Executive Summary

1. The underlying purpose of your inquiry is to help accelerate the end of smoking-related disease in the UK we would like to offer you information about the world’s greatest success story in smoking reduction - Sweden.

2. In doing that - and in responding to your Chair’s desire to hear “whether Government policy and regulation has kept up with the full range of ‘smoking’ and novel tobacco products” - we suggest that the Committee must not neglect the issue of oral, unheated, alternatives to smoking.

3. There is clear evidence that a surge in cancer in the UK is caused mainly by cigarette smoking. But also the widespread use of highly toxic chewed tobacco products being used by an estimated 500,000 South Asians in the UK is to blame. These products today lack any meaningful regulation.

4. Oral tobacco products have been ignored by policymakers, despite the overwhelming consensus of the world’s leading nicotine scientists about which products are dangerous and which are sufficiently safer to be authorised as alternatives to smoking. This has prevented smokers being offered a wider range of significantly safer alternatives.

5. Oral tobacco is a case of regulatory omission. For decades, this issue has been ignored. We hope that the Committee will examine this concerning oversight.

Analysis by Swedish Match

6. Swedish Match is the world’s biggest manufacturer of snus - a low-nitrosamine tobacco product placed under the lip. We would like to take the opportunity to share the Swedish experience in reducing smoking prevalence.

7. One in six Swedish men uses snus and it has been the dominant cause of the extraordinary reduction in Sweden’s smoking rate. Our nation had 50% of men smoking in the 1960s. EU figures show that adult daily smoking prevalence is down to 5 per cent (EU Barometer 2017, page 27). The chart shows that this is by far the lowest in the EU with the UK rate three times higher at 16 per cent. Tobacco control advocates say the ‘end-game’ for smoking will have been achieved when the smoking rate falls to 5 per cent.

Snus

8. The EU imposed a ban on snus in 1992. Sweden was exempted when it joined the EU in 1995. When four years ago the UK Department of Health was part of shaping the current EU Tobacco Products Directive a dozen global authorities urged it to end its prohibition on snus. To our knowledge, the underlying arguments in the letter was never addressed by the Department of Health, nor does its 2017 Tobacco Control Plan contain any reference to snus.

9. There is scientific consensus that snus is vastly safer than smoking, as exemplified below:

- *World Health Organisation*: snus is "considerably less hazardous" than smoking
- *EU Commission*: the health advantages over smoking are "undeniable"
US Food and Drug Administration: has authorised snus after exhaustive testing

“[Snus] 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,” Royal College of Physicians, 2016

10. The latest substantive research is in the Further Reading section of this submission.

11. What have been the implications of banning the world’s most successful substitute to smoking?

12. Up to 355,000 lives every year could be saved if snus was being consumed in the rest of the EU in the same way as in Sweden. (Rodu 2004, Snus Commission Report, 2017).

13. This tobacco mortality data indicates that the EU and the UK’s opposition to snus has led to a substantial and unnecessary increase in mortality. Sweden demonstrates what happens when a popular reduced risk substitute to smoking is freely available. Vaping is belatedly filling some of this gap in the UK.

Chewed Tobacco

14. Whereas snus is a missed opportunity, traditional chewed tobacco is a present danger to the UK’s South Asian population. Despite the magnitude of the problem and the deep concern expressed by the UK’s most senior academics, the government has not introduced product standards as it has with vaping. Nor has it bought in any of the tobacco control measures it has successfully used to tackle the harm from cigarettes.

15. Chewed tobacco is used by one in six of the UK’s 3 million South Asians. (British Dental Foundation, 2011.) Yet despite this widespread use it was not mentioned in the 2017 Tobacco Control Plan.

16. Scientists say that unregulated South Asian chewed tobacco is both highly addictive and “a major cause of oral cancer.” South Asian women suffer 3.7 times more oral cancer than the population average. (Tobacco Control, 2006, British Journal of Cancer, 2008). It is so dangerous that in December 2016 the Indian government announced a nationwide ban on chewed tobacco.

17. The seriousness of the problem in the UK was highlighted eleven years ago by two of Britain’s most respected academics, Professors Ann McNeill and Robert West. They urged DH to introduce standards to reduce the health impact, saying: “We are not suggesting that these products be banned. Instead, toxin standards should be set.” (Tobacco Control, 2006)

18. Yet in March of 2017 DH told Parliament: “The Government has not yet developed standards for these tobacco products, however, even with reduced levels of toxins they would not be completely safe.” (HL5576) This line of argument appears to contradict its approach to inhaled nicotine products: DH promotes e-cigarettes precisely because they have reduced levels of toxins. The logical conclusion would be to introduce strict standards on alternative reduced risk products (Heated and unheated tobacco and nicotine products) to ensure consumer safety and allow the smokers the choice of a wide range significantly safer products.
Conclusion

19. It is positive that the DH has accepted the role of vaping products as a harm reduction product: Its pragmatic approach to vaping products has turned the UK is the biggest market for vaping in the EU, with impressive numbers of people who have switched from combustible products to significantly less harmful alternatives, however, not one product fits all the consumers. On oral tobacco, however, DH has to date not publicly reviewed its current policy.

20. We would therefore propose that the government should start a consultation on oral tobacco and other products currently not covered by the EUTPD with a view to i) introducing product standards for all non-combusted products used orally and ii) announcing plans for how to establish a legal framework for placed tobacco products such as snus.

21. The fact that many people are unable or unwilling to quit using tobacco, has seen policy shift towards harm reduction. In Sweden, we can see how including substantially reduced risk and well-regulated oral tobacco and nicotine products in the mix can dramatically accelerate public health objectives.

December 2017

Further reading

What is snus

22. Snus is an oral tobacco product used in Scandinavia since the 19th Century. It is made from pasteurized, finely-ground tobacco leaves, along with approved food additives such as salt and flavourings. Snus is sold in small sachets or in loose form and is consumed by being placed between the gum and the lip. It is distinct from other oral tobacco products because of its ingredients and manufacturing methods, which are covered by the industry standard: Gothiatek. This was developed by Swedish Match and has been adopted by all Swedish snus manufacturers.

23. Since 1971 Sweden has regulated snus both as a food product and a tobacco product.

Snus and science - the example of Sweden

24. The relatively low risk associated with snus has been confirmed by a large number of researchers, NGOs, and government bodies, such as the Royal College of Physicians 2002\(^1\), 2007\(^2\), 2012\(^3\), the Swedish National Board of Health 2006\(^4\), SIRUS (Norway) in several reports\(^5\), New Zealand Health Technology Assessment 2007\(^6\) and in an Institute of Medicine report from 2011 and in an Institute of Medicine report from 2011\(^7\).

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\(^3\) Royal College of Physicians (2012). Fifty Years Since Smoking and Health: Progress. Lessons and Priorities for a Smoke-Free UK. London
\(^6\) Scheffels. Janne, Lund, Karl E., McNeill, Ann, Contrasting snus and NRT as methods to quit smoking. An observational study (2012), Harm Reduction Journal,
25. Over the past four decades there has been extensive scientific research in Sweden on the health effects of snus. This research was conducted by independent scientists at several Swedish universities; none was funded by the tobacco industry. It has been demonstrated convincingly that use of Swedish snus is not associated with cancer (including oral cancer), nor with cardiovascular disease (myocardial infarction, stroke). Because the use of snus does not involve inhalation of tobacco smoke, snus is also not associated with chronic lung disease, e.g. COPD including chronic bronchitis and emphysema.

26. These three groups of diseases (cancer, cardiovascular disease, chronic lung disease) account for c. 90 per cent of the excess mortality associated with cigarette smoking. This is at the heart of scientific discussion about the role of snus in harm reduction.

27. Earlier concerns about pancreatic cancer have been laid to rest by a new study from the Karolinska Institute. This has dispelled the last remaining notional link between snus and cancer.

28. The Karolinska study (International Journal of Cancer, May 2017) was the largest of its kind. It was a pooled analysis of nine studies comprising 400,000 men with 9 million life years, of whom 30 per cent had used snus. The authors found that snus is not a risk factor for pancreatic cancer.

29. Over the last three decades snus has replaced cigarettes as the tobacco product most commonly used by Swedish men. According to the most recent Eurobarometer study, Swedish tobacco consumption is at 25 per cent of the population, very close to the EU average of 26 per cent. Daily smoking prevalence in Sweden is now 5 per cent.

30. The Swedish smoking prevalence is very close to the aspirational tobacco end-game concept for smoking. This transition shows that tobacco harm reduction can be achieved at no cost to the taxpayer as result of voluntary choices rather than legal compulsion. Snus is a case study of how informed consumer choices can radically improve health outcomes.

31. This shift in tobacco habits has contributed to the fact that Swedish men have the lowest rate of tobacco-related mortality in Europe, including record low rates of both oral and pancreatic cancer.

32. In short, there is an overwhelming consensus within the scientific community that Swedish snus carries substantially less risk than cigarettes. In this regard snus also
stands out from other oral tobacco products: in Sweden and Norway snus is the most common smoking cessation aid\textsuperscript{16}. It has higher long-term quit rates than other cessation aids such as pharmaceutical nicotine replacement therapies.

33. The independently funded Environ report here has a full assessment of the science up to 2013.

**How snus is regulated**

34. All food stuffs of plant origin naturally contain small amounts of contaminants absorbed from the soil (such as heavy metals) or the environment (such as polycyclic hydrocarbons), or that are formed during storage (such as mycotoxins). Some of these contaminants are carcinogenic. The same holds true for the raw tobacco used in the manufacture of snus.

35. It is the concentration of these compounds which is important, not whether they can be detected. This is the basis for threshold values of contaminants in food. This approach was copied in the product standard for Swedish snus introduced in 2001. It sets maximum levels for nitrosamines, polycyclic hydrocarbons and heavy metals\textsuperscript{17}.

36. The permitted levels in Swedish snus are well below those recommended for oral tobacco by the WHO and the Swedish Food Authority. Detected levels in Swedish snus are well below those accepted in many common food stuffs.

37. Therefore, it is a fallacy to equate the health effects of Swedish snus with those of the unregulated oral tobacco commonly used by the UK’s South Asian communities.

38. With some products of African or Indian origin the levels of contaminants are several orders of magnitude higher than in Swedish snus. This is recognised by WHO Tobacco Regulatory Study Group: “Among the smokeless tobacco products on the market, products with low levels of nitrosamines, such as Swedish snus, are considerably less hazardous than cigarettes, while the risks associated with some products used in Africa and Asia approach those of smoking”\textsuperscript{18}.

39. A recent statement from the Swedish Food Authority concluded that their limits on contaminants in snus meant there is likely “no increased risk for the average consumer”\textsuperscript{19}.

40. Gothiatek is based on decades of research and is under continuous development. We seek continuously to reduce all toxic constituents and as the table below illustrates. Many unwanted constituents in snus is at lower levels that found in many common food products. Other important components of the standard are strict requirements concerning the quality of ingredients and manufacturing processes.


\textsuperscript{17} Rutqvist LE, Curvall M, Hassler T, Ringberger T, Wahlberg I: Swedish snus and the GothiaTek® standard. Harm reduction 2011, 8:11.

\textsuperscript{18} http://www.who.int/tobacco/global_interaction/tobreg/publications/9789241209519.pdf?ua=1

\textsuperscript{19} http://www.dn.se/ekonomi/nya-regler-for-cancerframkallande-amnen-i-snus/
<table>
<thead>
<tr>
<th>Unwanted substance</th>
<th>GOTHIATEK® Limits vs. average content&lt;sup&gt;20&lt;/sup&gt;</th>
<th>LIVSFS 2016:3</th>
<th>WHO TobReg</th>
<th>Constituents in food (100g) vs. snus (24g per can)&lt;sup&gt;21&lt;/sup&gt;</th>
</tr>
</thead>
<tbody>
<tr>
<td>NNN+NNK (ppm)</td>
<td>0.95/0.39</td>
<td>1.0</td>
<td>1.0</td>
<td>Tobacco specific (not found in food)</td>
</tr>
<tr>
<td>NDMA (ppb)</td>
<td>2.5/&lt;0.6</td>
<td></td>
<td></td>
<td>0.12 micrograms in 100g of fried bacon and in 17 cans of snus</td>
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<tr>
<td>Nitrite (ppm)</td>
<td>3.5/1.3</td>
<td></td>
<td></td>
<td>300 micrograms in 100g of broccoli and in 15 cans of snus</td>
</tr>
<tr>
<td>B(a)P (ppb)</td>
<td>1.25/&lt;0.6</td>
<td>1.5</td>
<td>2.5</td>
<td>0.19 micrograms in 100g of grilled meat and in 17 cans of snus</td>
</tr>
<tr>
<td>Arsenic (ppm)</td>
<td>0.25/&lt;0.06</td>
<td></td>
<td></td>
<td>9.4 micrograms in 100g of uncooked rice and in 7.5 cans of snus</td>
</tr>
<tr>
<td>Lead (ppm)</td>
<td>1.0/0.15</td>
<td>3</td>
<td></td>
<td>4 micrograms in 100g of salad and in 1 can of snus</td>
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<tr>
<td>Cadmium (ppm)</td>
<td>0.5/0.28</td>
<td></td>
<td></td>
<td>18 micrograms in 100g of shrimps and in 3 cans of snus</td>
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<tr>
<td>Chromium (ppm)</td>
<td>1.5/0.46</td>
<td></td>
<td></td>
<td>28.2 micrograms in 100g of fats/oils and in 3.5 cans of snus</td>
</tr>
<tr>
<td>Mercury (ppm)</td>
<td>0.02/&lt;0.02</td>
<td></td>
<td></td>
<td>13 micrograms in 100g of fish and in 54 cans of snus</td>
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<tr>
<td>Nickel (ppm)</td>
<td>2.25/0.87</td>
<td></td>
<td></td>
<td>30 micrograms in 100g of bread and in 2 cans of snus</td>
</tr>
<tr>
<td>Aflatoxin (ppb)</td>
<td>2.5/&lt;LOD (limit of detection)</td>
<td>5</td>
<td></td>
<td>Grows in colonies in nuts, dry fruit, hard to compare to snus. Snus have no measurable levels.</td>
</tr>
<tr>
<td>Ochratoxin A (ppb)</td>
<td>10/2.3</td>
<td></td>
<td></td>
<td>0.26 micrograms in 100g of raisins and in 5 cans of snus</td>
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<tr>
<td>Formaldehyde(ppm)</td>
<td>7.5/2.3</td>
<td></td>
<td></td>
<td>4900 micrograms in 100g of pear and in 47 cans of snus</td>
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<tr>
<td>Acetaldehyde (ppm)</td>
<td>25/6.5</td>
<td></td>
<td></td>
<td>1000 micrograms in 100g of banana and</td>
</tr>
</tbody>
</table>

<sup>20</sup> Average content in snus from Swedish Match (as is values) determined in the 2016 quality control program, published on https://www.swedishmatch.com/Snus-and-health/GOTHIATEK-GOTHIATEK-standard/

<sup>21</sup> Based on average content in snus from Swedish Match (as is values) as determined in the 2013 quality control program.
### Scientific assessment of snus by US Food and Drug Administration (FDA)

41. The FDA recently carried out a comprehensive assessment of snus before giving Swedish Match a Premarket Tobacco Approval (PMTA) in November 2015 and concluded snus were “appropriate for the protection of public health.” The FDA believed that the scientific evidence verified the low levels of harmful constituents, which leads to a substantial risk reduction compared with both other oral products and cigarettes.23

42. In its toxicological assessment, the FDA concluded:

- The proposed products have significantly lower levels of NNN and NNK compared with over 97% the smokeless products currently on US market
- Since NNN and NNK are among the most carcinogenic constituents of tobacco products, reduction of their levels in oral products could reduce the cancer risk for consumers
- If the users of the Swedish Match products had previously been using other oral tobacco products, they could decrease their excess cancer risk by 90% in comparison with moist snuff (US market share: 82%). There was 67% cancer risk reduction compared with the use of chewing tobacco (market share: 15%) and 38% reduction compared to the use of US-style snus, and 92% compared to use of dry snuff.

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