Bundesamt für Gesundheit BAG
Direktionsbereich Verbraucherschutz
CH - 3003 Bern
Switzerland
By email: tabakprodukte@bag.admin.ch

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Zweiter Vorentwurf zum Tabakproduktegesetz / Second preliminary draft Tobacco Products Act

We write as eighteen experts in the field of tobacco control and public health. We wish to provide some brief comments on the second preliminary draft Tobacco Products Act[1], which is currently open for consultation. We welcome the proposed legalization of trade in alternative products such as e-cigarettes and snus and specific regulation of these products. This will greatly expand the lawful opportunities for smokers to quit smoking. Our focus in this letter is the intention to permit the marketing of oral tobacco in Switzerland. We welcome this proposal and regard it as a valuable departure from the European Union's ethically and scientifically unjustified ban on oral tobacco.

E-cigarettes and vapour products

The case for permitting and regulating e-cigarettes has been made extensively. We recommend three key evidence and policy reviews: Public Health England[2]; the Royal College of Physicians (London)[3] and the U.S. National Academies of Science, Engineering and Medicine[4]. Each of these reports combined with the rapid declines in adult and teenage smoking in the United Kingdom and United States make a powerful case for allowing consumers to access a regulated low-risk alternative to cigarettes as a harm reduction strategy for those who cannot or do not wish to quit use of nicotine. There appear to be few if any material negative consequences.

Oral tobacco and snus

Where oral tobacco is available in Europe, it has had a highly beneficial effect on health by displacing smoking with a much lower risk product. We provide a brief review of public health data before looking at the experience of oral tobacco in several countries.

1. Oral tobacco is much less harmful than smoking

The Federal Bureau of Public Health acknowledged that the risks of oral tobacco would be lower, but raised concerns about residual risks. This is a legitimate concern, but what matters is the approximate *magnitude* of such residual risks. Because there is no combustion and therefore no harmful products of combustion, prolonged regular snus use is *much less harmful* than cigarette smoking. There is extensive epidemiology that demonstrates that compared to smoking, snus poses

1 Federal Office of Public Health (BAG) Second preliminary draft Tobacco Products Act, Switzerland, 8 December 2017 [link]

2 McNeill A, Brose LS, Calder R, Bauld L & Robson D. Evidence review of e-cigarettes and heated tobacco products 2018. A report commissioned by Public Health England. London: Public Health England. 6 February 2018 [link] [Press release]

3 Tobacco Advisory Group, Royal College of Physicians (London), *Nicotine without smoke: tobacco harm reduction*. 28 April 2016 [link]

4 National Academies of Science, Engineering and Medicine (US). The Public Health Consequences of E-cigarettes. Washington DC. January 2018. [link]

far lower risk (if any) of all forms of cancer, including oral cancer[5] and pancreatic cancer[6]. There are minor risks associated with nicotine exposure and these apply to oral tobacco use. However, i nicotine exposure through use of nicotine replacement therapy (NRT) is permitted for adolescents from age twelve and for pregnant women in the UK because nicotine poses only a small and weakly-established risk compared to smoking and because NRT use can prevent smoking.

On the basis of a thorough review of the available epidemiology, it is likely that the risks of snus use are close to negligible and no more than 1% of the risks of smoking[7] [8].

> *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. I also noted that switching to using snus should improve the health prospects of those smokers unable or unwilling to relinquish nicotine, and that there is no good evidence that introducing snus into a population would encourage smoking initiation or discourage cessation.*

2. Oral tobacco has had a highly beneficial public health impact

The Federal Bureau of Public Health (BAG) also expressed concerns that oral tobacco availability may lead to more tobacco use, not less. Again, there is a theoretical possibility that this could happen, but there is no evidence to support that concern and considerable evidence that the opposite effect is more likely – a displacement of smoking.

3. Sweden

There is clear data showing the patterns of snus in Europe use result in lower burdens of smoking-related cancer and cardiovascular disease, most notably in Sweden. Where available, snus has displaced smoking – both by increased smoking cessation and reduced smoking initiation - leading to significant population health improvements[9] [10]. According to the pan-European Eurobarometer survey, this effect is large. Sweden has by far the lowest rate of smoking in the European Union with an adult smoking prevalence of 7 percent compared to the EU-28 average of 26 percent and 17 percent in the UK, as measured in this survey[11]. In Northern parts of Sweden, smoking has almost been completely displaced by snus use[12] and it is likely that some who would otherwise have become smokers use snus from the outset.

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[5] 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]

[6] 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]

[7] Lee PN. Summary of the epidemiological evidence relating snus to health. *Regul Toxicol Pharmacol*. 2011;59(2). [link]

[8] Lee PN. Epidemiological evidence relating snus to health - an updated review based on recent publications. *Harm Reduct J*. England; 2013;10(1):36. [link]

[9] 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]

[10] 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]

[11] European Commission. Eurobarometer Special Survey 458: Attitudes of Europeans towards Tobacco and Electronic Cigarettes. 2017. Fieldwork March 2017. Published May 2017 [link]

[12] 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]

4. Norway

These positive effects are not confined to Sweden. Norway has also benefitted from reduced smoking rates[13] by remaining outside the European Union and securing an exemption from the snus prohibition in its European Economic Area agreement. Snus use appears to displacing smoking at all ranges in the Norwegian population, but the effect is especially pronounced in young adults, where smoking among under-25 has fallen to *one percent* among women and *five percent* among young men. These are very low levels by any standard.

Smoking and snus use in Norway 2008 - 2017

Source: Statistics Norway[14]

[13] 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]

[14] Statistics Norway, *Smoking Habits*, 18 January 2018 - overview [link] – in depth [link]

The charts show that smoking can approach very low levels with alternative nicotine products, and not just in Sweden – the 2017 EU average for adult daily smoking is 24 percent[15]. The charts also show significant change over a relatively short period – suggesting changes *within* the pattern of use of nicotine products may be more rapid than between nicotine use and complete cessation. Snus in Scandinavia and Nordics provides a 'proof of concept' for tobacco harm reduction, but in other countries it may be different products that provide the beneficial effects. The policy imperative is to have the availability of as many of the alternatives to smoking as possible.

5. Finland

In contrast, when Finland joined the European Union in 1994, the snus ban was imposed and the rate of decline in Finnish smoking slowed. Finland provides a cautionary message about the harmful impact of banning safer alternatives to smoking. It has been estimated that Finland has a materially higher smoking rate as a result, and hence higher rates of disease and premature death than would otherwise have been the case[16]:

> *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*.

It is important to recognize at least the possibility that there can be harmful effects arising from denying smoker access to much lower risk alternatives to smoking. While there may be concerns raised about snus or e-cigarettes, policymakers should also have concerns about not allowing these products on to the market or imposing excessive restrictions on them. The precautionary principle demands consideration of the impacts of both non-intervention and intervention.

6. United States

In 2015, the Food and Drug Administration of the United States evaluated eight Swedish Match snus products through its arduous 'Pre-market Tobacco Application' (PMTA) process, and concluded that the products are "*appropriate for the protection of public health*"[17]:

> *Under the PMTA pathway, manufacturers must demonstrate to the agency, among other things, that marketing of the new tobacco product would be appropriate for the protection of the public health. That standard requires the FDA to consider the risks and benefits to the population as a whole, including users and non-users of tobacco products.*

7. The European Union

The import, manufacture and sale of oral tobacco is prohibited in the European Union under the 2014 Tobacco Products Directive[18]. The case for lifting the ban on snus has been set out by the

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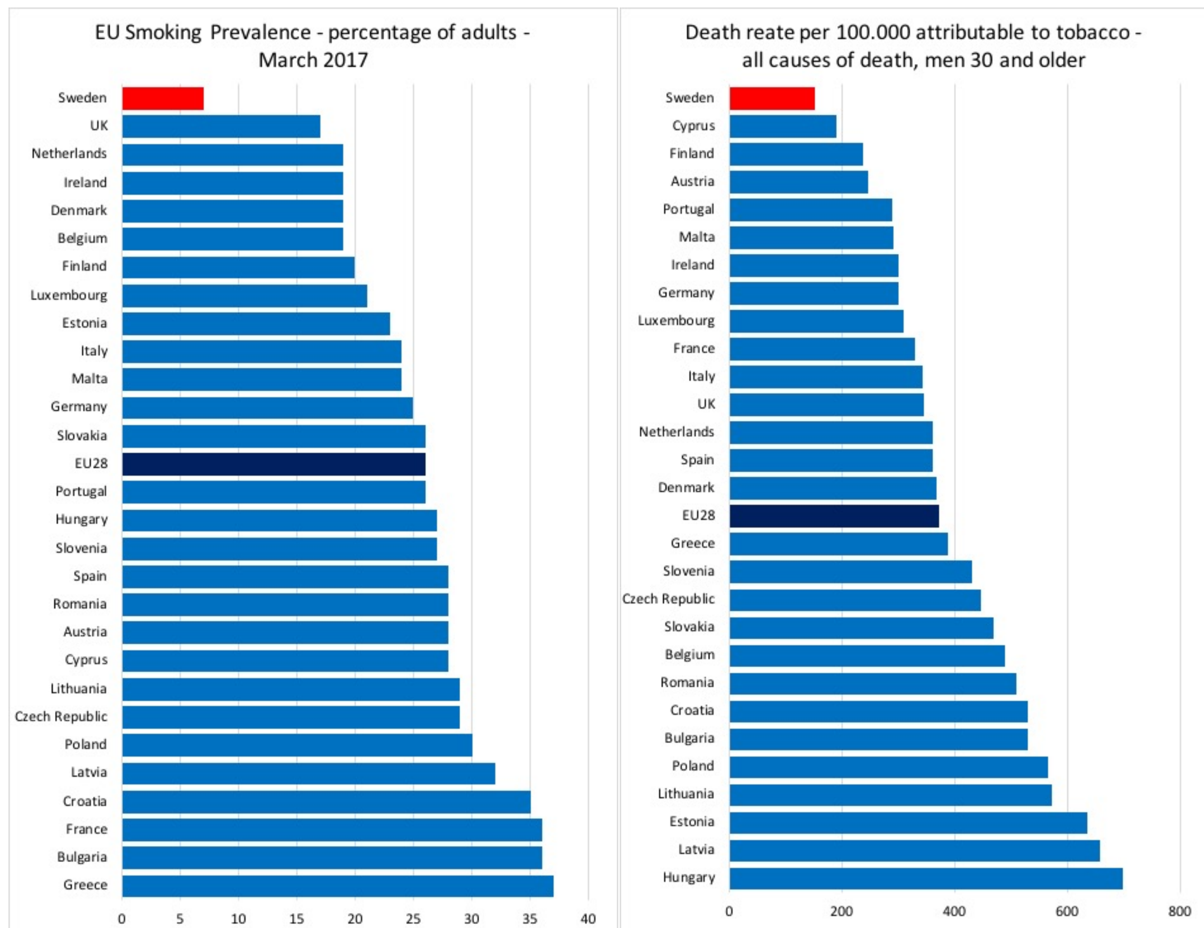
[15] European Commission. Eurobarometer Special Survey 458: Attitudes of Europeans towards Tobacco and Electronic Cigarettes. 2017. Fieldwork March 2017. Published May 2017 [link]

[16] 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 Finnished. Tobacco Truth blog. 24 September 2014 [link]

[17] U.S. FDA, FDA issues first product marketing orders through premarket tobacco application pathway, 10 November 2015 [link]

[18] The ban was introduced in 1992, and reaffirmed in Article 17 of the Tobacco Products Directive 2014/40/EU of April 2014 [link]

expert community in numerous communications: to the European Commission in May 2011[19]; to the Government of Sweden and European Council in February 2013[20]; to the European Parliament in September 2013[21] to UK government in October 2013[22] and to the Directorate General For Better Regulation in June 2017[23] arguing that the European Union prohibition of snus is unjustified and damaging and should be lifted. A detailed critique of the Commission's proposal to retain this prohibition was provided to the Commission and widely shared in March 2013[24]. There is no equivalent body of argument that supports the case for the prohibition. The EU ban on oral tobacco is deeply irrational, banning the product that is both responsible for Sweden's anomalously low smoking prevalence and tobacco-related mortality – see charts below.



Source: Eurobarometer, 2017[25]

Source: WHO & Ramström L. [26]

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[19] Letter to Commissioner Dalli: Advancement of the scientific basis for the EU TPD, May 2011 [link]

[20] Letter to Maria Larsson, Minister for Health, Government of Sweden 15 February 2103 [link] copied to Working Party on Public Health - Health Attachés, Brussels on 15 February 2013 [link]

[21] Letter to Martin Schulz, President of the European Parliament, copied to MEPs 23 September 2013 [link]

[22] Letter to Rt. Hon. Jeremy Hunt MP, Secretary of State for Health (UK/England), 7 October 2013. [link]

[23] Letter to Frans Timmermans, Lifting the unjustified European Union ban on oral tobacco or "snus" in the light of ongoing legal action, 1 June 2017 [link]

[24] 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]

[25] European Commission. Eurobarometer Special Survey 458: Attitudes of Europeans towards Tobacco and Electronic Cigarettes. 2017. Fieldwork March 2017. Published May 2017 [link]

[26] World Health Organisation, WHO global report: mortality attributable to tobacco, 2012 [link] data extracted by Lars Ramström, Global Forum for Nicotine, 2017 [link]

The current challenge to the legality of this European Union prohibition (European Court of Justice case C-151/17[27]) is based on the violation of the principle of proportionality and principle of equal treatment and non-discrimination and the violation of human rights. We can see no ethical justification for denying a smoker an alternative product that is much lower risk than cigarettes and has proved successful in reducing smoking at a population level.

The government of Switzerland would be right to avoid the mistakes made in the European Union over many years and to allow oral tobacco products onto the market to compete with cigarettes.

We believe the approach proposed approach is well founded in science, ethics, public health and law.

We hope these views are useful.

Your sincerely,

Professor Frank Baeyens
Faculty of Psychology and Educational Sciences
KU Leuven
Belgium

Clive D. Bates
Director, Counterfactual
Former Director, Action on Smoking and Health (UK)
London
United Kingdom

Professor Pierre Bartsch
Hon. Professor of Pneumology
University of Liège
Belgium

Professor Ron Borland PhD, FASSA
Nigel Gray Distinguished Fellow in Cancer Prevention,
The Cancer Council Victoria
Australia

Professor Karl Fagerström Ph.D.
Professor Psychology, Emeritus
Sweden

Dr. Konstantinos Farsalinos, MD, MPH
Onassis Cardiac Surgery Center
University of Patras
National School of Public Health,
Greece

Professor Peter Hajek
Wolfson Institute of Preventive Medicine
Queen Mary University of London
United Kingdom

Professor Martin Jarvis
Emeritus Professor of Health Psychology
Department of Behavioural Science and Health
University College London
United Kingdom

Professor Lynn T. Kozlowski, Ph.D.
Professor of Community Health and Health Behavior
University at Buffalo, The State University of New York
United States

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[27] Court of Justice of the European Union, Case C-151/17 24 March 2017 [link]

Leon Kośmider, PhD
Virginia Commonwealth University
Bioanalytical Laboratory within
Department of Pharmaceutics,
School of Pharmacy
Center for the Study of Tobacco Products
Richmond
United States

Jacques Le Houezec, PhD
Independent consultant in Public Health &
Tobacco dependence - Smoking Cessation
Specialist
Honorary Clinical Associate Professor, UK
Centre for Tobacco and Alcohol Studies,
School of Medicine, University of
Nottingham, UK.

Karl E Lund, PhD
Senior Researcher
Norwegian Institute of Public Health
Norway

Professor Bernd Mayer, PhD
Professor & Chair
Department of Pharmacology and
Toxicology
University of Graz
Austria

Professor Riccardo Polosa, MD
Professor of Internal Medicine
Università degli Studi di Catania,
Italy

Lars Ramström
Director
Institute for Tobacco Studies
Sweden

Professor Andrzej Sobczak
Head of Department of General and
Inorganic Chemistry
Medica University of Silesia
Poland

Professor Gerry V Stimson
Emeritus Professor Imperial College
London
Honorary Professor London School of
Hygiene and Tropical Medicine
United Kingdom

David Sweanor JD
Chair of the Advisory Board,
Centre for Health Law, Policy and Ethics,
University of Ottawa
Canada