHO’s TobReg expert committee argued in its 2010 report: “*Smokeless tobacco products should be regulated by controlling the contents of the products*”
- *The prohibition of snus is discriminatory.* It is self-evidently discriminatory to allow the manufacturing, import and sale of cigarettes in the internal market, but to ban a rival consumer nicotine product that is two orders of magnitude lower in risk to users. It is also discriminatory, and absurd, to prohibit smokeless tobacco products that are intended to be *sucked* once placed in the mouth but permit them if *chewed*. There is no basis at all for this distinction.
- *The prohibition of snus does not promote the internal market with a high level of health protection.* The ban works directly against the Community aim that forms the main legal base for the directive, that is the development of the internal market with a high level of health protection (Article 114 Treaty on the Functioning of the European Union). It prevents consumers accessing a much less dangerous product competing with cigarettes. It prevents companies marketing the much safer product, it protects the cigarette trade for no reason at all. Given the highly positive experience in Sweden and Norway, it is likely causing additional avoidable harm to health rather than providing a high level of health protection

*The prohibition of snus was not based on open and transparent decision-making.* The Commission’s case for a prohibition of snus is made in the [Impact Assessment](#) (pages: 50-52 and 61-76)<sup>21</sup>. A critique of the Commission’s reasoning<sup>22</sup> was provided to the Commission, Parliament and Council during the legislative process with adequate time to amend the draft directive. No substantive response was ever received. The critique concluded:

“... 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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<sup>19</sup> Maki J. The incentives created by a harm reduction approach to smoking cessation: Snus and smoking in Sweden and Finland. *Int J Drug Policy*. Netherlands; 17 June 2014;26(6):569–74. [\[link\]](#) and Rodu B. The Swedish Snus Experience Isn’t Finished. Tobacco Truth blog. 24 September 2014 [\[link\]](#)

<sup>20</sup> See especially: WHO Study Group on Tobacco Product Regulation Report on the Scientific Basis of Tobacco Product Regulation: WHO Technical Report Series, no. 951, 2008 [\[link\]](#), no. 955. 2010. [\[link\]](#); no 989. 2015. [\[link\]](#)

<sup>21</sup> European Commission COM(2012) 788 Final. Impact Assessment. [\[link\]](#)

<sup>22</sup> Bates CD, Ramström L. Proposed revision to the Tobacco Products Directive: a critique of the scientific reasoning supporting the proposed measures relating to oral tobacco , 18 March 2013 [\[link\]](#)

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- *The prohibition of snus ignored the views of citizens and stakeholders.* In 2010, the European Commission conducted a consultation on possible measures to include in a forthcoming revision of the Tobacco Products Directive<sup>23</sup>. The consultation showed a high level of support for lifting the snus prohibition – 57,175 EU citizens or 83.73% of those responding to the question favoured lifting the snus prohibition. Even among responses classed as ‘governmental representatives’, a clear majority (63.5%) favoured lifting the snus prohibition. It is difficult to find the reasons why these responses were ignored and a why minority view unsupported by evidence was adopted instead. Given the circumstances in which Commissioner Dalli left the Commission, we remain concerned that decision-making about snus policy following the 2010 consultation and before publication of the draft directive in 2012 may not have been focussed exclusively on citizen welfare and achieving Community objectives for health and the development of internal market.
- *The prohibition of snus violates the Charter of Fundamental Rights*<sup>24</sup>. Consumers assert that deliberately depriving smokers of options to address their health risks is a violation of:
  - Article 1, ‘human dignity’ as it causes needless suffering and debilitating illness;
  - Article 7, ‘respect for private and family life’, because it represents unwarranted interference in personal choices;
  - Article 35, ‘health care’, which stipulates that a high level of human health protection shall be ensured in EU policies and activities. Health protection includes enabling people to make choices that help them avoid ill-health, and denying this violates this right.

### Further considerations

- **Recent US regulatory findings.** In November 2015, the United States Food and Drug Administration completed its first Pre-Market Tobacco Product Application (PMTA) for a snus product. After an exhaustive review, it concluded that the product is “*appropriate for the protection of public health*”<sup>25</sup> and provides a summary of its findings, which are very positive. There is no analysis to support a different conclusion for Europe.
- **Key scientific facts in the 2004 legal case.** In 2004, a challenge to the ban by Swedish Match failed before the Court of Justice (see case C-210/03)<sup>26</sup>. However, the reasoning in that case was based on several concerns that are now unambiguously resolved. See, for example, the assertion of cancer risk at paragraph 65 of the judgement: “*it had been proved that smokeless tobacco products were a major risk factor as regards cancer*”. This is now known to be untrue, (see above). There is extensive epidemiology that demonstrates that snus poses far lower risk (if any) of all forms of cancer, including oral cancer<sup>27</sup> and pancreatic cancer<sup>28</sup>, than smoking.

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<sup>23</sup> European Commission, Public consultation on the possible revision of the Tobacco Products Directive 2001/37/EC, 24 September 2010 [[link](#)]. Report, July 2011 [[link](#)]. Compendium of Statistics. July 2011 [[link](#)]

<sup>24</sup> European Union Charter of Fundamental Rights. [[link](#)]

<sup>25</sup> Food and Drug Administration. FDA issues first product marketing orders through premarket tobacco application pathway, 10 November 2015. [[link](#)]

<sup>26</sup> Court of Justice of the European Union, Case C-210/03 Documentation 2003-04 [[link](#)]

<sup>27</sup> Rodu B, Jansson C. Smokeless tobacco and oral cancer: a review of the risks and determinants. *Crit Rev Oral Biol Med*. 2004 Sep 1;15(5):252–63. [[link](#)]

<sup>28</sup> Araghi M, Galanti M, Lundberg M, Lager A, Engström G, et. al. Use of moist oral snuff (snus) and pancreatic cancer: Pooled analysis of nine prospective observational studies, *Int J Cancer*, 9 May 2017[Epub ahead of print] [[link](#)]

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- **The ‘novel tobacco product’ argument is now obsolete** . The Court’s 2004 judgement rested heavily on an argument that snus products would be ‘novel’ in most EU countries and therefore presented novel risks which could theoretically justify a ban on precautionary grounds (see paragraphs 5, 7, 8, 37, 49, 51, 55, 65, 67 and finally the conclusion at paragraph 71 of the Court’s judgement)<sup>29</sup>. This argument was weak at the time it was made because there was already ample evidence of the positive impact of snus where it was on sale and no basis to presume it would be different elsewhere. However, the ‘novel product’ justification is now unambiguously invalid. Article 19 of the Directive provides a route to market for any novel tobacco products, but this route is denied to snus by the outright prohibition in Article 17. The ban on snus is already self-evidently discriminatory with respect to cigarettes and other smokeless tobaccos. The introduction of Article 19 to the 2014 directive means the snus ban is also discriminatory with respect to *any novel tobacco product*.

We hope that the Commission and Member States will carefully consider their responsibilities to act lawfully under the terms of the Treaties and not simply see the legal challenge to the snus prohibition as a bureaucratic hurdle to overcome. This is a bad regulation where the consequences are measured in disease and death.

We believe this is the appropriate moment to reset the European Union policy on oral tobacco in line with evidence, ethics, and law. In the first instance, this means replacing a disproportionate and discriminatory prohibition by lifting the ban on snus and treating this product in the same way as other smokeless tobaccos. In the longer term, it means creating a system of product standards that apply to smokeless tobacco products, as advised by WHO’s expert committee.

Ending the prohibition of snus would allow the European Union to take a fresh look at regulating all low-risk tobacco and nicotine products, including e-cigarettes, novel nicotine products and heated tobacco products, to ensure they are regulated proportionately and according to risk. This would be in line with the Better Regulation agenda and the Union’s primary policy objectives, which are to reduce tobacco-related morbidity and mortality and to develop the internal market with a high level of health protection.

We would welcome a considered response to the points raised in this letter and appropriate action to end the unjustified prohibition of oral tobacco in 27 European Union member states. The Court of Justice has invited written observations on the case C-151/17 from member states and the Commission with a deadline of 7<sup>th</sup> July or shortly thereafter. We hope that all parties will consider the views in this letter before filing any comments with the Court of Justice.

We are copying this letter to the Commissioner for Health & Food Safety, the Commissioner for the Internal Market, relevant Commission officials, the JURI committee of the European Parliament, and representatives of the Member States. We will also make it available to the public.

Your sincerely,

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<sup>29</sup> Court of Justice of the European Union, Case C-210/03 Judgement 14 December 2004 [[link](#)]

## Letter from experts in tobacco science and policy regarding the European Union snus prohibition

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**Attachments:** Letter to Commissioner Dalli, 10 May 2011 [[Open](#)]

Letter to Minister for Health, Government of Sweden, 15 February 2013 [[Open](#)]

Letter to President of the European Parliament, 23 September 2013 [[Open](#)]

Letter to UK Secretary of State for Health, 7 October 2013 [[Open](#)]

Bates CD, Ramström L. Critique of Commission Proposal, 18 March 2013 [[Open](#)]

**Declaration:** the signatories to this letter have no affiliation to the tobacco industry and the letter does not raise issues under Article 5.3 of the WHO Framework Convention on Tobacco Control.