A strong case to overturn the EU snus ban – 10 reasons why legal action should succeed this time

written by Clive Bates | 4 July 2016



Unscientific, unethical and unlawful EU snus ban

Good news confirmed today: Swedish Match, the main European snus manufacturer, will take legal action to overturn the European Union ban on snus - see Reuters 1 July 2016: Swedish Match to challenge EU snus ban in UK court. This ban is possibly the most absurd and harmful piece of legislation the European Union has ever concocted, and its demise is long overdue.

The EU snus ban was introduced in 1992 (directive 92/41/EEC) and reaffirmed in 2001 (2001/37/EC) and reaffirmed again in 2014 in the Tobacco Products Directive 2014/40/EU Article 17. The ban only exists because of posturing by self-indulgent and negligent politicians backed by prohibitionist harm-inducing NGOs. It has no scientific, ethical or legal justification whatsoever (see Death by regulation: the EU ban on low-risk oral tobacco) and can only be causing harm to health by denying smokers elsewhere in Europe benign alternatives to smoking that work so well in Sweden.

In 2003, Swedish Match challenged the identical ban in the previous Tobacco Products Directive 2001/37/EC (Article 8) and failed. See Case C-210/03 before the ECJ. However, a great deal has changed since then and even in 2003/4 I think they were unlucky to face a politicised court and improper scientific assessments of risk pushed by anti-scientific prohibitionists. But why should a legal challenge succeed now when a challenge failed in 2003-4? There are at least ten reasons to believe it will succeed this time.

1. The strength of the harm reduction concept

In C-210/03 Swedish Match did not rely heavily on harm reduction arguments – i.e. that the product has had a net health benefit where it is allowed onto the market. The evidence was thinner and contested at the time, but scientific and policy case for tobacco harm reduction is much more established now – see for example the Royal College of Physicians, 2007, *Harm reduction in nicotine addiction: Helping people who can't quit* and see the impressive data on Sweden: Ramström & Wikmans, 2014, *Mortality attributable to tobacco among men in Sweden and other European countries: an analysis of data in a WHO report*. A much more assertive case could be made today – not just that it is low-risk, but that snus, where permitted, has been positively beneficial for health. In its 2016 report, *Nicotine without smoke: tobacco harm reduction*, the Royal College of Physicians gives a clear endorsement of snus, and concludes the ban has caused harm in other snus-using countries:

> *The availability and use of an oral tobacco product known as snus in Sweden, documented in more detail in our 2007 report (and revisited in Chapter 7), 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. The magnitude of the contribution made by the availability of snus over and above conventional tobacco control measures is difficult to quantify, but a recent study of the effect of withdrawal of snus from the market in Finland in 1995, when both Finland and Sweden joined the EU, but only Sweden was allowed to continue its use, estimates that over the following 10 years the availability of snus reduced*

> *smoking prevalence in Sweden by an additional 3.7 percentage points. 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. [see original for references]*

2. Support from public health experts

There are now several public statements from experts supporting the lifting of the snus ban – including to the 15 scientists writing to Commissioner Dali in 2011 and another group to the UK Secretary of State in 2013 and a general statement in favour of 'harm reduction' including with smokeless tobacco from 53 experts in a letter to WHO Director-General Margaret Chan in May 2014. I have no doubt scientists with high integrity will now go on the record now to support lifting the ban and provide appropriate affidavits to the court if requested. There was minimal overt support for lifting the ban in 2003, and Swedish Match made the case without support from the scientific or public health community.

3. Official scientific report (SCENIHR)

The European Commission's Scientific Committee on Emerging and Newly Identified Health Risks (SCENIHR) accumulated evidence regarding the role of snus in 'harm reduction' in Sweden and Norway in the SCENIHR report on smokeless tobacco in 2007, which is discussed in detail here. Despite apparently strenuous drafting efforts to avoid drawing the obvious conclusion about lifting the ban in the report headlines, the *substance* of the report strongly supports lifting the ban.

4. WHO expert endorsement for regulation

Reports from WHO's TobReg expert committee argues that smokeless tobacco should be regulated, not banned, for example, WHO Study Group on Tobacco Regulation in its 2009 report "

> *"Smokeless tobacco products should be regulated by controlling the contents of the products"*

An elegant escape from the ban, and one that would improve products that are

not currently banned, would be to regulate the toxicity of *all* smokeless tobacco products placed on the market in the EU- without discriminating, absurdly, between those that are sucked and those that are chewed (see definitions of smokeless tobacco and 'oral tobacco' in 2014/40/EC Article 2(5) and 2(8) combined with the selective ban on oral tobacco in Article 17).

5. The Swedish Match interaction with the US Food and Drug Administration

The FDA has already scrutinised Swedish Match's public health case for snus in some detail. In November, the FDA granted a Pre-Market Tobacco Application (PMTA) for Swedish Match's products, to allow a new snus range to be placed on the market in the US. The PMTA does not authorise a reduced-risk claim, but it does mean the product has been evaluated by the FDA as 'appropriate for the protection of public health'. The FDA announcement of November 2015 states:

> *"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. […]*
>
> *"The PMTA decisions for these products reflect evidence showing that these products, marketed as described in the manufacturer's application, would result in a low likelihood of new initiation, delayed cessation or relapse. The FDA's review also determined that these products would likely provide less toxic options if current adult smokeless tobacco users used them"*

With this assessment, it is difficult to see how Europeans could make a case for a ban, especially when much of the evidence assessed by FDA comes from Europe.

This PMTA is part of Swedish Match's larger effort to make a Modified Risk Tobacco Product (MRTP) application to the FDA. Swedish Match has made a case for changing warnings and supplied 130,000 pages of documentation to justify its position – see this summary of the MRTP case (45-page extract – PDF) – and this application has attracted support from independent experts and consumers. At the time of writing, the MRTP application has not yet been decided by FDA, but if

approval is granted over the course of the case it will create a difficult comparison between US and Europe. In making its case to the FDA, Swedish Match has compiled a comprehensive and detailed case for the FDA – so it is likely to be better prepared than the UK government or European Commission to fight this case.

6. New provisions in the 2014 Tobacco Products Directive to deal with novel products

The inclusion in the new Tobacco Product Directive 2014/40/EU of an article detailing a process for notification of 'novel tobacco products' (Article 19) is a significant change in the revised directive and did not exist in 2001/37/EC. This is significant because the judgement in C-210/03 relied heavily on arguing that the non-discrimination principle did not apply because snus was a new product in the markets where it was to be banned (see paras 5, 7, 8, 37, 49, 51, 55, 65, 67 and finally the conclusion at para 71 of the judgement).

The position is now that either:

- snus is discriminated against because, absurdly, it is treated differently to smokeless tobacco products that are chewed rather than sucked.
- or snus is discriminated against because it is treated differently to other novel tobacco products.

There is no escape from this – the court's 'novel product' rationale from the 2003 case based is gone. Of course, snus isn't a novel product – it is widely known and well-understood and should be treated as any other smokeless tobacco product.

7. The obvious disproportionality of a ban compared to other smokeless tobacco and cigarettes

Some of the reasoning in case C-210/03 looks ridiculous now – and relies on several false premises. See, for example, the exaggeration of risk at para 65:

> *"it had been proved that smokeless tobacco products were a major risk factor as regards cancer"*

That is simply incorrect [see Lee PN, Epidemiological evidence relating snus to health–an updated review based on recent publications, Harm Reduct J. 2013; 10: 36. There is at worst a controversy about some kinds of cancer (e.g. pancreatic), but nothing remotely close to the cancer burden of smoking]

See also the unjustified rejection of the harm reduction concept at para 51:

> *"while part of the scientific community accepted that tobacco products for oral use could be used as substitute products for cigarettes, another part challenged the correctness of such a position"*

That other part of the scientific community is plain wrong, and they should be accepting responsibility for the death and disease their unscientific opinions have caused, for example in Finland, where the declining trend in smoking slowed following the snus ban. s

8. The weakness of the Commission justification for the ban

The Commission's case for banning snus is made in the Impact Assessment (pages: 50-52 and 61-76). It is easily and comprehensively dismantled in the following document: *Proposed revisions to the Tobacco Products Directive: a critique of the scientific reasoning supporting the proposed measures relating to oral tobacco* by Lars Ramström and me.

> *"We show that the scientific reasoning in the impact assessment has pervasive errors of fact and interpretation, selective use of evidence, important omissions, and poor conceptual framing. Legislation based on flawed scientific foundations will harm the health of Europeans, impede the development of the internal market and open the directive to legal challenge".*

We sent the Commission, Council and Parliament this document in time for it to be considered before the ban was finalised – see correspondence here – so they cannot plead ignorance. There was no response.

9. Formal consultation support for lifting the ban

The Commission consulted on plans for the new directive in 2010 and asked if the snus ban should remain; be lifted; or extended to all smokeless tobacco. Although the Commission claims support for the ban in its report on the consultation, the Public Consultation Statistics (page 5) show **83.15%** of those responding to the question favoured lifting the snus ban.

In your view, which option addresses the problem most effectively?				
	Number of requested records	% Requested records(85513)	% of total number records(85513)	% of total number records(70925)
No change	10285	12,03%	12,03%	14,50%
Lifting the ban on snus	58971	68,96%	68,96%	83,15%
Ban on all types of smokeless tobacco products	1669	1,95%	1,95%	2,35%
N/A	-	-	17,06%	-
Total	70925	82,94%	100,00%	100,00%

But interestingly, the *Governmental Representatives Response Statistics* also show a majority (see page 25). This table (extracted below) has obvious totalling errors, but it looks like 217 of 342 (not 252 as stated) that expressed a view or **63.5%** were in favour of lifting the ban on snus. Total governmental responses were 436.

In your view, which option addresses the problem most effectively?				
	Number of requested records	% Requested records(436)	% of total number records(436)	% of total number records(252)
No change	90	20,64%	0,11%	35,71%
Lifting the ban on snus	217	49,77%	0,25%	86,11%
Ban on all types of smokeless tobacco products	35	8,03%	0,04%	13,89%
N/A	-	-	99,60%	-
Total	252	78,44%	100,00%	100,00%

10. The alleged criminality of former Commissioner Dalli and/or his associates

It is clear that persons close to EU Health Commissioner Dalli were actively soliciting a bribe from Swedish Match to lift the ban on snus. It is disputed whether Dalli resigned or was fired as a result – for our purposes it hardly matters. The stench around Dalli means we cannot be sure an objective approach was taken in drawing up the Commission proposal in 2012. See the OLAF report of the investigation into Dalli leaked to Malta Today, coverage in the New York Times of Dalli's behaviour, and the excellent relentless investigative journalism of

Daphne Caruana Galizia.

UK government Department of Health reaction

No doubt the UK government will feel obliged to defend this case. But why? The case for lifting the ban is extremely strong.

It would be much easier (and more honest) for the UK *not* to contest the Swedish Match action and to lift the ban. It would then need to defend itself in court against infraction proceedings brought by the Commission, which would be straightforward, given the strength of the case to lift the ban.