



REGARDING ECJ C 151/17

His Excellency Mr

Permanent Representation of the

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**1050 Bruxelles/Brussel
Belgique**



MAY 21, 2017

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Possible decision by your country to respond to Court of Justice of the European Union, Reference C-151/17, regarding lifting the ban on snus as Tobacco Harm Reduction.

Your Excellency,

We are grateful for the determination showed by your country and the institutions of the European Union in the battle against smoking. Yet even with good intentions the fast-moving nature of technology and fresh scientific research sometimes means that aspects need to be reviewed by the institutions outside the normal cycle of Directives.

New Nicotine Alliance Sweden, and the global umbrella consumer organisation INNCO represent the interests of smokers who wish to find a safer alternative to smoking cigarettes.

We are writing to you about one anomaly which is currently being assessed by the European Court of Justice; that is the complete ban on the smoking substitute snus outside of Sweden.

We would like to bring to your attention a legal case before the ECJ to which the New Nicotine Alliance (UK) is a party. We would be grateful if you could bring this letter to the attention of your relevant ministry.

In the event your country decides to file a reply to the ECJ, we see great value in this opportunity to provide you with the most recent facts and context.

The issue of the ban on the sale of snus is perplexing to the nicotine users we represent because Sweden, where 18% of men use snus, is doing far better than anywhere else in the EU at reducing smoking and tobacco related disease.

Two months ago, The [New Scientist](#) reported that only 5% of Swedish men smoke in their 30s – the lowest rate of smoking in the EU

If there was any evidence that using snus was remotely as harmful as smoking, then there might be grounds for keeping this ban. However, this is not the case:

- EU Commission: “It is undeniable that for an individual substitution of tobacco smoking by the use of moist snuff [snus] would decrease the incidence of tobacco related diseases.”: [SCENIHR \(2008\)](#)
- World Health Organisation: Snus is “considerably less hazardous than cigarettes”: page 273 [WHO Tob. Reg. Report 951](#)

In a letter to [The Times of London](#), veteran research professionals Farsalinos, Le Houezec, Polosa and Ramström wrote that not only did Sweden have by far the lowest rates of lung cancer and heart disease in Europe but that “younger Swedish men, who are the highest users of snus, have the lowest levels of oral, oesophageal and pancreatic cancer.”

Indeed, the evidence supporting the comparative safety of snus was so compelling, that in 2015 the US Food and Drug Administration chose snus as the first nicotine product to be authorised ([FDA authorisation](#))

We are intending to mount a media campaign on this issue and sincerely hope that your country will take this opportunity to demonstrate that the EU process is able to be responsive to EU citizens and open to transparently advancing scientific data.

Prior to launching our campaign, we would appreciate meeting with you, and/or relevant representatives from your country, to listen to your understanding of the evidence.

There is a consensus amongst a large global collective of prominent scientists and tobacco control professionals, (largely independent from institutionalized supranational and national tobacco control institutions), that the internationally generally accepted assessment from Sweden on snus is a misrepresentation of the science, the potential for harm reduction, and finally the positive health economics of snus as a cigarette alternative product.

Should your country decide make an observation to the ECJ on this matter, may we offer a suggestion for one possible reasoned and evidence based position. Though further research may be warranted, there is sufficient compelling and robust evidence present that snus offers smokers a significantly safer alternative to cigarettes, and as such snus should be made available to adult consumers in the EU. The current snus ban should be lifted and snus should be regulated in line with the TPD provisions for e-cigarettes and other novel tobacco products. This cohesive category of harm reduction products would then best be closely monitored for future regulatory fine-tuning, and strictly enforced in terms of age restrictions to ensure the products are not made accessible to minors.

We feel that this would be a logical and non-discriminatory approach, an approach also offering 100 million smokers in the EU one further proven harm reduced alternative. In effect this would afford the smokers, as well as youth and non-smokers, a considerably higher level of health protection than maintaining the current ban will.

Alternatively or additionally, should your country decide to comment to the ECJ, your country may wish to consider highlighting the absence of any reasonable scientific and health economic evaluation regarding snus use in Sweden. This is indicative of that the more than 150-year tradition of use of snus in Sweden causes negligible or non-measurable health and societal consequences, despite representing 50% of total tobacco consumed in Sweden.

Furthermore and as of 2017, [The Swedish Public Health Agency](#) and [The National Board of Health and Welfare](#), both are agencies under the Ministry of Health, have entirely ceased monitoring and reporting data for snus use in the official health determinants surveys and reports. Snus use data has been collected and reported since 1988, but will no longer be.

A clear and very recent indication of the information problem regarding snus, one that may be of interest to your country position on this principally important issue, is that the Karolinska Institute in Stockholm on May 9th 2017, published a definitive [correction](#) of a since the early 2000's widely advertised claim that snus use increases risk of pancreatic cancer.

With this correction, it would seem clear and acknowledged also by science in Sweden, though not yet by policymakers; that snus use does not cause any measurable increases in lung disease, cancer or cardiovascular disease compared to never users of tobacco. In our opinion, the significance and implications of these recent developments cannot be stressed enough. We hope this update may be of informational value to your country.

We would be grateful for the opportunity to discuss this important case further with you or your representatives, at home or in Brussels, and to answer any questions or concerns you may have. We would also greatly appreciate an email from your offices that you have received this communication from us in good order and that e-mail is an acceptable format. If the format is not correct, please kindly inform us on the correct route of communication and we shall immediately resend the documents accordingly.

Kindest regards,

Erik Atakan Befrits

Judy Gibson

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Please see Appendix 1-3 for supplementary discussion and background documentation that you and your staff may find helpful to further explain the points made in our letter.

All links in the letter and these appendices are live in this version of this document and can be followed directly while reading the text, for easy referencing.

APPENDICES

Appendix 1

Background to the legal action against the ban on snus, brought by the New Nicotine Alliance, UK

NNA contends that snus fulfils the criteria for a tobacco harm reduction product and hence should be available in the EU. The legal ban on snus denies smokers of the choice of a much safer nicotine product than cigarettes.

The introduction of snus into the EU would form part of a coherent strategy of tobacco harm reduction that help people avoid smoking. The current scientific evidence, and the fact that Sweden, where snus is used, now has the lowest lung cancer and tobacco-related mortality in Europe, indicates that snus is a suitable and appropriate product for individuals who are seeking to avoid smoking and other combustible tobacco products.

The rapid rise in the popularity of electronic cigarettes, a grass roots consumer driven phenomenon, shows that many smokers want to avoid smoking-related harms. There is the potential to reduce smoking when acceptable products are available to consumers; such uptake being at no cost to public funds.

The legal challenge

The Swedish Match legal challenge against the ban on snus

Swedish Match – the main manufacturer of Swedish snus – has brought a challenge in the UK High Court against the ban of the sale of snus. Their legal argument is that the law discriminates against snus compared with cigarettes and with lower risk nicotine products, that the ban is disproportionate, is against the principle of subsidiarity in removing national regulatory discretion, breaches the duty to give reasons for the ban, and is an unjustified restriction on the free movement of goods.

The NNA legal challenge against the ban on snus

NNA asked the UK High Court to be joined to the case as an ‘intervenor’. NNA is acting as a third party in the public interest, and brings added facts and argument to the case.

The New Nicotine Alliance (NNA) submits to the court that the ban on snus is disproportionate given the low risk of snus compared with other nicotine products. It is an unsuitable means by which to achieve the aim of public health protection because it removes from consumers the option to use a safer nicotine product.

NNA argues that the ban is (a) disproportionate, and (b) contravenes the right to a high level of health protection.

Significantly, for the first time in a challenge against UK (and EU) tobacco legislation, NNA argues that the ban infringes human rights. NNA argues that the ban

contravenes the EU Charter of the Fundamental Rights vis Art 1 'human dignity', Art 7 'respect for private and family life', and Art 35 'health care'.

Art 35 stipulates that a high level of human health protection shall be ensured in the EU policies and activities. NNA argues that the ban is inappropriate as it prevents smokers from having access to a safer product and is an unsuitable means for achieving a high level of health protection.

Progress with the case

The High Court agreed on Jan 26th 2017 that there was a case for a review of the legislation. Because the UK Tobacco and Related Products Regulations 2016 are based on the EU Tobacco Products Directive 2014, the case was referred to the European Court of Justice, on 9 March 2017.

Implications of the case

The ECJ ruling will apply across the EU.

Further information

The NNA submission to the High Court can be found [here](#), along with supporting expert and witness statements from [Gerry Stimson](#), [Karl Lund](#), [Louise Ross](#) and [Judy Gibson](#).

Appendix 2

The human rights argument advanced by the New Nicotine Alliance

The New Nicotine Alliance (NNA) **legal case is the first time that a ‘right to health’ argument has been used to challenge a bad tobacco control law.**

NNA’s case to the European Court of Justice is based on EU law and the EU Charter of Fundamental Rights (CFR) [1]. NNA’s argument is that the ban on snus is disproportionate, and that it is contrary to the human right to health. Given the evidence that snus is substantially safer than smoking cigarettes, and that it protects against smoking, it is both unethical and contrary to EU law to deny access to this product.

NNA supports the idea of ‘tobacco harm reduction’ as it is often formulated, in offering smokers and would-be smokers a low risk alternative to smoking. It is as an approach that is preferable to an abstinence only strategy, which is in effect a ‘quit or die’ approach.

NNA also supports the idea that many people like using nicotine and thus – especially if lower risk forms of nicotine are available - there must be major limitations on the ability of the state to interfere with that choice. Tobacco harm reduction recognises that many people find the use of nicotine pleasurable. This is reflected in our arguments that the ban on snus is contrary to the principles of autonomy and choice that flow from Articles 1 and 7 of the Charter of Fundamental Rights of the European Union (CFR).

NNA contends that the ban on snus infringes the human right to health. The availability of snus is an aspect of personal health and personal autonomy by which consumers can avoid the health hazards of smoking. The ban on tobacco for oral use limits smokers’ choice of safer alternatives, by excluding a product that is significantly less harmful to health than cigarettes. The NNA therefore submits that the ban on snus engages issues under European law, in particular those articles in the Charter of Fundamental Rights of the European Union (CFR) that protect autonomy and choice - Articles 1 (human dignity), Article 7 (respect for private and family life) and Article 35 (health care).

Human dignity

Article 1 of the CFR is an overall obligation to respect human rights, and protects ‘human dignity’. The issue of dignity is linked to personal autonomy: a principle by which individuals make choices on the conduct of their life, which presupposes a range of choices.

Respect for private and family life

Article 7 on ‘respect for private and family life’ is a broad-ranging right that is often closely connected with other rights including autonomy such as freedom of religion, freedom of expression, freedom of association and the right to respect for property. Article 7 has been held to apply to issues of quality of life, self- determination, a right

to establish relationships, self-identity, choices in relation to medical treatments to prolong life, and decisions on parenthood by insemination techniques.

Rights to health

European states are obliged to further the health of their citizens. The preamble to the European Social Charter [2] states that: 'Everyone has the right to benefit from any measures enabling him to enjoy the highest possible standard of health attainable' and Article 11 requires Parties to take measures to prevent disease and to encourage individual responsibility in matters of health.

Health protection

Moreover, all EU law must take into account 'health protection'. Facilitating a high level of health protection is required under Title XIV of the Treaty of Lisbon that 'A high level of human health protection shall be ensured in the definition and implementation of all Union policies and activities'. A high level of health protection is relevant to all EU legislation including the Tobacco Products Directive.

The EU Charter of Fundamental Rights stipulates in Article 35 that a high level of human health protection shall be ensured in the definition and implementation of all the Union's policies and activities. NNA argues that the EU legislators based the TPD law on a limited understanding of 'health protection' in violation of Article 35. By banning tobacco for oral use, the EU prevents access to a product that significantly reduces harm to consumers as compared to cigarettes. The EU legislators, we believe, took a narrow definition of 'health protection' to mean protection from products, whereas it should have taken a broader public health definition to include making it possible for people to take action to avoid ill-health through the choices they make.

NNA bases its argument on an interpretation of Article 35 of the CFR that a high level of health protection must allow access to snus. A similar argument may be made on the basis of other international treaty obligations.

The relevant obligation is Article 12 of the International Covenant on Economic, Social and Cultural Rights [3], which has been ratified by 165 countries including all EU states. Article 12 recognizes: 'the right of everyone to the enjoyment of the highest attainable standard of physical and mental health' and that States Parties must take steps regarding 'the prevention, treatment and control of epidemic, endemic, occupational and other diseases.' This has been interpreted by the UN Special Rapporteur on the Right to Health to include access to harm reduction resources for people who use drugs [4]. We similarly argue that Article 12 includes access to tobacco harm reduction resources, ie safer nicotine products.

Tobacco harm reduction is consistent with obligations in the international treaty on tobacco control. All European Union states are signatories to the Framework Convention on Tobacco Control (FCTC), the international health treaty that aims to reduce the use of tobacco [5]. The preamble to the FCTC notes obligations (as mentioned above) under the Article 12 of the International Covenant on Economic, Social and Cultural Rights. Moreover Article 1d of the FCTC specifically refers to

harm reduction as one of the defining strategies of tobacco control, which is: ‘a range of supply, demand and harm reduction strategies that aim to improve the health of a population by eliminating or reducing their consumption of tobacco products and exposure to tobacco smoke’.

As mentioned above the European Social Charter requires states to encourage individual responsibility in matters of health. This view links to a basic principle of public health, which is one of creating the conditions in which people can lead healthier lives. In particular, as stated in the constitution of the World Health Organisation [6], that: ‘Informed opinion and active co-operation on the part of the public are of the utmost importance in the improvement of the health of the people.’ [6] Empowering individuals and communities to take control of their health is a fundamental principle of public health, as set out in the Ottawa Charter on Health Promotion [7].

Tobacco harm reduction is consistent with the broad public health aim of enabling people to take action to reduce risks to their health. They cannot do that unless they have access to the resources that help them do this. That is why a ban on snus is inconsistent with helping people to lead healthier lives. Snus has to be legalised because snus saves lives.

[1] Charter of Fundamental Rights of the European Union ([2000/C 364/01](#))

[2] European Social Charter <https://www.coe.int/en/web/conventions/full-list/-/conventions/rms/090000168007cf93>

[3] <http://www.ohchr.org/EN/ProfessionalInterest/Pages/CESCR.aspx>

[4] Open Letter by the Special Rapporteur on the right of everyone to the highest attainable standard of mental and physical health, Dainius Pūras, in the context of the preparations for the UN General Assembly Special Session on the Drug Problem (UNGASS), which took place in New York in April 2016.

<http://www.ohchr.org/Documents/Issues/Health/SRLetterUNGASS7Dec2015.pdf>

[5] Framework Convention on Tobacco Control
http://www.who.int/fctc/text_download/en/

[6] Constitution of the World Health Organisation http://www.who.int/governance/eb/who_constitution_en.pdf

[7] Ottawa Charter on Health Promotion. World Health Organization 1986

<http://www.who.int/healthpromotion/conferences/previous/ottawa/en/>

Appendix 3

What do we know about snus?

What is snus?

Snus is a moist, smokeless powdered tobacco. It is sold as a loose powder or pre-packaged in a small sachet (a bit like a mini tea bag). It contains ground tobacco, salt and may contain food-grade smoke aroma flavourings, such as citrus, bergamot, juniper, herb or floral flavours. Most Scandinavian snus is produced in Sweden where it is regulated as a food under the Swedish Food Act. The nicotine content varies among brands.

Is snus an appropriate and acceptable harm reduction product?

Snus fulfils the criteria for a tobacco harm reduction product. It is a low risk nicotine product and delivers acceptable doses to those who use it. In countries in which it is allowed it is popular and has contributed to declines in smoking and smoking related diseases.

How does snus differ from other oral tobaccos?

Snus is a smokeless tobacco. Unlike some other smokeless tobacco types, Swedish snus is not fermented and is pasteurised, which inhibits the growth of bacteria that help the formation of tobacco-specific nitrosamines (an important group of carcinogens in tobacco products). Snus is refrigerated in order to inhibit the growth of toxins.

How is snus used?

Snus is placed between the upper lip and gum. The nicotine is released into the saliva, with the rate of release affected by the amount of saliva. New users experiment (titrate) to find the best rate of nicotine release. <http://www.wikihow.com/Use-Snus>

Is there a quality standard for snus?

The Gothiatek standard, a voluntary quality standard for snus products, has maximum levels for constituents, including nitrosamines, metals, nitrite, agrochemicals, mycotoxins and aldehydes. <https://www.swedishmatch.com/Snus-and-health/GOTHIATEK/GOTHIATEK-standard/>

Is snus safe and are there any long-term health effects?

Snus is considered by scientists to be 95%, and possibly closer to 99%, less risky than smoking.

Snus poses no respiratory risk. Respiratory diseases, predominantly lung cancer, chronic obstructive pulmonary disease (COPD) and pneumonia account for 46% of

deaths due to smoking, according to the Scientific Committee on Emerging and Newly Identified Health Risks, 2008.

http://ec.europa.eu/health/ph_risk/committees/04_scenihhr/docs/scenihhr_o_013.pdf

Individual studies can produce contradictory findings so evidence must be sought from overviews of key studies and pooled results. A recent systematic review and meta-analysis examined the evidence relating to snus and health across six major Swedish, Norwegian, Danish and Finnish studies, up to 2010. This concludes that the evidence provides scant support for any major adverse health effects of snus: snus is not associated with cancers of the oropharynx, oesophagus, pancreas, or heart disease or strokes. Compared with smoking snus poses about 1% of the risk of cancer or cardiovascular disease. <https://www.ncbi.nlm.nih.gov/pubmed/21163315>

Snus and lung cancer in Sweden

The rise in the use of snus has resulted in Sweden having the lowest lung cancer mortality and tobacco-related mortality in Europe. It is estimated that if the Swedish smoking prevalence was extrapolated to the rest of the EU, there would be a 54% reduction of male mortality from lung cancer. (Rodu B. and Cole, P. 2009. "Lung Cancer Mortality: Comparing Sweden with Other Countries in the European Union." Scandinavian journal of public health 37(5):481–86.)

<http://journals.sagepub.com/doi/abs/10.1177/1403494809105797>

Health effects of switching to snus

Given the lower risk profile for snus it has been calculated that the life expectancy of smokers who switch from smoking to snus is little different to the life expectancy of those who stop smoking altogether. The authors of this study conclude that:

'Individual smokers who switched to snus instead of continuing to smoke and new tobacco users who only used snus rather than smoking would achieve large health gains compared with smokers'.

[http://www.thelancet.com/journals/lancet/article/PIIS0140-6736\(07\)60677-1/abstract](http://www.thelancet.com/journals/lancet/article/PIIS0140-6736(07)60677-1/abstract)

This finding is confirmed by a recent analysis of six major studies which found that switching from smoking to snus is associated with major reductions in morbidity and that switching to snus appears to have much the same reduced health risk as quitting smoking.

<http://europepmc.org/abstract/MED/23454227>

Does snus pose a risk to others?

Snus poses no risk to others, such as work colleagues and family members as there is no combustion and consequently no 'second hand' smoke and no risk of fire.

Snus and stopping smoking

Snus is now the most popular product for smokers in Sweden and Norway when they wish to stop smoking and the success rate is higher when using snus than when using pharmaceutical Nicotine Replacement Therapy products.

<https://academic.oup.com/ntr/article/14/10/1221/1749452/Association-Between-Willingness-to-Use-Snus-to>

Has snus replaced smoking in Sweden and Norway?

Consumers in both Sweden and Norway are choosing to use snus rather than to smoke. There has been a major increase in the use of snus and a concomitant decline in the smoking of tobacco. In Sweden, snus overtook cigarettes in 1996; In Norway the rise of snus and the decline in smoking resulted in male use of snus overtaking cigarettes by 2006. This happened despite snus use in Sweden and Norway occurring in a context where active promotion of the product was banned and health authorities warned smokers against snus use.

What are the levels of smoking in Sweden?

The prevalence of current adult smoking in Sweden in 2014 was 11% and Sweden now has the lowest prevalence of smoking in the EU. In the same survey in 2014 the prevalence of adult current smoking in the UK was 22% ([European Commission. Attitudes of Europeans towards Tobacco and Electronic Cigarettes. European Commission; Brussels, Belgium: 2015. Special Eurobarometer 429](#)).

'Daily smoking' is even lower in Sweden at 8% compared with 19% in the UK in 2014.

Smoking is fast disappearing in some groups of Swedish men: in 2016 in the 30 to 44 years age group only 5% are daily smokers, less than a quarter of the level in the UK men. <https://www.folkhalsomyndigheten.se/documents/statistik-uppfoljning/enkater-undersokningar/nationella-folkhalsoenkaten/2016/Tobaksvanor-nationella-resultat-tidsserier-2016.xls>

How does the use of snus reduce smoking?

Snus is used to avoid the uptake of smoking, to stop smoking, and to reduce smoking.

The decline in Sweden and Norway has come about by smokers using snus to avoid smoking, and by the fact that younger nicotine users are choosing to use snus rather than to smoke, and that the uptake of snus does not lead to tobacco smoking. (<https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4245639/> and <https://www.ncbi.nlm.nih.gov/pubmed/27834883>)

Overall in Sweden and Norway the total level of tobacco use has remained stable or declined – what is most important is that there has been a major shift away from smoking.

Snus can therefore be considered protective against smoking.

Might other factors in Sweden account for the switch to snus?

No. Sweden has implemented fewer tobacco control measures than the UK. Laws on tobacco use and promotion are less strict than in the UK. They don't have a fully 'comprehensive' smoking ban. Smoking is allowed in designated purpose built smoking rooms in some workplaces and some public places like airport terminals. Smoking is also permitted in designated smoking areas outside in train stations and bus terminals. They don't have especially high tobacco taxes. There is a ban on tobacco advertising and promotion, but advertising and promotion is allowed at points of sale, as are tobacco product displays. There are total restrictions on tobacco sponsorships.

The clear difference between Sweden and the UK is due to snus. Overall the UK ranks number 1 in implementing tobacco control measures, whilst Sweden ranks joint 9th in 2016. <http://www.tobaccocontrolaws.org/legislation/country/sweden/summary>

Sweden consistently gets far better results with fewer controls on smoking.

What does the Royal College of Physicians, Tobacco Advisory Group say about snus?

'The availability and use of an oral tobacco product known as snus in Sweden, documented in more detail in our 2007 report...demonstrates proof of the concept that a substantial proportion of smokers will, given the availability of a socially acceptable and affordable consumer alternative offering a lower hazard to health, switch from smoked tobacco to the alternative product. Particularly among men, the availability of snus as a substitute for smoking has helped to reduce the prevalence of smoking in Sweden, which is now by far the lowest in Europe...Trends in snus use in Norway are similar to, and perhaps stronger than, those in Sweden, and there the use of snus is strongly associated with quitting smoking.' [Royal College of Physicians, Tobacco Advisory Group \(2016\). Nicotine without smoke: Tobacco harm reduction](#)

Legal status of snus

Snus is banned from sale in the EU (except in Sweden).

The UK Tobacco and Related Products Regulations 2016 and EU Tobacco Products Directive 2014 on which it is based states that 'no person may produce or supply tobacco for oral use'. Tobacco for oral use is defined as:

A tobacco product which is –

- (a) intended for oral use, unless it is intended to be inhaled or chewed; and
- (b) in powder or particulate form or any combination of these forms, whether presented in *a sachet portion or a porous sachet, or in any other way*'.

How did snus come to be banned?

In 1989 the UK Oral Snuff (Safety) Regulations were passed in response to the introduction of the moist snuff marketed as 'Skoal Bandits'. This ban was quashed on appeal by the manufacturer.

In the EU, Directive 92/41 banned sales of snus, to harmonise rules in that three member states had already banned tobacco for oral use.

In 1995, on accession to the EU, Sweden obtained an exemption from the ban.

In 2001 the Tobacco Products Directive continued the ban.

The ban was also continued in the 2014 Tobacco Products Directive.