Expert Report

Report of Professor Martin Jarvis
for the High Court of Justice, Queen's Bench Division, Administrative Court

Case Name	In the matter of an Application for Judicial Review *The Queen on the application of Swedish Match AB -v- The Secretary of State for Health*
Claim number	
Dated	28 June 2016
Specialist field	Nicotine and Tobacco Dependence
On behalf of the	Claimant
On the instructions of	Hill Hofstetter Limited (solicitors)
Subject matter	Critical evaluation of the scientific evidence on which Directive 2014/40/EU is based

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Glossary

Abbreviation	Meaning
AMI	Acute myocardial infarction
BaP	Benzo(a)pyrene – a pentacyclic hydrocarbon
COPD	Chronic Obstructive Pulmonary Disease
DSM-IV	The 4th Edition of the Diagnostic and Statistical Manual of Mental Disorders published by the American Psychiatric Association
ESTOC	European Smokeless Tobacco Council
FDA	United States Food and Drug Administration
IA	Impact Assessment for the Tobacco Products Directive commissioned by the European Commission (December 2012)
ICD	International Classification of Diseases – a document that includes a scale by which the severity of substance dependence is measured
NNN, NNK	Types of tobacco-specific nitrosamines
PAH	Polycyclic hydrocarbons
PMTA	Pre-Market Authorisation of a novel tobacco product issued by the American Food and Drug Administration
SCENIHR	Scientific Committee on Emerging and Newly Identified Health Risks
SCENIHR 2008	Scientific Committee on Emerging and Newly Identified Health Risks Report published in 2008
SIRUS	Norwegian Institute for Alcohol and Drug Research
TPD 2014	Tobacco Products Directive (2014/40/EU)
TSNA	Tobacco-specific nitrosamines
WHO	World Health Organisation

A Introduction

Purpose of statement

1. I have been asked to provide this report in support of an application for judicial review of one aspect of the UK implementation of Tobacco Products Directive 2014/40/EU (the "TPD 2014").

2. This report critically analyses and evaluates the scientific evidence available to the EU Commission at the time of drafting the Directive.

The author

3. I am Professor Martin Jarvis. My current position, since 2004, is Emeritus Professor of Health Psychology in the Department of Epidemiology & Public Health, University College London.

4. I specialise in all aspects of nicotine and tobacco dependence. In particular, I have researched and published extensively on nicotine absorption and dependence from different forms of tobacco products, including both cigarettes and smokeless types; on smoking cessation methods; on the uptake of smoking in adolescents; on dose measurement in passive smoking; on tobacco harm reduction; and on the interaction of social, psychological and pharmacological factors in determining smoking patterns and prevalence.

5. Full details of my professional qualifications and publications are given in the appended curriculum vitae.

Summary of my instructions

6. Swedish Match has instructed me to give my expert opinion as to whether the scientific evidence available to the EU Commission in December 2012, at the time of proposal for the TPD 2014 justifies the continuation of the marketing ban on snus outside Sweden.

7. I was asked to consider this question in the current context, where there is no ban on smoked tobacco products (particularly cigarettes), other forms of smokeless tobacco products (including chewing tobacco and products typically used in South Asia such as paan) or electronic cigarettes.

8. I was asked to cover the following issues in my report:

    8.1. the available evidence on the harmfulness of snus as compared with other tobacco products such as cigarettes, other smokeless tobacco products and electronic cigarettes;

    8.2. the addictiveness of snus compared with other tobacco products;

    8.3. whether snus serves as a 'gateway' to other forms of tobacco consumption, particularly cigarettes, amongst younger people; and

    8.4. the available scientific evidence on snus as a cessation aid for smokers.

9. I was also requested to provide a critique, where appropriate, of the Commission's reasoning or approach to these matters.

10. Numbers in brackets refer to numbered publications which are listed in section E of this report.

Executive summary

11. Snus is a form of oral tobacco sold in Sweden and Norway and has pre-market authorisation in the US. Under the TPD 2014, snus is banned from being sold in any EU country outside Sweden.

12. In reaching its conclusion to ban snus, the EU Commission relied on two reports, the 2008 Scientific Committee on Emerging and Newly Identified Health Risks Report, which in turn formed the basis of the 2012 Impact Assessment for the Tobacco Products Directive. In summary, the EU Commission ignored parts of the reports and drew conclusions from those two reports that are misleading or simply incorrect. There was also information available at the time which was omitted from the reports.

13. Had the EU Commission applied the reports correctly and had the reports incorporated all available evidence, the EU Commission ought to have concluded that the ban on snus is not justified on the available scientific evidence.

14. In summary, the available scientific evidence shows that:

    14.1. Snus is less harmful to health than cigarettes and some other smokeless tobacco products which are currently regulated but not banned in the EU. This is demonstrated by reference to lower cigarette smoking rates (Figure 1) and lower smoking related diseases (Figures 2 & 3) (in particular cancer and cardiovascular disease) and smoking related deaths in Sweden (the "Swedish Experience") as well as several epidemiological studies on a range of tobacco-related diseases;

    14.2. Snus is no more addictive, and probably less addictive that cigarettes and some other smokeless tobacco products which are currently regulated but not banned in the EU;

    14.3. Snus has a proven track record of being an aid to smoking cessation; and

    14.4. Snus is not established as a "gateway" product to cigarette smoking, either in adolescents or adults.

15. For these reasons, the EU Commission wrongly concluded that snus should be banned. In my view, snus should be regulated and not banned.

B Snus and Smokeless Tobacco Products (STPs) – background information

Snus - product description and use

16. Swedish snus is a smokeless tobacco product that is traditionally used in Scandinavia. Its use dates back to the 19th century and possibly earlier. Swedish snus is distinct from other types of STPs because of the composition of the product, the manufacturing methods, and the specific standards for several unwanted substances implemented by all major manufacturers. In Sweden, snus is regulated as a food product since 1971 and the Swedish Food Authority has set maximum limits for several unwanted substances in snus, such as NNN and NNK. Swedish snus is the dominant form of smokeless tobacco in the Nordic countries although all major manufacturers are based in Sweden. In recent years some STPs have been launched in North America that are marketed as "snus" in addition to Swedish snus. However, the chemical properties of some of these products are distinct from traditional Swedish snus, and none of them are manufactured according to the same quality standards as those produced by the major Swedish manufacturers. Throughout this report, snus refers to the traditional Swedish snus product.

17. Swedish snus is a moist to semi-moist, smokeless tobacco product made from ground tobacco leaves and food-approved additives (table salt, sodium carbonate, humectants, and flavourings) (1). Because the tobacco is ground into a powder instead of being cut, the final product is intended to be placed in the mouth rather than chewed. Today the dominant snus brands come in portion packed small sachets made from a non-woven, food-grade fabric. Some snus users continue to use traditional loose snus that they form into a pinch before it is placed in the mouth.

18. Snus production involves a heat-treatment process which substantially decreases the microbial activity in the final product. This contributes to its chemical stability and shelf life. The manufacturing methods and ingredients have essentially remained the same over the past 200 years. However, production changes introduced over the past 3-4 decades by the major manufacturers have resulted in substantial decreases in the levels of unwanted substances in Swedish snus including potentially carcinogenic tobacco-specific nitrosamines (TSNAs) and polycyclic hydrocarbons (PAHs).

19. In Sweden, snus has been regulated since 1971 both as a food product (because it is consumed in the mouth) and as a tobacco product.

20. In Norway, snus has been regulated since 1973 as a tobacco product.

21. In the United States of America, snus received a Premarket Tobacco Product Approval (PMTA) from the Food & Drug Administration in 2015.

Snus - manufacturing and production standards

22. As set out above, snus is regulated in Sweden as a food product. Regulatory approval as a food product means that the hygienic requirements for snus production are the same as for food

stuffs. All ingredients and flavourings must be food-approved. In addition, in 2016 the Swedish Food Authority set maximum levels for certain unwanted substances in snus: two types of TSNAs (NNN and NNK), BaP, lead, and aflatoxins (3,4).

23. All food stuffs of plant origin may contain small amounts of contaminants absorbed from the soil (such as heavy metals) or the environment (such as PAHs), or formed during storage (such as mycotoxins). Some of these contaminants may be carcinogenic (2,3). The same holds true for the raw tobacco used in the manufacture of snus (5).

24. However, what is important is not whether such compounds can be detected or not, but at what concentrations they exist in the product. In food regulation, for example, accepted threshold values for potentially toxic constituents in food stuffs are measured by reference to concentration of such compounds, not their mere existence.

25. Analogous to food regulation, a voluntary product standard for Swedish snus, the Gothiatek standard (1), was introduced by the snus industry in 2001. In 2007, the Gothiatek standard was accepted as a standard for all STPs by the European Smokeless Tobacco Council (ESTOC), an organisation representing all the major manufacturers of snus.

26. The Gothiatek standard sets maximum permissible levels for several unwanted substances (1). The mandated maximum levels have been lowered on several occasions since the introduction of the standard (6). In 2010 the WHO Study Group on Tobacco Product Regulation proposed maximum levels for some nitrosamines (NNN, NNK) and one PAH (BaP, benzo(a)pyrene) in STPs (7). These levels are, however, higher than the maximum levels currently mandated by Gothiatek (**Table 1**).

27. The levels of such substances in Swedish snus are well below the levels for STPs proposed by the WHO Scientific Advisory Committee on Tobacco Product Regulation (7), as well as below the maximum levels for snus recently set by the Swedish Food Authority in its recent regulation which came into force on 11 April 2016 (2).

28. In terms of levels of unwanted substances Swedish snus stands out from other smokeless tobacco products (7) in that most other smokeless tobacco products, whether intended for chewing or nasal absorption, are made without the rigorous attention to quality standards that characterize snus manufacture.

29. The relatively low risk posed by Swedish snus is demonstrated by the American Food and Drug Administration's (FDA) recent approval of a premarket authorization (PMTA) for Swedish snus products manufactured according to the Gothiatek standard. The statutory requirement for a PMTA order is that marketing of the product is *"appropriate for the protection of public health…determined with respect to the risks and benefits to the population as a whole including users and non-users of the tobacco product…"* (8, 9)

30. In conjunction with the order, FDA officials have presented estimates of the reduction in carcinogenic risk associated with snus compared to some other STPs (10). For instance, the

reduction in risk compared to dry snuff (currently allowed by the TPD 2014) was estimated at 92% (see **Table 2**).

31. It is therefore inappropriate to equate health effects of Swedish, low-nitrosamine snus with those from other forms of smokeless tobacco with unregulated levels of potential toxicants. In some such products, e. g. of African or Asian origin, which are currently allowed by the TPD 2014, the levels of contaminants may be substantially higher than in Swedish snus (11, 12).

Other STPs

32. It is worth noting that many STPs currently allowed under the TPD 2014 contain much higher levels of unwanted substances (such as TSNAs) than snus (11, 12). These products are manufactured without any product standards and the TPD 2014 sets no maximum level for any unwanted substance in the STPs that are allowed.

Tobacco products - the "continuum of risk" concept

33. It is now well-accepted by the scientific community (13) that risks of health effects caused by use of different tobacco products vary greatly depending on the product. Use of combusted tobacco in the form of conventional cigarettes gives rise to the highest risk, and exclusive use of STPs in general a considerably lower risk (7). The fact that use of STPs does not entail exposure to tobacco smoke helps to explain this risk differential. The difference in risk associated with use of different tobacco products is often referred to as a "continuum of risk".

34. The relatively lower risks from smokeless tobacco products in general, and Swedish-style snus in particular, have been acknowledged by a host of researchers, NGOs, and government bodies including the Royal College of Physicians 2002, 2007, 2012 (14, 15, 16), the Swedish National Board of Health 2006 (17), SIRUS (Norway) in several reports (for instance 18-20), New Zealand Health Technology Assessment 2007 (21), and in an Institute of Medicine report from 2011 (22).

35. In addition, the Royal College of Physicians in London confirms that:

> *"[…] consumption of non-combustible tobacco is of the order of 10-1,000 times less hazardous than smoking, depending on the product".* (14)

36. The World Health Organization (WHO) Scientific Advisory Committee on Tobacco Product Regulation has confirmed that (7):

> *"Among the smokeless tobacco products on the market, products with low levels of nitrosamines such as Swedish snus, are considerably less hazardous than cigarettes…"*

37. In the same report by the WHO Scientific Advisory Committee on Tobacco Product Regulation it was also stated that:

"the differences in risk associated with use of different smokeless tobacco products mean that it would be scientifically inappropriate to consider smokeless tobacco as a single product for the purposes of estimating risk or setting policies." (7)

38. The main factors which help to explain the risk differential between cigarettes and STPs, and between different STPs are:

38.1. **Combustion:** The process of combustion generates a very large number of substances in tobacco smoke. Cigarette smoke contains several thousand compounds formed during the combustion of the tobacco, many of which are carcinogenic or otherwise highly toxic (5). They are typically not found in tobacco that is not combusted.

38.2. **Content of potentially hazardous substances**: The levels of potentially hazardous substances vary markedly between different STPs depending on the manufacturing methods. These substances include TSNAs (which can form naturally in the raw tobacco leaves under certain conditions), PAHs (resulting from fire-curing of the tobacco or air-pollution), heavy metals (taken up in plants, including in the tobacco plant, from the soil), and mycotoxins (formed by certain moulds on the raw tobacco in unfavourable conditions). Also, some types of STPs are made with betel leaves and areca nuts which contain specific alkaloids that add to the toxicity of the product (23).

39. In conclusion:

39.1. Most STPs, and in particular Swedish snus, are generally less harmful to health than cigarettes. In comparison to other STPs, Swedish snus is at the lower end of the risk scale in terms of adverse health effects.

39.2. While most STPs are essentially unregulated in their composition, Swedish snus is subject to stringent regulatory standards. Its actual manufacture goes beyond the stringent regulatory and voluntary standards to which it is subject.

C The 2012 Impact Assessment for the Tobacco Products Directive ("IA") and the 2008 Scientific Committee on Emerging and Newly Identified Health Risks Report ("SCENIHR 2008")

40. For the purposes of the TPD, the EU Commission produced an Impact Assessment in December 2012. The approach towards STPs in the IA is based on the scientific assessment provided by the 2008 SCENIHR. Paragraph 1.2.2 in the IA states:

"In terms of oral tobacco, it was concluded that the scientific opinion on the health effects of STP (SCENIHR 2008) should form the scientific basis for any future risk management decision of the Commission."

41. I will set out below my general comments on the IA and SCENIHR 2008, followed by my analysis of the specific points which I was instructed to cover (health risks, the gateway hypothesis and use of snus as a cessation aid). Where appropriate, I also comment on STPs other than snus.

General comments on the IA and SCENIHR 2008

Disconnect between SCENIHR 2008 Abstract/Executive Summary and Main Report

42. There is an unfortunate disconnect between the Abstract and Executive Summary of SCENIHR 2008 and the main body of the text. What is most striking is that the relevant conclusions in section 3.8 of SCENIHR 2008 are not highlighted or even mentioned in either the Abstract or the Executive Summary.

43. Section 3.8 of SCENIHR 2008 deals with the health effects of STPs, particularly in comparison with cigarette smoking, and the potential public health impact of the availability of moist snuff (snus) on the tobacco market.

44. SCENIHR 2008 notes that:

> *"Respiratory diseases, predominantly lung cancer, COPD and pneumonia, account for 46% of the deaths caused by cigarette smoking in the EU [...] . There is no consistent evidence that any STP causes any of these major respiratory diseases. Complete substitution of STP for tobacco smoking would thus ultimately prevent nearly all deaths from respiratory disease currently caused by smoking, which in total represent nearly half of all deaths caused by smoking.* (3.8.1)
>
> *It is reasonable to draw a conservative conclusion that substitution of smoking by snus use would, in due course, reduce the cardiovascular mortality that currently arises from tobacco use by at least 50%. (3.8.1)*
>
> *In northern Sweden, the availability of snus and the way in which it has been used may have been beneficial to public health since the harm to health caused by any use of snus as a gateway into smoking may have been more than outweighed numerically by the numbers quitting smoking for snus*. (3.8.2)
>
> *Gateway progression from snus to smoking has not been a significant problem in Swedish young people (3.8.2)*
>
> *In Sweden, where there has apparently been substantial transfer from smoking to snus, the availability of snus may have been beneficial to public health*. (3.8.2)"

Conclusion incorrectly presented in IA

45. The IA relied on SCENIHR 2008 for assessing the state of the scientific evidence on snus as at December 2012. However, it did not properly reflect SCENIHR 2008 in presenting its conclusions.

46. The IA mentions a number of potential negative health effects and possible detrimental impacts on overall tobacco control policies which could result from STP availability. In regard to oral tobacco (that is, snus) the IA concluded on page 70:

> *"Summarising the findings on oral tobacco, it is not possible at this stage to draw the conclusion that oral tobacco is an effective smoking cessation aid in the long-term. Any impacts therefore on smoking-related diseases remain uncertain [….] On the other hand, it is likely that new oral tobacco users would be recruited [….] who would otherwise not have used tobacco (entry gate) and current smokers who would otherwise have quit using tobacco altogether might switch to oral tobacco or use both products (dual use). This would lead to increased adverse health effects [….] In this light, it appears difficult to reconcile lifting the ban with the precautionary principle"*

47. This conclusion does not correctly reflect the statements from sections 3.8.1 and 3.8.2 of SCENIHR 2008 listed in paragraph 40 above. Indeed, in my view it contradicts the specific findings about gateway effects not being a significant problem, the fact that use of snus is associated with substantially fewer health risks than smoking, and that the availability of snus has been beneficial to public health in Sweden. It also fails to take into account emerging new data on the efficacy of snus for smoking cessation (clinical trials on snus as a smoking cessation aid) and inappropriately invokes the "uncertainty principle".

Incorrect conclusion in relation to replacement of cigarettes with snus

48. The IA is incorrect in stating that it is impossible to draw conclusions about the ability of snus to replace cigarettes among smokers and the subsequent effects on smoking-related morbidity and mortality. The findings from Sweden are compelling in this regard and the "Swedish Experience" is recognised within the scientific community by a range of authoritative institutions and researchers (14-18, 21, 22, 24-27).

49. The position in Sweden (often referred to as the "Swedish Experience") is as follows:

    49.1. The shift from smoking cigarettes to using snus in Sweden, was initially a grass-roots phenomenon prompted by the reports published in the mid 1960s about the adverse health effects of cigarettes. The shift occurred mainly in men, as snus use traditionally was regarded as a male preserve.

    49.2. Cigarette smoking prevalence among Swedish men is today the lowest in Europe (11%). Snus is used by 18% of the male Swedish population (29). The effect of the shift from smoking to using snus is reflected in the Swedish public health statistics which show that Swedish men have the lowest mortality from lung cancer and lowest overall tobacco-related mortality in all of Europe (25, 30) (Figures 2 &3). These are statistically significant

figures and are accepted by reputable opinion as being causally connected (for example, by the Royal College of Physicians, 27).

49.3. Swedish tobacco control policies have probably also contributed to record low rates of smoking. However, it should be noted that Sweden does not score particularly highly on its "tobacco control score" (31). This is a measure that summarises a country's tobacco control activities. When the tobacco control score is plotted against smoking prevalence in different countries, Sweden is an outlier whose record low smoking rate does not seem to be explained by tobacco control activities alone (Figure 4).

50. The Swedish Experience underpins current discussions (13, 27) about the potential for tobacco harm reduction within tobacco control (that is, the benefit that would arise if current cigarette smokers who are unable or unwilling to give up their tobacco habit were encouraged to switch to less risky nicotine-delivery products such as electronic cigarettes or snus)

51. Confirming the Swedish position, the Royal College of Physicians in London stated in 2008 (27):

> *"In Sweden, the availability and use of by men of an oral tobacco product called snus, one of the less hazardous smokeless tobacco products, is widely recognized to have contributed to the low prevalence of smoking in Swedish men and consequent low rates of lung cancer"*
>
> *"…the Swedish data provide proof of concept that substitution of smokeless for smoked tobacco can be effective as a harm reduction strategy"*

52. The Royal College of Physicians' report also noted that:

> *"People smoke because they are addicted to nicotine, but nicotine itself is not especially hazardous; it is the other constituents of tobacco smoke that cause most of the harm"*
>
> *"…harm reduction is therefore feasible in tobacco smoking by providing smokers with nicotine from a source that does not involve inhaling tobacco smoke"*
>
> *"Use of smokefree nicotine by smokers would also reduce involuntary exposure of others, particularly children, to tobacco smoke"*
>
> *"Use of smokefree nicotine would help to denormalize smoking, decrease exposure of children and young people to smoking role models and hence reduce uptake of smoking"*

53. Further, rather than taking the Swedish Experience into account, the IA relies on the Norwegian example to draw conclusions about the availability of snus and its impact on smoking prevalence.

54. SCENIHR 2008 concluded that overall smoking prevalence in Norway had decreased at comparable rates in men and women in recent years whereas a marked increase in oral tobacco (snus) use during the same time period had mostly occurred among men. In the IA, this observation is used as an indication that the availability of snus may not have impacted

smoking prevalence significantly but that other factors, such as the introduction of various tobacco control policies explain the decreased smoking.

55. The IA does not reflect that a population decrease in smoking prevalence is a complex phenomenon, attributable to the conjoint effects of a range of factors including excise tax changes, other tobacco control policies (age limits, smoking bans, information campaigns etc), societal attitudes toward smoking, smokers' access to cessation interventions (telephone quit lines, pharmaceutical cessation aids etc). In Sweden and Norway, the availability of widely accepted STPs (in particular snus) as an alternative to cigarettes is an additional factor. It is impossible to quantify with any degree of reliability the impact each factor has on the decrease in smoking prevalence, particularly in population subsets based on gender, ethnicity or age.

56. However, the population-based surveys from Sweden and Norway showing snus to be the most frequently reported cessation aid among smokers clearly indicate that the availability of snus has been an important factor. That is particularly the case in Sweden where tobacco control policies alone do not seem to explain the record low smoking prevalence (Figure 4).

57. Smoking prevalence among men in Norway has decreased, while at the same time snus use has increased. The prevalence of using snus among women is lower than among men. The Norwegian and Swedish figures, taken together with the surveys regarding snus as a cessation aid, show without ambiguity that the availability of snus is an important factor,.

58. The hypotheses that lifting the ban on oral tobacco would lead to recruitment of consumers who would otherwise not have used tobacco, or would undermine current smoking cessation policies, are completely conjectural, without any supporting evidence, and contradicted by credible evidence from Sweden and Norway.

59. In summary, the evidence set out in SCENIHR 2008 on availability of snus and its impact on cigarette smoking does not support the conclusions expressed in the IA.

Inconsistent conclusions on snus and STPs

60. The IA is inconsistent in that it uses the same public health arguments to support a ban on oral tobacco as for regulating other types of STPs and electronic cigarettes. The IA discriminates against snus as it invokes the "uncertainty principle" for a ban on snus, while at the same time allowing electronic cigarettes and "novel products" despite the considerable uncertainties about the public health effects of those other products.

61. These issues are set out in section 5.2.1 of the IA.

62. The IA states that it is unclear if electronic cigarettes are effective as a smoking cessation aid (page 28). With electronic cigarettes there cannot, by definition, be any long-term studies because the products have not been on the market long enough. The (limited) long-term health effects are considerably more well-documented for snus than for other types of STPs.

63. The "uncertainty principle" or "precautionary principle" should apply in cases of scientific uncertainty to protect the public against risks that may exist but that cannot as yet be quantified. It is not appropriate where there is extensive scientific analysis available to enable an informed analysis to be made, as is the case for snus given the long experience of its use in Sweden and Norway. Yet it is proposed that snus is banned, but these other products, where there is much greater uncertainty, are regulated.

Misleading statements in the IA on cancer

64. SCENIHR 2008 cited increased risks for various forms of cancer (e.g. head & neck cancer, oesophageal cancer, cancer in paranasal sinuses, laryngeal cancer, stomach cancer, pancreatic cancer, lung cancer) reported for a wide range of STPs (including products of Asian and North-African origin).

65. When these reports are mentioned in the IA, there is no mention of the fact that subsequent meta-analyses of studies (32, 33) which pooled the findings from studies specifically examining use of Swedish snus provided no clear evidence of increased risks for any type of cancer.

Misleading statements on reducing carcinogen levels

66. The IA misleadingly states that (p 65):

> *"Products with lower levels of carcinogenic tobacco-specific nitrosamines (TSNA) have also been on the market for too short time for any convincing support in favour of the presence or absence of a lower cancer risk. The WHO Study Group on Tobacco Product Regulation concludes in its report from 2009 that existing evidence has not established that lowering TSNA or PAH in smokeless tobacco will lower cancer risks"*

67. This statement ignores the fact that:

67.1. snus has been on the market in Sweden since the 1800s;

67.2. there is an extensive epidemiological evidence base regarding the risk (or rather the absence of risk) of the principal "tobacco-related" cancers with long-term use of snus (SCENIHR 2008 section 3.8.1); and

67.3. snus is accepted as being much less risky than cigarettes and many other STPs.

68. The lower risk associated with snus is demonstrated, for example, by recent the PMTA order by the FDA (34) which, based on the relatively low level of nitrosamines in snus, cites substantial cancer risk reductions with snus compared to most of the STPs on the U.S. market today, including dry, nasal snuff which is available on the European market (**Table 2**).

69. Whilst the WHO Study Group (7) has acknowledged that the use of STPs in general is less risky than smoking cigarettes, the WHO Study Group noted that it is difficult to establish the extent to which a further lowering of unwanted substances in STPs, including snus, will contribute to reduced cancer risks from present levels. However, despite such difficulties, the WHO Study Group proposed maximum levels of nitrosamines and BaP in STPs (levels that actually are the

same or higher than those currently mandated by the Swedish Food Authority for snus products) (Table 1). This establishes that, despite the uncertainty about the impact on cancer risks, the WHO Study Group judged it worthwhile to recommend lowering permissible toxicant levels. Swedish snus already satisfies these recommended lower limits (as well as the even lower levels mandated by the Gothiatek standard).

Failure of the IA to live up to its stated aim of maximising population health gains

70. The IA drew attention to the 700,000 deaths annually attributable to cigarette smoking in the EU and rightly emphasised the overriding importance of enhancing public health in approaching choices between different policy options:

> *"A high level of **health protection** has been taken as a basis for this impact assessment when choosing between different policy options [...] the revision will contribute to the overall aim of the EU to promote the well-being of its people [...] and the Europe 2020 strategy as keeping people healthy and active longer, and helping people to prevent avoidable diseases and premature death."*

71. However, the IA's detailed consideration of issues related to the availability of snus failed to live up to the promise of properly weighing the overall impact of snus on public health. It focused on postulated and hypothetical adverse effects, such as snus acting as a gateway to smoking among young people, for which real-world evidence is entirely lacking (see below at paragraph 100 and following). By contrast, the IA failed to recognise the clear evidence of the net public health benefits experienced in Sweden from snus availability, including, for example, the lowest rates of smoking prevalence and smoking-attributable mortality in Europe. No account is taken of the fact that there is good reason to expect that, were snus made available more widely in the EU, it could similarly lead to a significant net public health benefit elsewhere in Europe.

Specific issues

Snus - Health Risks

72. SCENIHR 2008 acknowledges that STPs in general, and snus in particular, are less risky than cigarettes for individual consumers (35). It states that:

> *"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."*

73. In contrast with the well-documented adverse impacts of long-term smoking on individual health prospects, the body of science (including comprehensive reviews of the epidemiological evidence) that was available to the Commission in 2012 showed no evidence of a causal effect of long term use on any of the principal diseases or conditions that contribute to the excess mortality associated with smoking.

74. Such conditions include cancer (notably lung and oral cancer) and cardiovascular disease (myocardial infarction, stroke). As use of snus does not entail inhalation of tobacco smoke there is no association between snus and chronic obstructive pulmonary disease (COPD). Cancer (most notably lung cancer), cardiovascular disease and COPD together account for about 90% of the tobacco-attributable mortality observed among cigarette smokers (36,37).

Other STPs – Health Risks

75. As set out at paragraph 33 above, the "continuum of risk" concept means that some other types of STPs that are currently allowed by the TPD 2014 present lower health risks compared to cigarettes. However, the extent of the risk reduction with these other products is less certain because there is considerable variation between the products in terms of their content of potentially hazardous substances (11, 12, 23) as well as much less epidemiological evidence. Swedish snus, which is manufactured to consistent and stringent regulatory standards, is the best documented STP in terms of both chemical properties and health effects.

76. It is not possible to arrive at definitive estimates of usage patterns and long-term health risks from electronic cigarettes because such products have not been on the market for long enough. Although today there is evidence emerging, as at December 2012 there was much less evidence for electronic cigarettes than for snus on issues related to smoking cessation, addiction potential, dual use and uptake among adolescents. Yet the TPD 2014 prescribed that electronic cigarettes should be regulated, but that snus – citing the "uncertainty principle" - should be banned.

Snus - cancer and pancreatic cancer

77. SCENIHR 2008 concluded that:

> *"STPs are carcinogenic to humans and the pancreas has been identified as a main target organ*."

78. This conclusion, that smokeless tobacco products are carcinogenic to humans, does not draw any distinction between snus and other smokeless tobacco products. It is inadequate as a summary statement of overall cancer risk and snus use. It does not mention the observed absence of risk from snus for almost all cancers, in particular lung cancer. However, the reference to pancreas as a main target organ was based largely on two studies of snus users. The methodological flaws in some previous meta-analyses of the risk of pancreatic cancer in relation to snus use are set out in a published study (71).

79. Pancreatic cancer involves a small numbers of deaths. As a starting point, Sweden has a low rate of pancreatic cancer relative to other European countries. Furthermore, deaths from pancreatic cancer in Sweden have declined over the past few decades as snus use has increased and cigarette smoking declined (52). Thus even if the weak and inconsistent association between snus use and pancreatic cancer is accepted as real, it does not critically challenge the broader truth that cancer risks from snus are greatly reduced by comparison with cigarette smoking.

Snus - oral cancer

80. An increased risk of oral cancer associated with use of oral tobacco was cited as an important reason for the introduction of the ban of these products in 1992. On this issue, the SCENIHR 2008 Executive Summary states:

> *"…a high risk for development of oral cancer has been shown for various STPs* (smokeless tobacco products) *but has not been proven for Swedish moist snuff (snus)."*

81. A total of seven epidemiological studies addressing the issue of snus and oral cancer were published between 1991 and 2008 (38-44). The overall results showed no increased risk associated with use of snus (32). Four of these studies also presented analyses restricted to individuals who had never smoked to avoid potential confounding from previous smoking history. No increased risk was observed among snus users who had never smoked (32). No additional study has been published since. This means that snus is the only STP for which there is a substantial scientific evidence base which supports a lack of association with oral cancer.

Cardiovascular disease and stroke

82. The balance of scientific evidence does not suggest that snus use increases the risk of cardiovascular disease. It does not appear to cause stroke or acute myocardial infarction (AMI) (32). However, there is some evidence that in those who do suffer AMI, snus use may be associated with fatal outcomes (45).

83. Whether the increased risk of fatal cases reflects a direct effect of snus or an effect of confounding is unclear. The IA at section 5.2.1 noted:

> *Hansson concluded in a study from February 2012 that current snus users had a higher probability of dying from acute myocardial infarction (AMI) as compared to non-users, and that this increase may be explained in confounding factors, although a small increased risk of sudden death from AMI among snus users cannot be ruled out*

84. A thorough meta-analysis which reviewed and combined the available evidence concluded that any true increase in risk of myocardial infarction resulting from snus use, if it exists, is very much less than that from smoking (33).

Snus - other adverse health effects

85. Snus – like a raft of other consumer products - is not completely safe. Some negative health effects have been established, including adverse pregnancy outcomes (46-48), localized gingival recession (49), and dependence. However, the public health impact of these adverse effects pales into insignificance in comparison with the public health impact of cigarette smoking; and there is no evidence that these effects are worse with Swedish snus than with other types of STPs currently allowed within the EU.

86. As to the adverse pregnancy outcomes that have been observed among some women who continued to use snus during their pregnancy, such effects are likely to be similar with any

source of exposure to nicotine, for instance, from smoking, other STPs, "novel" tobacco products, pharmaceutical nicotine products, or electronic cigarettes.

87. The issue of dependence is dealt with at paragraphs 91 to 99 below.

Other STPs and electronic cigarettes - other adverse health effects

88. The long-term health effects of other STPs are less well characterized. By definition, no such studies are available for "novel" tobacco products.

89. Long-term studies of the impact on health of electronic cigarettes are unavailable because the products have not been on the market long enough. There is consensus within the scientific community that exclusive use of electronic cigarettes is much less hazardous to health than conventional cigarettes because the vapour produced by electronic cigarettes does not include most of the highly toxic compounds formed during combustion of tobacco (see for example, SCENIHR 2008).

90. However, it is not possible to arrive at definitive estimates of the long term health risks from use of electronic cigarettes because such products have not been on the market for long enough. Tobacco-associated diseases typically develop after several years or decades of smoking. It is scientifically arguable that, if there are adverse effects from electronic cigarette vapour, such effects may take a considerable time to emerge, especially since the great majority of electronic cigarette users are people who carry excess disease risks from their previous history of cigarette smoking.

Addictiveness

91. SCENIHR 2008 concluded that:

> *"Smokeless tobacco delivers quantities of nicotine comparable to those typically absorbed from cigarette smoking, although delivery of nicotine from STPs lacks the high initial concentration and speed of delivery that results from inhalation of tobacco smoke, and may therefore have relatively less addiction potential than cigarettes."* (Executive Summary)

92. Addiction to tobacco is a complex condition that involves psychological, behavioural, social and neuro-pharmacological components. Nicotine is the constituent in tobacco which is believed to contribute the most to the development of addiction. This means that all forms of tobacco, whether smokeless or combusted, have the potential to be addictive. As noted in SCENIHR 2008, the speed at which nicotine is delivered to the brain is probably a major determinant of the addiction potential of a nicotine-delivery product (35).

93. The speed of nicotine delivery to the brain varies depending on the type of tobacco used:

    93.1. With inhaled cigarette smoking there is a rapid uptake of nicotine from the lungs and nicotine at high concentrations reaches the brain within seconds.

93.2. With smokeless tobacco used orally the nicotine uptake to the blood is much slower and the delivery of nicotine lacks the puff-by-puff transient peaks seen with cigarette smoking.

93.3. Dry, nasal snuff delivers nicotine to the blood more rapidly compared to smokeless tobacco used orally although it does not produce the transient high levels in the blood to the brain typically seen during cigarette smoking (72).

93.4. Nicotine uptake from use of electronic cigarettes is much less well documented in the literature. It appears to vary, depending both on the user and the device used to produce the vapour, with more recent tank systems being more effective than early "cigalike" types.

94. The uptake and distribution in the body of nicotine from Swedish snus have been well documented through a series of clinical studies including three controlled clinical trials. Two of these trials have been published in international, peer-reviewed scientific journals (50, 51). The third is not yet published but results are described in detail in a recent application to the FDA and are available on the FDA website (52).

95. In those trials, subjects were randomly allocated to Swedish snus or different types of pharmaceutical nicotine products such as nicotine gum. It was observed that a typical, 1.0 gram pouch of snus delivered about the same amount of nicotine to the user as a 4 mg nicotine gum. However, the speed of the delivery to the blood was slightly higher with the snus pouch.

96. Product-specific instruments/questionnaires have been developed and validated which can be used to quantify an individual's level of addiction, for instance the Fagerström Test for Cigarette Dependence (53). However, overall diagnostic criteria for addiction (such as given by the International Classification of Diseases (ICD9) or the Diagnostic and Statistical Manual of the American Psychiatric Association (DSM-IV)) may not allow valid, quantitative comparisons between users of different tobacco products.

97. To circumvent this problem, a systematic literature review was done of controlled clinical trials of tobacco cessation where subjects had been randomly allocated to some form of intervention or to a control group with no intervention (73). The percentage success rate in giving up smoking among the no intervention controls who were snus users as compared with those who were cigarette smokers was then interpreted as reflecting differences in dependence between users of these different products.

98. The results of those trials confirmed the conclusions in SCENIHR 2008 (35): the "spontaneous" cessation rate in trials involving users of STPs was roughly two to three times higher (range: 19.1-33.0%) than that observed in trials including cigarette smokers (range: 9.8-11.2%). These observations are in line with the SCENIHR 2008 findings in showing that cigarettes are by far the most dependence-producing tobacco product and that STPs as a category is less strongly associated with dependence.

99. In summary, although it is clear that all types of STPs (including snus) can be addictive, there is persuasive evidence that STPs are less addictive than cigarette smoking. There may be some variation in the level of addictiveness between different STPs, but there is no evidence that addiction to snus is higher than with any other STPs produce. In fact, among the mentioned STP cessation trials, the "spontaneous" cessation rate was the highest in the trial that involved snus.

The gateway hypothesis

100. The "gateway hypothesis" is that use of an initial substance causally leads on to the use of another (usually regarded as more damaging or serious) substance. Uptake of tobacco is a phenomenon that typically occurs during adolescence. It is frequently associated with factors such as risk-seeking behaviour, poor school performance, truancy, use of alcohol and illicit drugs, social deprivation and tobacco use by parents (55).

101. More recent conceptualisations of the process of uptake of drug use prefer a 'common liability' model (56), where the child's personal, family and socio-economic circumstances put the child at generally increased risk of drug uptake, and where the sequence of drugs used reflects opportunity or chance factors and has no causal significance.

102. In some scientific literature and in the IA it is hypothesized that snus may act as a "gateway" to future cigarette smoking among some adolescents (57). However, the IA cites no scientific references that would support a finding that snus acts in this way. In contrast, SCENIHR 2008 (35) summarises the available evidence on snus as showing:

> *"The Swedish data, with its prospective and long-term follow-up do not support the hypothesis that smokeless tobacco (i.e. Swedish snus) is a gateway to future smoking"*

103. The SCENHIR report notes that there is "some evidence" from the U.S. (based on STPs other than snus) that STPs may have this effect, but that marked social and cultural differences suggest caution in translating findings from one geography to another.

104. The 'gateway' hypothesis is notoriously difficult to test. For this hypothesis to possess any validity there would need to be evidence that the availability of snus has led to increased smoking and overall higher tobacco consumption than if it had not been available. However, as noted in SCENIHR 2008 (35), there is no credible evidence to this effect.

105. In fact, the available evidence points in the opposite direction. In Sweden, where snus has replaced cigarettes as the most commonly used tobacco product, smoking rates among adolescents as well as adults are at internationally record lows, particularly among males (58, 74). Overall tobacco consumption (cigarettes taken together with other tobacco products) is not higher in Sweden than in comparable European countries (59).

106. As in other respects, it appears to me that the IA fails to reflect the underlying evidence as it is in important respects inconsistent with that evidence.

Smoking cessation - Snus

107. Snus has never been marketed as a smoking cessation aid. However, in Sweden smokers started to switch from cigarettes to snus in the late 1960s and early 1970s (1). Snus has now replaced cigarettes as the most commonly used tobacco product and smoking prevalence rates have declined to internationally record lows, particularly among men (58).

108. In recent decades, Norwegian smokers have also started to switch to snus from cigarettes. The switch has mainly been concentrated in younger smokers. In Norway as in Sweden, population surveys show that snus is the most frequently reported smoking cessation aid (18-20, 24, 28, 54, 60). The trends in Norway have been well-documented through a series of scientific publications from the Norwegian Institute for Alcohol and Drug Research (SIRUS) (18-20, 54), which is an institution funded by the Norwegian state and which operates under the auspices of the Department of Health.

109. Epidemiological studies from both Sweden and Norway have found that snus is the most frequently reported aid used in switching away from cigarettes. Use of snus for smoking cessation is also reported to be associated with higher long term cessation than use of pharmaceutical nicotine (24, 60, 68). SCENIHR 2008 concluded:

> *"Observational data from Sweden indicates that snus has been used more often than pharmaceutical nicotine products by some men as an aid to stop smoking"* (35).

110. SCENIHR 2008 noted that there were no published randomised clinical trials of use of STPs in smoking cessation. In the absence of such evidence it was considered impossible to draw reliable conclusions about the effectiveness of STPs as an aid to smoking cessation. That lack of trial evidence was hardly surprising, as snus was marketed as a consumer nicotine product, not a cessation aid.

111. However, since SCENIHR 2008 was published, results from two randomised trials of snus as an aid to smoking cessation have been published (61, 62, 67). This is noted in the IA. These trials were designed as placebo-controlled, double-blind studies where the subjects were randomly allocated to receive either snus or an identical placebo product without tobacco or nicotine.

112. Smoking status was rigorously evaluated using internationally accepted criteria and was biochemically verified. This type of study design is generally regarded as the "gold standard" for clinical trials.

113. Follow-up was 24-48 weeks after study entry which is a typical duration for clinical smoking cessation trials. The internationally recognized Cochrane Collaboration (which pools data from all available studies meeting required methodological standards in order to reach views on efficacy) uses 6 month follow up data as its standard for evaluating smoking cessation treatments (63).

114. In summary, the trials demonstrated that smokers allocated to snus were two to three times more likely to quit smoking compared to smokers who were allocated to the placebo product (67). There is therefore both experimental evidence from randomised clinical trials and

compelling evidence from observational studies that snus can function as a replacement for cigarettes among smokers.

Smoking cessation - other STPs and electronic cigarettes

115. The evidence for the effectiveness of electronic cigarettes for smoking cessation was, in 2012, more preliminary than that for snus. At that time, electronic cigarettes had only been on the market for 3 or 4 years. While their ability to substitute for cigarettes in some smokers was already apparent, few formal trials of electronic cigarettes as aids to cessation had been published. For other types of STPs there was little if any available evidence.

Dual use - snus and cigarettes

116. Daily combined use of both cigarettes and snus (dual use) is uncommon in Sweden but is more prevalent in Norway (24, 64). In some cases, dual use represents a transitional state as smokers motivated to give up smoking move initially to dual use, and then to non-smoking, exclusive snus use. In other cases, dual use might be a stable phenomenon among smokers who are not motivated to quit smoking but who use snus as an alternative source of nicotine, for instance, in situations where it is not possible for them to smoke.

117. Dual use is more common among adolescents, possibly because many in the process of starting tobacco use try both products if available to them, before eventually settling on one.

118. The phenomenon of dual use of cigarettes and STPs including snus raises the question of potential health consequences.

119. In summary, available epidemiological studies have not identified any adverse health effect that is specific to or more pronounced among dual users (65, 66). Most of the health effects appear to be related to the dual user's smoking habits. As dual users tend to smoke fewer cigarettes, the adverse effects appear to be, if anything, less pronounced compared to those among exclusive cigarette smokers.

Dual Use – other STPs and cigarettes

120. Dual use of cigarettes and electronic cigarettes or "novel" tobacco products is currently not as well researched and documented as dual use of cigarettes and STPs.

Snus availability and current smokers' willingness to quit

121. In the IA it is hypothesized that availability of snus might undermine current tobacco control policies by making current smokers less motivated to quit (57). However, there is no scientific evidence for such a proposition. In fact, available studies show results to the contrary.

122. Several studies have followed smokers and have estimated the probability of having quit smoking by the end of follow up in relation to use of snus at baseline. Typically these studies demonstrate that the probability of quitting is higher for dual users at baseline than for those who only smoked (66). These findings are supported by the results of the two mentioned

randomised clinical trials of snus as a smoking cessation aid, which both showed that providing snus to smokers resulted in two- to three-fold increase in the long-term quit rate (61, 62, 67).

123. In summary, the concerns raised in the IA about the availability of snus undermining current tobacco control policies are hypothetical. They lack empirical support and the available scientific evidence indicates that availability of snus may actually contribute to increased rates of quitting among smokers rather than the opposite.

Other STP availability and current smokers' willingness to quit

124. The Impact Assessment does not raise this theoretical possibility for other STPs, electronic cigarettes or "novel" tobacco products.

D Summary and conclusions

125. Given the positive public health outcomes flowing from the availability of snus in Sweden and Norway, and given that the European market currently is dominated by combustible cigarettes, it is not sound public health policy to maintain a snus ban in the rest of Europe.

126. Cigarette smoking continues to be an enormous public health problem. Allowing alternative, less harmful products to compete with cigarettes may have significant public health benefits. Snus in particular has a proven track record in that regard as illustrated by the experiences from Sweden and Norway.

127. Snus is the STP for which there is the most extensive, product-specific, scientific documentation about long-term public health effects. The comparatively low levels of potentially toxic substances in snus, reflecting the fact that it is manufactured subject to consistent and stringent standards, probably help to explain why certain health outcomes that are associated with some other types of STPs have not been documented with snus, such as oral cancer.

128. Snus is not completely free of health effects. It is inter alia associated with some adverse pregnancy outcomes. But these are not specific to or particularly pronounced with snus compared to cigarettes or other nicotine-delivery products. Banning snus while allowing other STPs with unregulated (and typically much higher) levels of potential toxicants cannot be justified on scientific or public health grounds.

129. Snus is the most frequently used smoking cessation aid in both Sweden and Norway and appears to be more effective than pharmaceutical nicotine replacement therapy. The efficacy of snus as a smoking cessation aid has also been established in two rigorously designed, independent controlled clinical trials. The IA criticizes the trials for not being more long-term. However, the duration of follow-up (24-48 weeks) is fully comparable to most other clinical smoking cessation trials and complies with the Cochrane Collaboration standard. The trial results are complemented and supported by the more long term data provided by the epidemiological, population-based studies from Norway and Sweden.

130. Arguments about possible unintended consequences of a lifting of the snus ban, such as, increased youth initiation of tobacco and decreased/delayed smoking cessation are largely based on theoretical considerations and lack empirical confirmation. In markets where snus is available (Sweden, Norway), there is no scientific evidence supporting the existence of such effects. This means that it is unreasonable to invoke the "uncertainty principle" to support a continued snus ban.

131. The current ban on oral tobacco (snus), while cigarettes, other STPs and electronic cigarettes are allowed on the market subject to regulation, lacks any reasonable or coherent scientific basis. Reasons for this conclusion include that:

    131.1. Snus has substantially fewer detrimental health effects than either cigarettes or many smokeless tobacco products that are currently allowed on the market (including some Asian and North-African types of smokeless products).

    131.2. The levels of potentially toxic/carcinogenic substances are much lower in snus than in many other STPs that are currently allowed by the TPD 2014.

    131.3. Evidence from the USA (summarised in Table 2 below) tends to confirm that snus is significantly less damaging to public health than other forms of SMT.

    131.4. Long-term snus use does not cause the principal diseases responsible for some 90% of cigarette-attributable mortality.

    131.5. There is evidence that using snus is less addictive than cigarette smoking.

    131.6. Both observational data and randomised controlled clinical trials confirm that snus is an effective aid to smoking cessation.

    131.7. The available epidemiological data from Sweden and Norway do not support the hypothesis that the availability of snus is a gateway to smoking among adolescents.

    131.8. Observational epidemiological studies from Sweden and Norway demonstrate that snus is a gateway ***from*** smoking. There is an inverse relationship between the prevalence of snus use and cigarette smoking: smoking prevalence drops when snus use increases.

    131.9. The state of the scientific evidence on STPs and electronic cigarettes (which are regulated, not banned) is far more uncertain than is the evidence for snus.

Statement of compliance

I understand my duty as an expert witness is to the court. I have complied with that duty and will continue to comply with it. This report includes all matters relevant to the issues on which my expert evidence is given. I have given details in this report of any matters which might affect the validity of this report. I have addressed this report to the court.

I further understand that my duty to the court overrides any obligation to the party from whom I received instructions.

Declaration of Awareness

I confirm that I am aware of the requirements of Part 35 and Practice Direction 35, and the Guidance for the Instruction of Experts in Civil Claims 2014.

Statement of truth

I confirm that I have made clear which facts and matters referred to in this report are within my own knowledge and which are not. Those that are within my own knowledge I confirm to be true. The opinions I have expressed represent my true and complete professional opinions on the matters to which they refer.

Statement of conflicts

I confirm that I have no conflict of interest of any kind, other than any which I have already set out in this report. I do not consider that any interest which I have disclosed affects my suitability to give expert evidence on any issue on which I have given evidence and I will advise the party by whom I am instructed if, between the date of this report and the trial, there is any change in circumstances which affects this statement.

Signature _____

Date _____

E Appendices

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72. Russell MAH, Jarvis MJ, Feyerabend C (1980): A new age for snuff? Lancet 1(8166), 474-475

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74. Hublet A, De Bacquer D, Valima R, Godeau A, Schmid H, Rahav G, Maes L, (2006). Smoking trends among adolescents from 1990 to 2002 in ten European countries and Canada. BMC Public Health 6: 280

Curriculum Vitae – Professor Martin Jarvis

Name: Martin John Jarvis MA BA MPhil CPsychol DSc (Med) OBE

Nationality: British (Born Norwich, England 30.6.1939)

Marital Status: Married

Degrees

- BA (Cantab) 1961 (MA 1964)
- BA (London) 1968
- MPhil (London) 1978
- DSc (Medicine) (London) 1997

Honours

- Officer of the British Empire, January 2002
- John Slade Award, Society for Research on Nicotine and Tobacco, 2008

Present post

Emeritus Professor of Health Psychology, Department of Epidemiology and Public Health, University College London (from July 2004)

Previous career

1958 – 1961	Classics Tripos, Cambridge University
	Part 1: First Class Honours
	Part 2: 2 : 1 Honours
1959	Manners Scholar, Corpus Christi College, Cambridge
1960	Boyd Scholar, Corpus Christi College, Cambridge
1964 – 1968	Psychology Degree, Birkbeck College, University of London. First Class Honours. Top first.
1968	University Scholar in Psychology
1969 – 1970	Postgraduate student in Departments of Physiology and Pharmacology, University College London.
1970 – 1972	Part-time lecturer, Department of Psychology Brunel University.
1971 – 1973	Research Associate, Departments of Physiology and Pharmacology, University College London.

1974 – 1976	Research Worker, Neuropsychology Section, Institute of Psychiatry.
1976 – 1978	MPhil. in Clinical Psychology, Institute of Psychiatry.
1978 – 1989	Research Worker, Addiction Research Unit, Institute of Psychiatry.
October 1986 - February 1996	Honorary Senior Lecturer, Departments of Psychology and Psychiatry, Institute of Psychiatry
January 1982 - February 1996	Honorary Senior Clinical Psychologist, The Bethlem Royal and Maudsley Hospitals
1989 – 1991	Senior Scientist, Imperial Cancer Research Fund
February 1996 – September 1999	Reader in Health Psychology, Department of Epidemiology and Public Health, University College London
October 1999 – June 2004	Professor of Health Psychology, Department of Epidemiology and Public Health, University College London
June 1991 - June 2004	Principal Scientist, Cancer Research UK (ICRF until 2002)
1997	DSc (Medicine) London University for work on: Passive Smoking: Dose Measurement and Effects

Professional contributions

1982	Convener and chairman Symposium on "Problems and Progress in Smoking Cessation." Annual Conference of the British Psychological Society. York. April 1982.
1982	Consultant to BBC Television series "So you want to stop smoking?"
1983	Member International Agency for Research on Cancer Review Board on Passive Smoking. New York December 1983.
1983	Member UICC Workshop on Smoking Cessation, Belfast November 1983, and contributing author UICC Guidelines on Smoking Cessation.
1984	Consultant to NCI funded research project on enhancing compliance with nicotine chewing gum in general practice. Principal investigators Best JA and Wilson D, Waterloo and McMaster Universities, Canada.
1984-	Assistant Editor British Journal of Addiction
1985	Member Health Education Council Expert Panel on Passive Smoking.

1986	Member Peer Review Panel, Addiction Research Foundation, Toronto, Canada
1986	Consultant to Thames TV documentary "Passing Clouds"
1986	Invited speaker, Consensus Conference on Passive Smoking in the Workplace, Green College, Oxford.
1987-1993	Member Substance Abuse Committee, Mental Health Foundation.
1989-1993	Member Steering Committee for Health Education Authority/Department of Health Teenage Smoking Campaign.
1990	Member European Community Expert Panel on Passive Smoking
1991	Member of Editorial Board for ICRF/CRC publication: Passive Smoking: a Health Hazard.
1992-1998	Honorary Treasurer, Society for the Study of Addiction
1993	Consultant to Science Museum Science Box exhibition on passive smoking.
1993-	Member ASH Council
1994-	Member Scientific Committee on Tobacco and Health (Advisory Committee to Chief Medical Officer, Department of Health).
1994-	Member Technical Advisory Group, Scientific Committee on Tobacco and Health (Advisory Committee to Chief Medical Officer, Department of Health).
1995-	Member National Smoking Education Campaign Steering Group.
1996	Trustee, ASH
1997-2000	Chair, Nominations Committee, Society for Research on Nicotine and Tobacco
1997	Member Tobacco Advisory Group of the Royal College of Physicians
1999-2000	Specialist Adviser to House of Commons Health Select Committee for their inquiry into the Tobacco Industry and the Health Risks of Smoking
2000 -	Chair, Technical Advisory Group, Scientific Committee on Tobacco & Health
2000-	Deputy Chair, Scientific Committee on Tobacco and Health
2000-	Member World Health Organisation Scientific Advisory Committee on Tobacco Product Regulation

2001-2003; 2015 -2016	Deputy Chair, ASH
2002, 2005	Senior Scientific Reviewer, US Surgeon General's report
2004	Specialist Adviser to Health Select Committee for their inquiry into the *Choosing Health* White Paper
2005	Specialist Adviser to Health Select Committee for their inquiry into the government's proposals to restrict smoking in public places
2007	Member IARC working group on reversal of risk after quitting smoking, and contributing author: Tobacco Control: Reversal of Risk after Quitting Smoking. IARC Handbooks of Cancer Prevention, Volume 11. IARC, Lyon 2007.
2010-2015	Member Cancer Research UK Population Research Committee
2010-2015	Chair Cancer Research UK Tobacco Advisory Group

Membership of professional bodies

- British Psychological Society
- Society for the Study of Addiction
- Society of Behavioral Medicine
- Society for Research on Nicotine and Tobacco

Refereeing

- Lancet
- British Medical Journal
- Addiction
- Preventive Medicine
- American Journal of Public Health
- Tobacco Control
- Nicotine and Tobacco Research
- International Journal of Epidemiology
- Journal of Epidemiology and Community Health
- Journal of Clinical Epidemiology
- European Respiratory Journal

Grants held

- £6,000 from Health Education Authority, to fund follow-up school survey in Bristol (1985-6)
- £49,000 from Tobacco Products Research Trust, for longitudinal study of development of smoke intake in young adult smokers (1986-1988).

- £950,000 (with Dr. MAH Russell) from Medical Research Council. Programme grant to fund research into psychological and pharmacological basis of tobacco dependence (1988-1993).
- £1,610,000 (with Dr. MAH Russell) from Medical Research Council. Programme grant to fund research into psychological and pharmacological basis of tobacco dependence (1993-1998).
- £37,000 from Office of Population Censuses and Surveys to quantify smoke intake from active and passive smoking by cotinine assay in the Health Survey for England (1993).
- £55,000 (with Dr C Feyerabend) from Social and Community Planning Research/University College London to quantify smoke intake from active and passive smoking by cotinine assay in the Health Survey for England (1994).
- £26,000 (with Dr C Feyerabend) from Social and Community Planning Research/University College London to quantify smoke intake from active and passive smoking by cotinine assay in the Scottish Health Survey (1995).
- £70,000 from Social and Community Planning Research/University College London to quantify smoke intake from active and passive smoking by cotinine assay in the Health Survey for England (1996).
- £50,000 from Social and Community Planning Research/University College London to quantify smoke intake from active and passive smoking by cotinine assay in the Health Survey for England (1997).
- £30,000 (with Dr C Feyerabend) from Social and Community Planning Research/University College London to quantify smoke intake from active and passive smoking by cotinine assay in the Scottish Health Survey (1998).
- £75,000 (with Dr C Feyerabend) from Social and Community Planning Research/University College London to quantify smoke intake from active and passive smoking by cotinine assay in the Health Survey for England (1998)
- £75,000 (with Dr C Feyerabend) from National Centre for Social Research/University College London to quantify smoke intake from active and passive smoking by cotinine assay in the Health Survey for England (1999-2000)
- £134,000 from Camden & Islington Health Authority to fund Smokers' Clinic (2000-2001)
- £60,000 (with Professor S Sutton) from British Heart Foundation and Kings Fund BBC for evaluation of *Kick the Habit* campaign (2000)
- £377, 582 (with Professors Derek Cook, Peter Whincup, Ian Day) from MRC: Evolution of smoking behaviour in adolescence: the influence of environmental and genetic factors (2000-2003).
- £80,000 (with Dr C Feyerabend) from National Centre for Social Research/University College London to quantify smoke intake from active and passive smoking by cotinine assay in the Health Survey for England (2001-2002)
- £308,763 (with Professor Jane Wardle and Professor Stephen Sutton) From Department of Health for: Identifying protective and risk factors for smoking: a cohort study following 5000 teenagers from 11-16. (2001-2004)

Recent invited talks

- Smoking and health inequalities. Invited presentation to conference of NHS Modernisation Working Group, June 2000
- The challenge of health inequalities. Invited presentation to Department of Health conference on National Smoking Plan "A Smoke Free Future", London, January 2001
- Smoking cessation. Invited presentation to Royal College of Physicians of Edinburgh Consensus Conference on Management of Chronic Obstructive Pulmonary Disease, Edinburgh, March 2001
- Pharmacological treatments in smoking cessation. Dutch Conference on Cessation Guidelines, Zutphen, December 2003
- Working in the hospitality industry: who is exposed to environmental tobacco smoke and how much? Invited presentation at conference on Passive Smoking and the Hospitality Industry, Royal College of Physicians May 2004.
- The behavioural epidemiology of nicotine dependence. Invited plenary at European conference of Society for Research on Nicotine and Tobacco, Tubingen October 2004
- Mechanisms and biomarkers of tobacco and cancer: measuring tobacco dose. Invited plenary at American Association for Research on Cancer conference Frontiers in Cancer Prevention Research, Seattle October 2004.
- Nicotine and smoking: insights from the Health Survey for England. Invited presentation at Economic and Social Data Service conference London, October 2004.
- The future market for nicotine. Invited plenary at Department of Health Tackling Tobacco in England conference, Hammersmith November 2004.
- Passive smoking health risks, and patterns of exposure. Invited presentation at Smoke Free North East conference Secondhand Smoke: the Case for a Smoke Free NortheEast, Newcastle December 2004.
- The facts behind smoking. Invited presentation at 7th National Symposium on Lung Cancer, Amsterdam, the Netherlands, January 2005

PUBLICATIONS

Book chapters

1. Jarvis MJ, Ettlinger G. Cross-modal perception in chimpanzees and monkeys. In Chivers D.J. and Herbert, J. (Eds) *Recent Advances in Primatology* Vol. 1. Academic Press, London. 1978

2. Jarvis MJ. Safer smoking. In: Smoking and Arterial Disease. Greenhalgh, RM (Ed.) *Pitman Medical*, London 1980.

3. Jarvis MJ. Role de la nicotine dans la dependance au tabac. in Molimard R (Ed) *Comptes Rendues de la Premiere Journee de la Dependance Tabagique*. 983 Paris, UER Biomedicale des Saints-Peres.

4 Russell MAH, Jarvis MJ. Theoretical background and clinical use of nicotine chewing gum. in: Pharmacological Adjuncts in Smoking Cessation. Grabowski J, Hall S. (Eds.) *NIDA Research Monograph* 53 Washington, DC: US Government Printing Office. 1985 pp 110-130.

5. Jarvis MJ. Uptake of environmental tobacco smoke. In: Environmental Carcinogens: Methods of Analysis and Exposure Measurement, Vol. 9, Passive Smoking. IK O'Neill, KD Brunnemann, B Dodet, D Hoffmann (Eds). pp 43-58, *IARC Scientific Publication* No. 81, IARC, Lyon 1987.

6. Jarvis MJ. Nicotine replacement as sole therapy or as adjunct. In Pomerleau OF, Pomerleau CS (Eds) *Nicotine Replacement: A Critical Evaluation*. pp145-162. New York, Alan R. Liss, 1988.

7. Jarvis MJ, Marsh A, Matheson J. Factors influencing choice of low-tar cigarettes. In Wald NJ, Froggatt P. (Eds) *Nicotine, Smoking and the Low-tar Programme*. pp 220-228 Oxford University Press, 1989.

8. Jarvis MJ. Isolating the role of nicotine in human smoking behaviour. In Wald NJ, Froggatt P. (Eds) *Nicotine, Smoking and the Low-tar Programme*. pp170-181 Oxford University Press, 1989.

9. Jarvis MJ. Helping smokers give up. pp 285-307 In Pearce S, Wardle J.(Eds) *The Practice of Behavioural Medicine*. Oxford University Press, 1989.

10. Jarvis MJ. Tobacco smoking: an everyday drug addiction. In Glass IB (Ed) *International Handbook of Addiction Behaviour*. Routledge: London 1991; 95-99.

11. Jarvis MJ. Dependence on smokeless tobacco. *US National Cancer Institute Monograph (Smoking and Tobacco Control Monograph No. 2)* 1992; 239-245.

12. Jarvis MJ. Passive smoking. In Heller T, Bailey L and Pattison S. (Eds) *Preventing Cancers*. Buckingham: Open University Press 1992; 121-129.

13. Jarvis MJ. Change in the addictions: does treatment make a difference? In Edwards G & Lader MH (Eds). *Addiction: Processes of Change*. Oxford University Press 1994, 233-249.

14. Foulds J & Jarvis MJ. Smoking cessation and prevention. In Calverley PMA and Pride N. (Eds) *Chronic Obstructive Pulmonary Disease*. London: Chapman and Hall, 1995; 373-390

15. Stolerman IP, Jarvis MJ. Evidence that nicotine is addictive. In Clarke PBS, Quik, M, Adlkofer F, Thurau, K (Eds) Advances in Pharmacological Sciences. *Effects of nicotine on biological systems II*. Birkhäuser Verlag 1995, 195-202.

16. Jarvis MJ. Patterns and predictors of smoking cessation in the general population. In: Bolliger, CT, Fagerstrom KO (Eds) The Tobacco Epidemic: Progress in Respiratory Research Vol. 28, S. Karger, Basel., 1997; pp 151-164.

17. Jarvis MJ, Sutherland G. Tobacco smoking. In: Johnston M, Johnston D (eds). Comprehensive Clinical Psychology. Vol 7 Health Psychology. Pergamon, 1998: 645-674. (Bellack A, Hersen S, eds)

18. Jarvis MJ, Wardle J. Social patterning of health behaviours: the case of cigarette smoking. In: Marmot M, Wilkinson R, eds. Social Determinants of Health. OUP 1999; 240-255.

19. Wardle J, Farrell M, Hillsdon M, Jarvis MJ, Sutton S, Thorogood M. Smoking, drinking, physical activity and screening uptake and health inequalities. In: Gordon D, Shaw M, Dorling D, Davey-Smith G, eds. Inequalities in Health. Bristol: The Policy Press, 1999:213-239.

20. Jarvis MJ. Patterns of use, epidemiology, adverse effects, and specific issues concerning treatment for nicotine dependence. In: Gelder M, Lopez-Ibor J, Andreasen N, eds. New Oxford Texbook of Psychiatry. Oxford: Oxford University Press, 2000:554 - 559.

20. Jarvis MJ. Pharmacological approaches to smoking cessation. In: Lu R, Mackay J, Niu S, Peto R, eds. Tobacco: the growing epidemic. London: Springer, 2000:705-707. Proceedings of the Tenth World Conference on Tobacco or Health, 24-28 August 1997, Beijing, China

21. Bobak M, Jha P, Nguyen S, Jarvis MJ. Poverty and smoking. In: Jha P, Chaloupka F, eds. *Tobacco control in developing countries*. Oxford: Oxford University Press, 2000: 41-61.

23. Jarvis MJ Smoking and stress. in Stansfeld S, Marmot M (eds) *Stress and the Heart: Psychosocial Pathways to Coronary Heart Disease.* London, BMJ Books 2002; 150-157.

21. Cooke LJ, Wardle J, Jarvis MJ. Behaviour Change. In Marmot M, Elliott P (Eds) Coronary Heart Disease Epidemiology, Oxford: Oxford University Press 2005.

22. Jarvis MJ, Wardle J. Social patterning of health behaviours: the case of cigarette smoking. In: Marmot M, Wilkinson R, eds. Social Determinants of Health. OUP 2005 (Second Edition)

Refereed Articles

1. Bostock H, Jarvis MJ. The relationship between reaction time, cardiac cycle and form of the cerebral evoked potential. *Journal of Physiology* 1969; 202: 60-62.

2. Bostock H, Jarvis MJ Changes in the form of the cerebral evoked response related to the speed of simple reaction time. *Electroenceph Clin Neurophysiol* 1970; 29: 137-45.

3. Steiner J, Jarvis MJ Parrish J. Risk-taking and arousal regulation. *Br J Med Psychol* 1970; 43: 333-8.

4. Jarvis MJ, Lader MH The effects of nitrous oxide on reaction time and cerebral evoked potential. *Br J Pharmacol* 1970; 39: 254-5

5. Jarvis MJ, Lader MH The effects of nitrous oxide on the auditory evoked response in a reaction time task. *Psychopharmacologia* 1971; 20: 201-12.

6. Dawson GD, Jarvis MJ Waite PME An indexing system for magnetic tape. *J.Physiol* 1972; 224: 111-2.

7. Jarvis MJ, Ettlinger G. Transfer of spatial alternation between responding in the light and in the dark. *Neuropsychologia* 1975; 13: 115-6

8. Ettlinger G, Jarvis MJ. Cross-modal transfer in the chimpanzee. *Nature* 1976; 259: 44-6.

9. Jarvis MJ, Ettlinger G. Cross-modal recognition in chimpanzees and monkeys. *Neuropsychologia* 1977; 15: 499-506.

10. Russell MAH, Jarvis MJ, Feyerabend C. A new age for snuff? *Lancet* 1980; 1: 474-5.

11. Russell MAH, Jarvis MJ, Iyer R, Feyerabend C. Relation of nicotine yield of cigarettes to blood nicotine level of smokers. *Br Med J* 1980; 280: 972-6.

12 Jarvis MJ, Russell MAH, Saloojee Y. Expired air carbon monoxide: a simple and cost-effective breath test of tobacco smoke intake. *Br Med J* 1980; 281-284-5.

13. Russell MAH, Raw M, Jarvis MJ Clinical use of nicotine chewing gum. *Br Med J* 1980; 280: 1599-1602.

14. Raw M, Jarvis MJ, Russell MAH. A comparison of nicotine chewing gum and psychological treatments for dependent smokers. *Br Med J* 1980; 281: 481-484.

15. Wardle J, Jarvis MJ. The paradoxical fear response to blood, injury and illness: a treatment report. *Behavioural Psychotherapy* 1981; 9: 13-24.

16. Russell MAH, Jarvis MJ, Devitt G, Feyerabend C. Nicotine intake by snuff users. *Br Med J* 1981; 283: 814-817

17. Jarvis MJ, Raw M, Russell MAH, Feyerabend C. Randomised controlled trial of nicotine chewing-gum. *Br Med J* 1982; 285: 537-40.

18. Russell MAH, Jarvis MJ, Feyerabend C, Ferno O. Nasal nicotine solution: a potential aid to giving up smoking? *Br Med J* 1983; 286: 683-4

19. Jarvis MJ. The treatment of cigarette dependence. *Br J Addict* 1983; 78: 125-30.

20. Jarvis MJ, Russell MAH, Feyerabend C. Absorption of nicotine and carbon monoxide from passive smoking under natural conditions of exposure. *Thorax* 1983; 38: 829-33.

21. West RJ, Jarvis MJ, Russell MAH, Carruthers ME, Feyerabend C. Effect of nicotine replacement on the cigarette withdrawal syndrome. *Br J Addict* 1984; 79: 215-219

22. Jarvis MJ, Russell MAH. Measurement and estimation of smoke dosage to non-smokers from environmental tobacco smoke. *Europ J Respir Dis* 1984; Suppl. 133: 68-76.

23. Jarvis MJ, Tunstall-Pedoe H, Feyerabend C, Vesey C, Saloojee Y. Biochemical markers of smoke absorption and self-reported exposure to passive smoking. *J Epidemiol Community Health* 1984; 38: 335-39.

24. Jarvis MJ, West R, Tunstall-Pedoe H, Vesey C. An evaluation of the intervention against smoking in the Multiple Risk Factor Intervention Trial. *Preventive Medicine* 1984; 13: 501-509.

25. Jarvis MJ. Gender and smoking: do women really find it harder to give up? *Br J Addict* 1984; 79: 383-87.

26. Devitt G, West R, Jarvis MJ. Test for assessing tar/nicotine yield. *Am J Public Health*, 1984; 74: 391.

27. West R, Russell MAH, Jarvis MJ, Feyerabend C. Does switching to an ultra-low nicotine cigarette induce nicotine withdrawal effects? *Psychopharmacology* 1984; 84: 120-23.

28. West R, Russell MAH, Jarvis MJ, Pizzey T, Kadam B. Urinary adrenaline concentrations during 10 days of smoking abstinence. *Psychopharmacology* 1984; 84: 140-41.

29. West R, Jarvis MJ, Russell MAH, Feyerabend C. Plasma nicotine concentrations from repeated doses of nasal nicotine solution. *Br J Addict* 1984; 79: 443-45.

30. Russell MAH, West RJ, Jarvis MJ. Intravenous nicotine simulation of passive smoking to estimate dosage to exposed non-smokers. *Br J Addict* 1985; 80: 201-206.

31. Jarvis MJ, Russell MAH. Tar and nicotine yields of UK cigarettes 1972-1983: sales-weighted estimates from non-industry sources. *Br J Addict* 1985; 80: 429-434.

32. Jarvis MJ, Russell MAH, Feyerabend C, Eiser JR, Morgan M, Gammage P, Gray EM. Passive smoke exposure: salivary cotinine levels in a representative population sample of non-smoking schoolchildren. *Br Med J* 1985; 291: 927-929.

33. McNeill A, Jarvis MJ, West R. Brand preferences among schoolchildren who smoke. *Lancet* 1985; 2: 271-272.

34. Russell MAH, Jarvis MJ, West RJ, Feyerabend C. Buccal absorption of nicotine from smokeless tobacco sachets. *Lancet* 1985; 2: 1370.

35. McNeill AD, West R, Jarvis MJ, Russell MAH. Do older children take in more smoke from their cigarettes? Evidence from carbon monoxide levels. *J Behav Med* 1986; 9: 559-565.

36. Russell MAH, Jarvis MJ, West R. Use of urinary nicotine concentrations to estimate exposure and mortality from passive smoking in non-smokers. *Br J Addict* 1986; 81: 275-281.

37. Russell MAH, Jarvis MJ, Feyerabend C, Saloojee Y. Reduction of tar, nicotine and carbon monoxide intake in low tar smokers. *J Epidemiol Community Health* 1986; 40: 80-85.

38. Jarvis MJ, Belcher M, Vesey C, Hutchison, DCS. Low cost carbon monoxide monitors in smoking assessment. *Thorax* 1986; 41: 886-887.

39. Jarvis MJ, Russell MAH. Sales-weighted tar, nicotine and carbon monoxide yields of UK cigarettes: 1985. *Br J Addict* 1986; 81: 579-581.

40. Feyerabend C, Bryant A, Jarvis MJ, Russell MAH. Determination of cotinine in biological fluids of non-smokers by packed column gas-liquid chromatography. *J Pharm Pharmacol* 1986; 38: 917-919.

41. McNeill AD, West RJ, Jarvis MJ, Jackson P, Bryant A. Cigarette withdrawal symptoms in adolescent smokers. *Psychopharmacology* 1986; 90: 533-536.

42. West RJ, Jarvis MJ. Effects of nicotine on finger tapping rate in non-smokers. *Pharmacology Biochemistry and Behavior* 1986; 25: 727-731.

43. McNeill AD, Jarvis MJ, West RJ. Subjective effects of cigarette smoking in adolescents. *Psychopharmacology* 1987; 92: 115-117.

44. Jarvis MJ, Hajek P, Russell MAH, West RJ. Nasal nicotine solution as an aid to cigarette withdrawal: a pilot clinical trial. *Br J Addict* 1987; 82: 983-988.

45. Jarvis MJ, Tunstall-Pedoe H, Feyerabend C, Vesey C, Saloojee Y. Comparison of tests used to distinguish smokers from nonsmokers. *Am J Public Health* 1987; 77: 1435-1438.

46. Russell MAH, Jarvis MJ, Sutherland G, Feyerabend C. Nicotine replacement in smoking cessation: absorption of nicotine vapor from smoke-free cigarettes. *Journal of the American Medical Association* 1987; 257: 3262-3265.

47. McNeill AD, Jarvis MJ, West R, Russell MAH, Bryant A. Saliva cotinine as an indicator of cigarette smoking in adolescents. *Br J Addict* 1987; 82: 1355-1360.

48. Jarvis MJ, Russell MAH, Benowitz NL, Feyerabend C. Elimination of cotinine from body fluids: implications for non-invasive measurement of tobacco smoke exposure. *Am J Public Health* 1988; 78: 696-698.

49. Jarvis MJ, McNeill AD, Russell MAH. Passive smoking in adolescents: one-year stability of exposure in the home. *Lancet* 1987; 1: 1324-1325.

50. Jarvis MJ, Jackson P. Cigar and pipe smoking in Britain: implications for smoking prevalence and cessation. *Br J Addict* 1988; 83: 323-330.

51. Hajek P, Jarvis MJ, Belcher M, Sutherland G, Feyerabend C. Effect of smoke-free cigarettes on 24 hours cigarette withdrawal: a double-blind placebo controlled study. *Psychopharmacology* 1989; 97: 99-102.

52. McNeill AD, Jarvis MJ, Stapleton J, West RJ, Bryant A. Nicotine intake in young smokers: longitudinal study of saliva cotinine concentrations. *American Journal of Public Health* 1989; 79: 172-175.

53. McNeill AD, Jarvis MJ, Stapleton J, Russell MAH, Eiser JR, Gammage P, Gray EM. Prospective study of factors predicting the uptake of smoking in adolescents. *J. Epidemiol Community Health* 1989; 43: 72-78.

54. Jarvis MJ. Application of biochemical intake markers to passive smoking measurement and risk estimation. *Mutation Research* 1989; 222: 101-110.

55. Strachan DP, Jarvis MJ, Feyerabend C. Passive smoking, salivary cotinine concentrations, and middle ear effusion in 7 year old children. *British Medical Journal* 1989; 298: 1549-1552.

56. Jarvis MJ, Russell MAH. Treatment for the cigarette smoker. *International Review of Psychiatry* 1989; 1: 139-147.

57. Belcher M, Jarvis MJ, Sutherland G. Nicotine absorption and dependence in an over the counter aid to stopping smoking. *British Medical Journal* 1989; 298: 570.

58. Jarvis MJ, Goddard E, McNeill AD. Do attitudes predict uptake of smoking in teenagers? Case not proven. *Social Science and Medicine* 1990; 31: 997-1001.

59. Strachan DP, Jarvis MJ, Feyerabend C. The relationship of salivary cotinine to respiratory symptoms, spirometry and exercise-induced bronchospasm in seven-year-old children. *American Review of Respiratory Disease* 1990; 142: 147-151.

60. Jarvis MJ, McNeill AD. Children's purchases of single cigarettes: Evidence for drug pushing? *British Journal of Addiction* 1990; 85: 1317-1322.

61. Russell MAH, Jarvis MJ, Jones G, Feyerabend C. Non-smokers show acute tolerance to subcutaneous nicotine. *Psychopharmacology* 1990; 102: 56-58.

62. Jarvis MJ, McNeill AD, Bryant A, Russell MAH. Factors determining exposure to passive smoking in young adults living at home: quantitative analysis using saliva cotinine concentrations. *International Journal of Epidemiology* 1991; 20: 126-131.

63. Coleman MP, Key TJA, Wang DY, Allen DS, Hermon C, Fentiman IS, Allen DS, Jarvis MJ, Pike MC, Sanders TAB. A prospective study of obesity, lipids, apolipoproteins and ischaemic heart disease in women. *Atherosclerosis* 1992; 92: 177-185.

64. Jarvis MJ. A time for conceptual stocktaking. *Br J Addict* 1991; 86: 643-647.

65. Russell MAH, Jarvis MJ. Skin patches for the prevention of lung cancer. *European Journal of Cancer* 1991; 27: 223-224.

66. Townsend J, Wilkes H, Haines A, Jarvis MJ. Adolescent smokers seen in general practice: health, lifestyle, physical measurements, and response to antismoking advice. *Br Med J* 1991; 303: 947-950.

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75. Cohen S, Tyrrell DAJ, Russell MAH, Jarvis MJ, Smith AP. Smoking, alcohol consumption and susceptibility to the common cold. *American Journal of Public Health* 1993; 83: 1277-1283.

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Table 1

Substance	Gothiatek limit	Swedish Food Act limit	WHO TobReg recommended limit
NNN+NNK (ppm)	0.95	1.0	1.0
NDMA (ppb)	2.5		
Nitrate (ppm)	3.5		
B(a)P (ppb)	1.25	1.5	2.5
Arsenic (ppm)	0.25		
Lead (ppm)	1.0	3	
Cadmium (ppm)	0.5		
Chromium (ppm)	1.5		
Mercury (ppm)	0.02		
Nickel (ppm)	2.25		
Aflatoxin (ppb) (B1+B2+G1+G2)	2.5	5	
Ochratoxin A (ppb)	10		
Formaldehyde (ppm)	7.5		
Acetaldehyd e(ppm)	25		
Crotonaldehyde (ppm)	0.75		
Agrochemicals	According to Swedish Match internal quality system for agrochemicals **		

Table 1: Comparison of maximum limits of unwanted substances in snus mandated by the Gothiatek standard, the Swedish Food Act, and limits suggested by the WHO TobReg Committee. All limits are based on wet weight and a 50% moisture content in the final products, ppm: parts per million (ug/g), ppb: parts per billion (ng/g). NNN, NNK, NDMA are nitrosamines, B(a)P is a PAH, aflatoxin and ochratoxin are potentially carcinogenic toxins produced by certain moulds, agrochemicals include mainly pesticides.

Figure 1

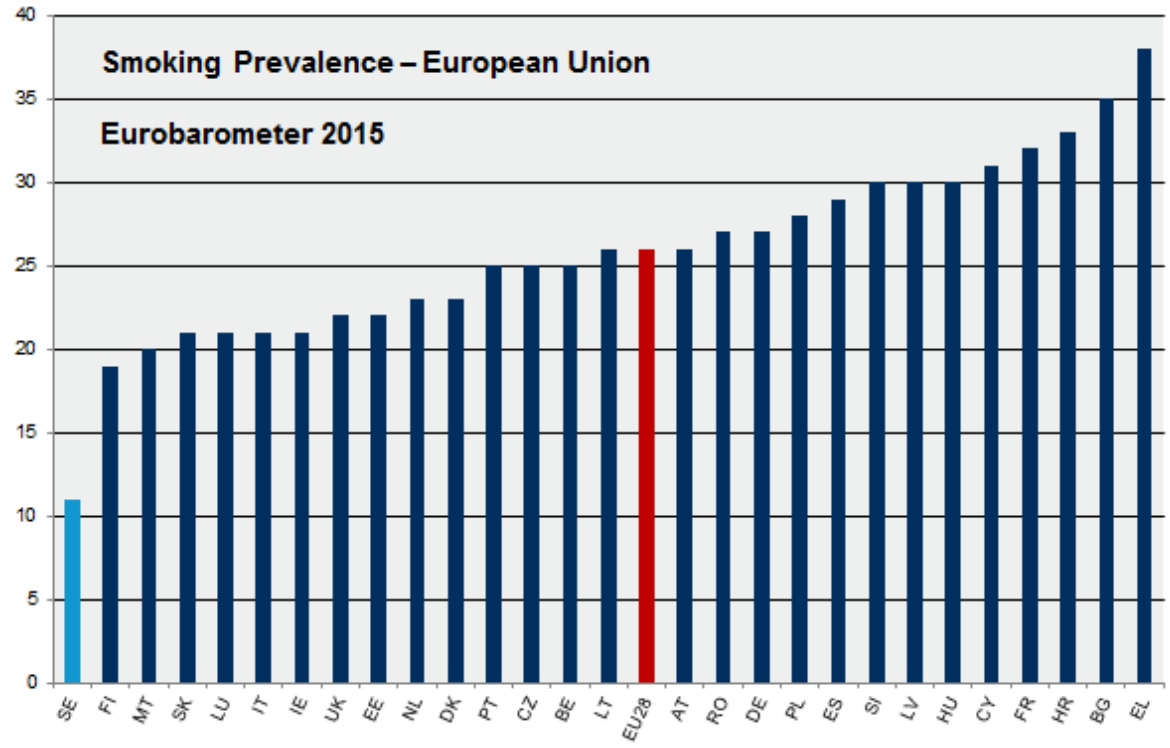

Figure 1: Percentage of daily smokers in European Union countries: Eurobarometer, 2015

Figure 2

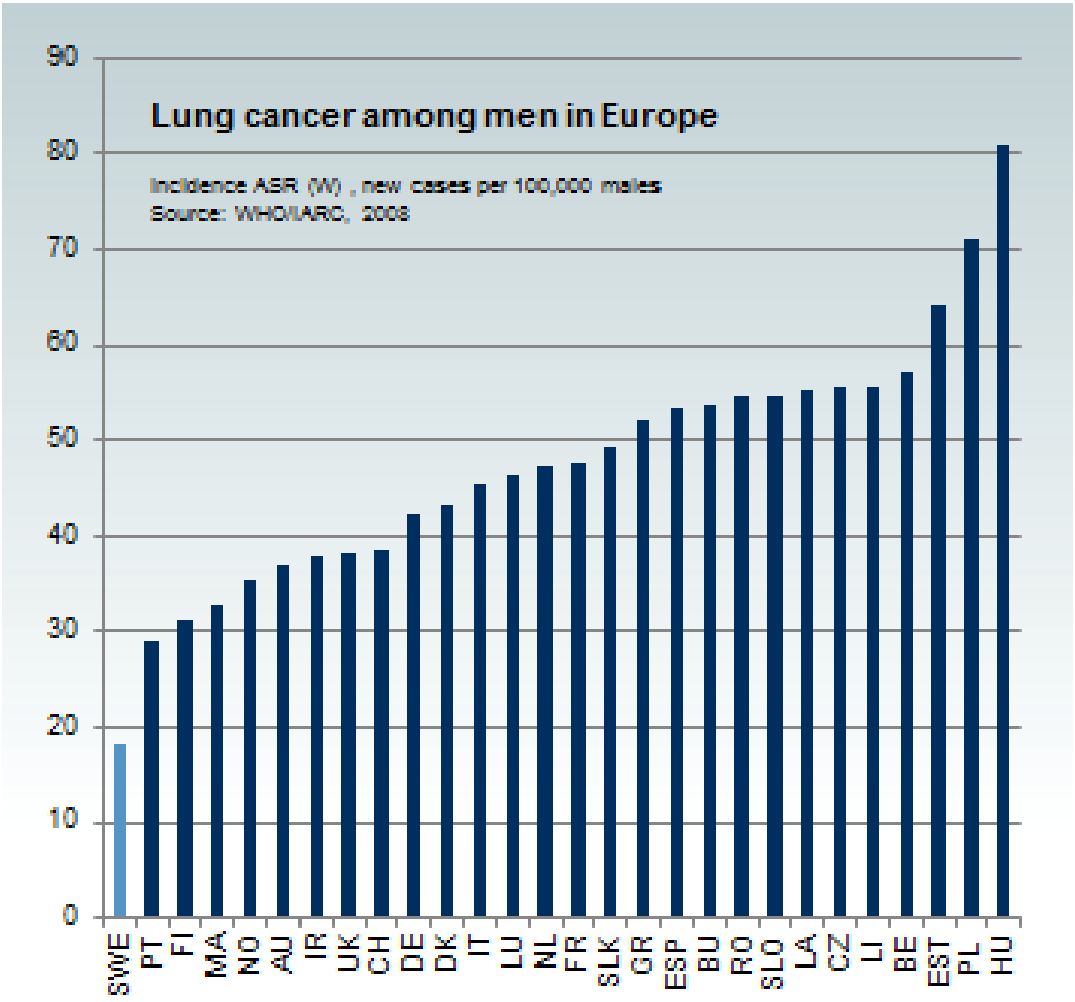

Figure 2: Lung cancer incidence (per 100,000) among males in European Union countries (69)

Figure 3

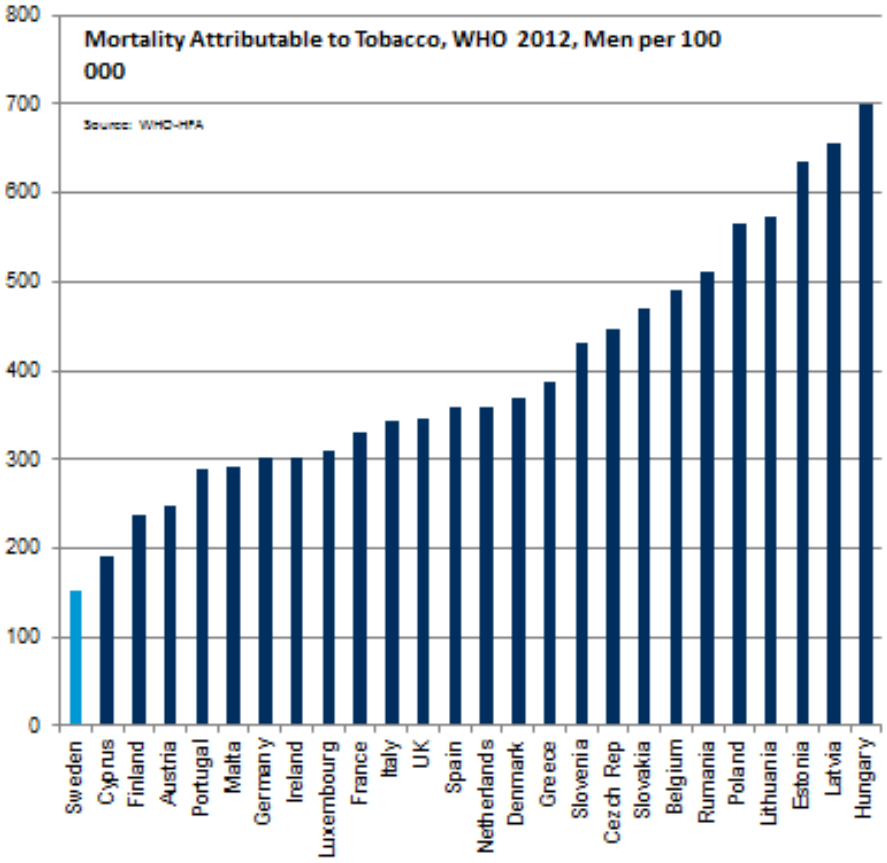

Figure 3: WHO estimates for total mortality (per 100,000) attributable to tobacco among males aged 30 and above in European Union countries (70)

Figure 4

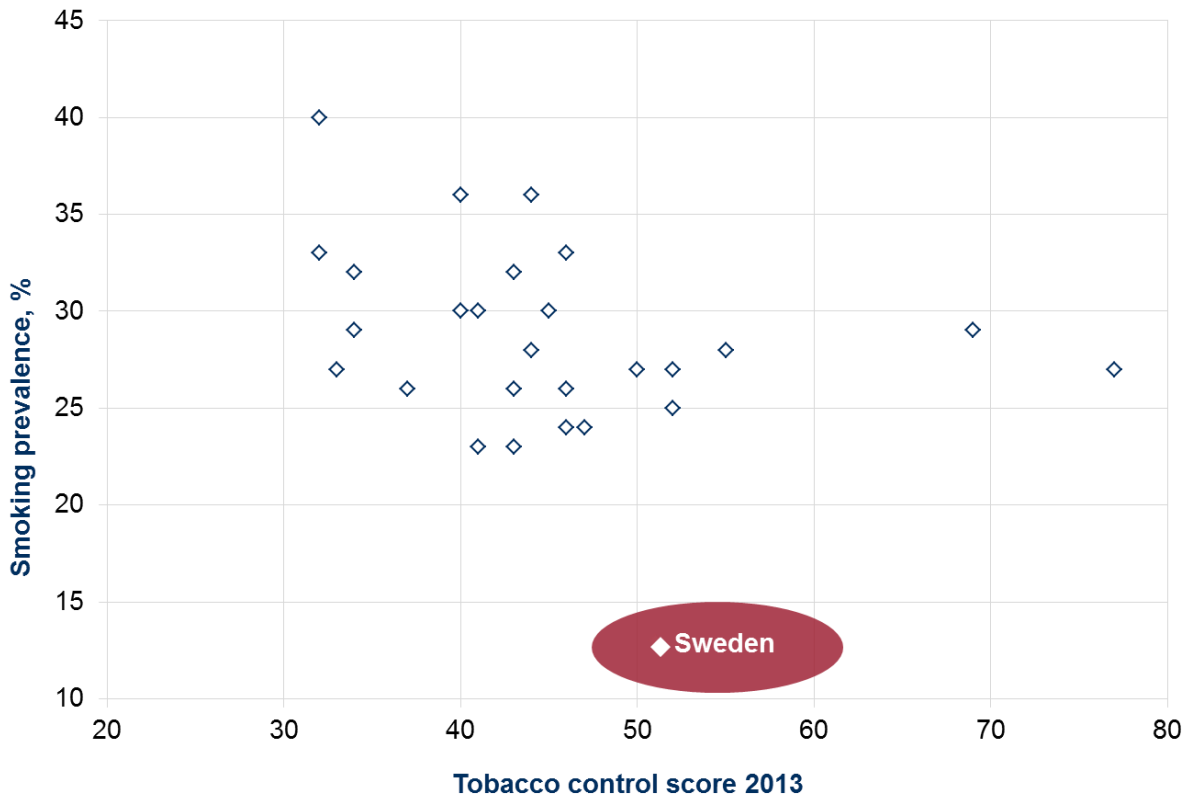

Figure 4: Smoking prevalence versus the 2013 "tobacco control score" for the European Union countries (31, 69). The score is a metric representing the extent to which a country has introduced key tobacco control activities. A higher score represents a higher level of tobacco control activity.

Table 2

Product	Risk reduction(%) in snus by comparison with ...
Moist snuff	**90**
Chewing tobacco	**67**
U.S.-style snus	**38**
Dry snuff	**92**

Table 2: Reduction in cancer risk resulting from exclusive use of snus manufactured according to the Gothiatek standard by comparison with selected other smokeless tobacco products that are currently prevalent on the U.S. market. Estimates cited by FDA in February, 2016 in conjunction with announcement of a premarket authorization (PMTA) order for eight snus products in the U.S.