



Folkhälsomyndigheten

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|--------------------------------|---|
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| Anna Jansson                   | FDA-2014-N-1051   |
|                                | <b>Registration number Public Health Agency of Sweden</b> |
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### **Comments concerning the Modified Risk Tobacco Product Applications submitted by Swedish Match North America (FDA-2014-N-1051) to the Food and Drug Administration**

The Public Health Agency of Sweden hereby submits a commentary regarding the experiences of use of snus in the Swedish population. We provide both information on tobacco use in Sweden, where snus has been consumed during several decades, and about the most recent summary on health effects of snus.

The Public Health Agency has a national responsibility for public health issues and promotes good public health by building and disseminating knowledge to professionals involved in the area of public health. According to the agency's assignment the agency works towards a reduced use of all tobacco products. All tobacco products are considered harmful and included in tobacco prevention and control work in Sweden. The National Board of Health and Welfare has issued national guidelines for methods for disease prevention through changes in lifestyle. Their recommendations on how to support smoking cessation with replacement products explicitly states that snus should not be recommended as a smoking cessation aid (1). The Swedish tobacco prevention work is in line with international policy documents, such as the WHO Framework Convention on Tobacco Control.

#### **Tobacco use in Sweden**

In Sweden, data from the national public health survey ("Health on equal terms") show that daily tobacco use is more common among men (25 percent) than among women (15 percent) (2). Looking at snus specifically, 11 percent of the population are daily users of snus and 4 percent are occasional users. Daily use is more common among men (18 percent) than among women (4 percent). The proportions of smokers among men and women are at more comparable levels, 9 and 11 percent respectively. Data also shows that dual tobacco use occurs. Eleven percent of daily users of snus also smoke daily and 22 percent smoke occasionally. This type of dual use is most common in the youngest age group studied in the survey (16–29 year olds), where 43 percent of daily snus users smoke occasionally.

Since 2004, the prevalence of daily smoking in the population has declined from 16 percent to 10 percent in 2014. This decline were more pronounced in the female population (from 19 percent to 11 percent), compared to the male population (14 percent to 9 percent). During that period, snus use has not increased. Among men, a decline in the prevalence of snus use has been observed (from 22 percent to 18 percent). Among women, the proportion of daily snus users has remained relatively stable (3–4 percent).

The decline in smoking prevalence in Sweden can have a number of explanations, such as new tobacco regulations, cessation programs and a more informed public. The SCENIHR report mentions that the trends “could also be due to successful non-smoking programs or other socio-cultural factors, and it is therefore not clear whether or by how much the availability of snus has influenced smoking prevalence” (3). Furthermore, experiences from other countries show that smoking prevalence can be reduced to levels comparable to those observed in Sweden, without the availability of snus. In Australia, where federal legislation prohibits the commercial sale of smokeless tobacco (4), there has been a significant decrease in daily smokers aged 18 years and older (from 25 percent in 1991 to 13 percent in 2013) (5).

Figure 1–4 below illustrates tobacco prevalence in Sweden 2004–2014 divided by gender and age group, figure 5 illustrates the tobacco prevalence in the total population, and table 1 provides information on dual use.

Among adolescent boys (17–18 years old when surveyed) snus use is almost as common as smoking, shows data from the Swedish Council for Information on Alcohol and Other Drugs (6). Twenty-two percent uses snus, while 28 percent smoke. Girls smoke to a similar extent as boys (29 percent), but are less often snus users (4 percent). The survey also shows that, in this population, a combined use of snus and cigarettes is more common than snus use only.

Historically, research has shown that transitions between products occur, and that smokers become users of snus and snus users become smokers. The magnitude and directions of these transitions may be different over time and between generations, and how the young generation today shifts between tobacco products is not completely understood. A recent review conclude that “The results of the studies are not definitive but they indicate an increased risk. It cannot be ruled out that the significant increased snus consumption among adolescents, and the resulting nicotine dependence, could lead to increased smoking” (7). In its Public Health Status Report 2009, the Swedish National Board of Welfare concludes that, in the context of changes in levels of snus use and transitions between cigarettes and snus, there is insufficient evidence to make any conclusions on the effects of snus on public health in Sweden. It should also be noted that the Swedish National Board of Welfare comes to different conclusions in some areas regarding snus, based on more recent evidence and data, in its Public Health Status Report 2009 compared to the 2005 report.

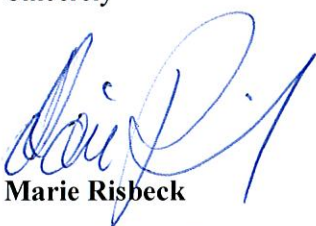
### **Health effects of snus use**

Snus use is associated with several risks. Users are exposed to nicotine under long periods of time, as many uses snus continuously during the day. This causes both addiction and affects health. Nicotine dependence is regarded as a medical condition in the Diagnostic and Statistical Manual and tobacco dependence is classified as a disorder in the International Classification of Diseases. The most recent review regarding health effects of snus use was presented by the Norwegian Institute of Public Health in November 2014 (7).

In their review the Institute concludes that there is evidence of an association between use of snus and increased risk of certain types of cancer, type 2 diabetes and death following a myocardial infarction or stroke. The Institute also states that there is some evidence of associations between use of snus and increased risk of adverse pregnancy outcomes, increased weight, including becoming overweight or obese, and high levels of cholesterol.

It is possible that all effects of snus use are not yet fully understood. This might be especially true about the effects on the female population, since most studies have been conducted on middle-age men and often with a limited number of subjects studied.

Sincerely



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## References

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7. Norwegian Institute of Public Health. Helseerisiko ved bruk av snus. (In Norwegian, [summary in English available]) 2014. Available at: [http://www.fhi.no/eway/default.aspx?Main\\_6157=6246:0:25,5498&MainContent\\_6246=6503:0:25,5508&Content\\_6503=6259:112871:25,5508:0:6250:1:::0:0](http://www.fhi.no/eway/default.aspx?Main_6157=6246:0:25,5498&MainContent_6246=6503:0:25,5508&Content_6503=6259:112871:25,5508:0:6250:1:::0:0) [February 17, 2015]

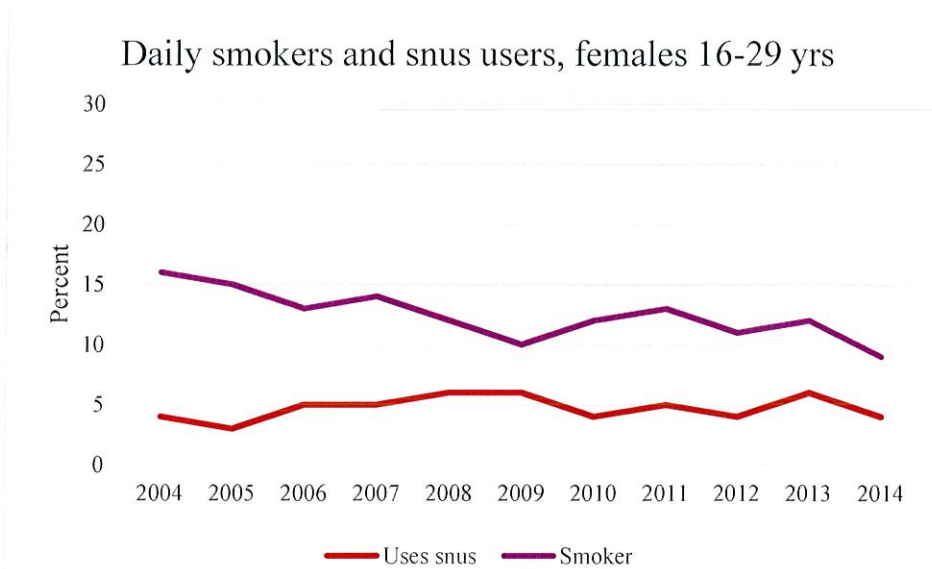


Figure 1a. The proportion of females 16 to 29 years of age that uses snus or smokes at a daily basis 2004-2014.

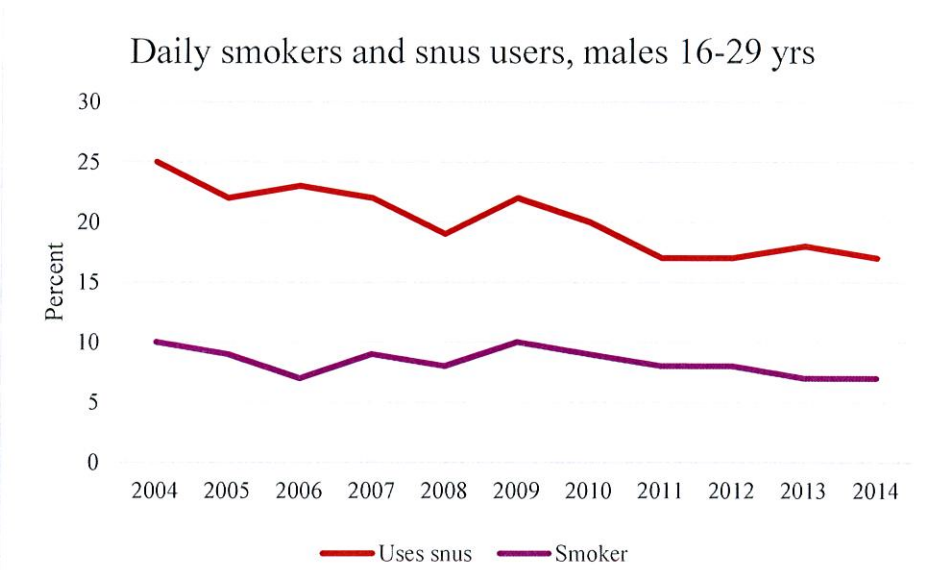


Figure 1b. The proportion of males 16 to 29 years of age that uses snus or smokes at a daily basis 2004-2014.

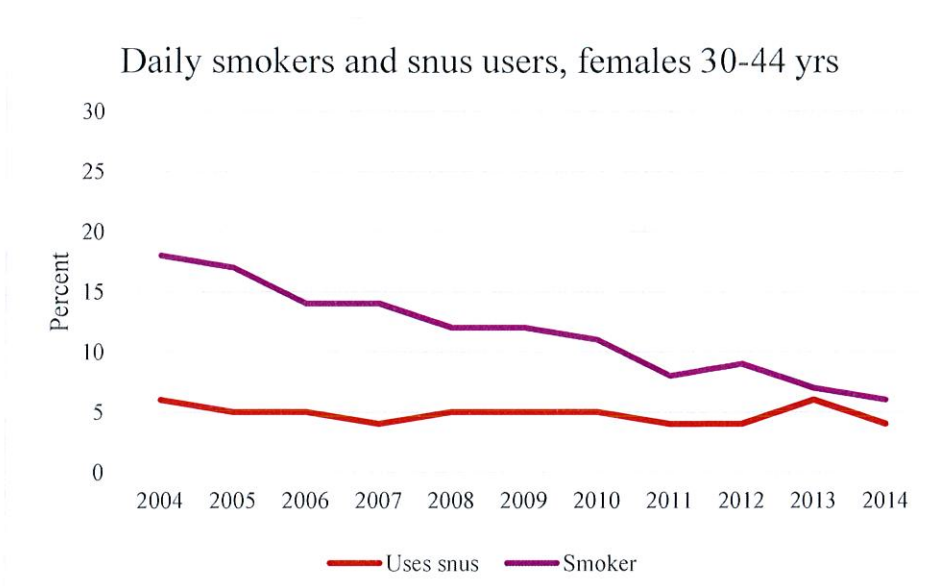


Figure 2a. The proportion of females 30 to 44 years of age that uses snus or smokes at a daily basis 2004-2014.

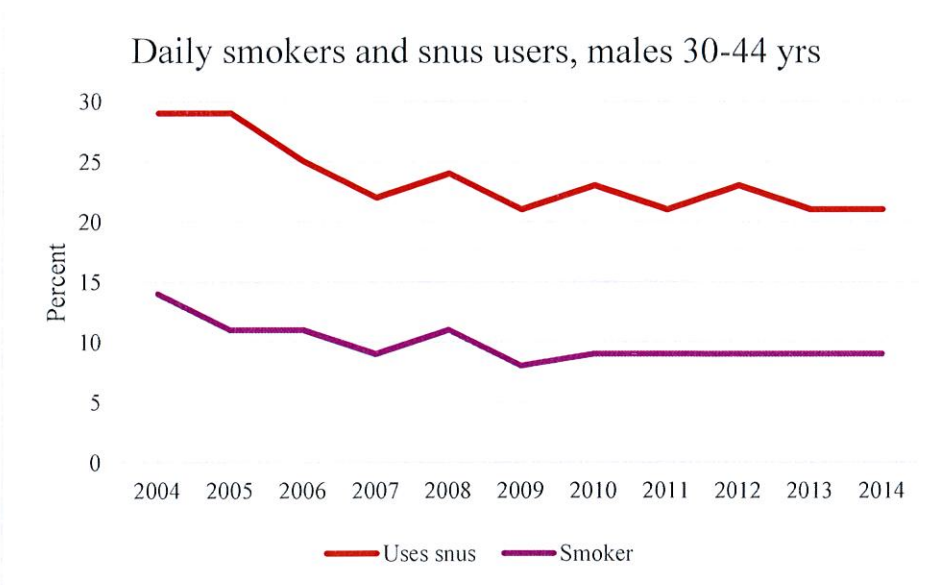


Figure 2b. The proportion of males 30 to 44 years of age that uses snus or smokes at a daily basis 2004-2014.

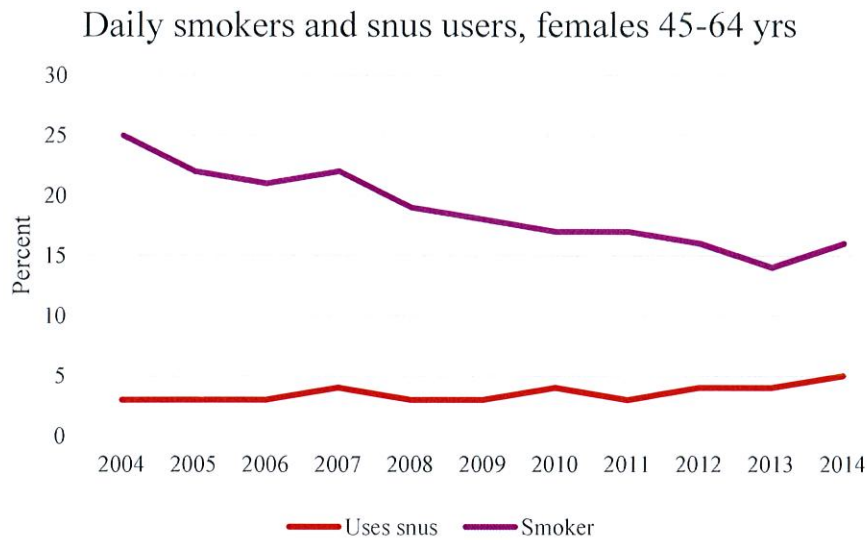


Figure 3a. The proportion of females 45 to 64 years of age that uses snus or smokes at a daily basis 2004-2014.

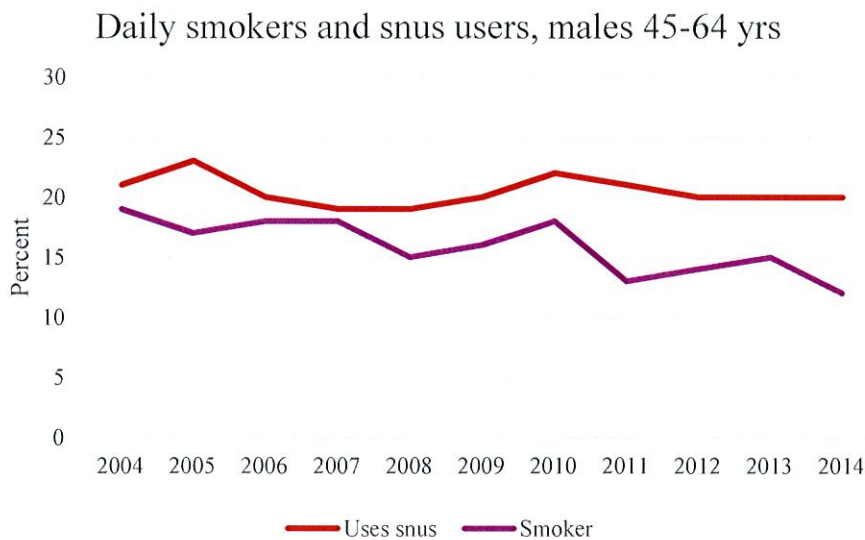


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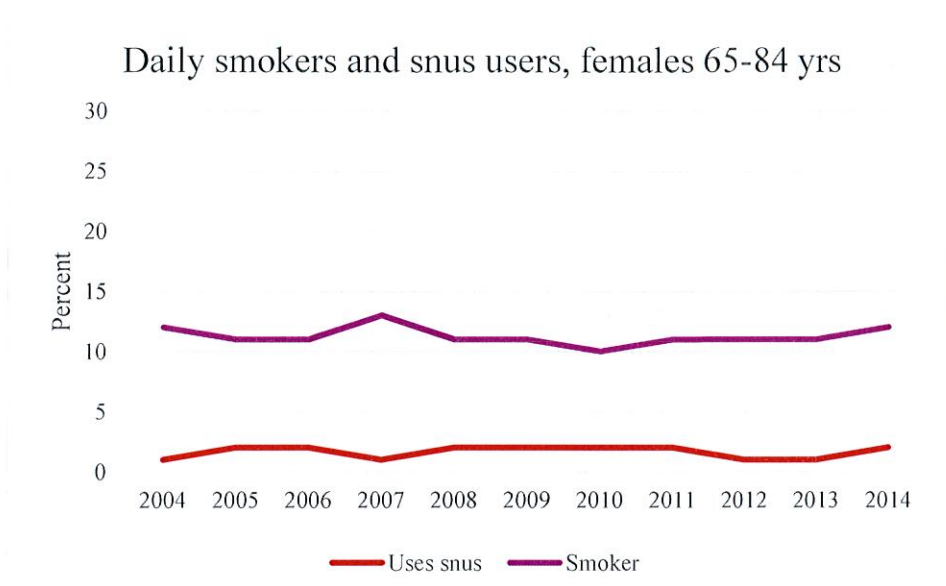


Figure 4a. The proportion of females 65 to 84 years of age that uses snus or smokes at a daily basis 2004-2014.

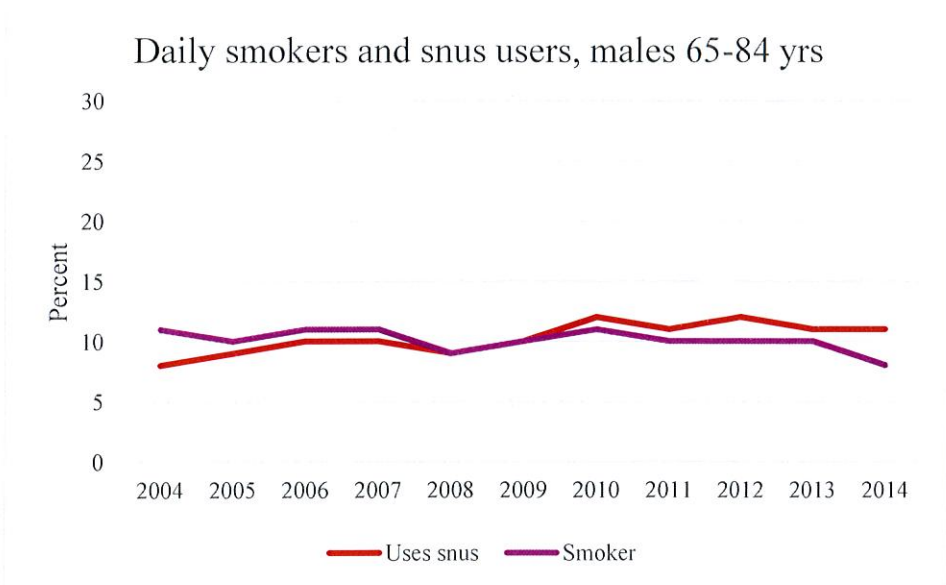


Figure 4b. The proportion of males 65 to 84 years of age that uses snus or smokes at a daily basis 2004-2014.

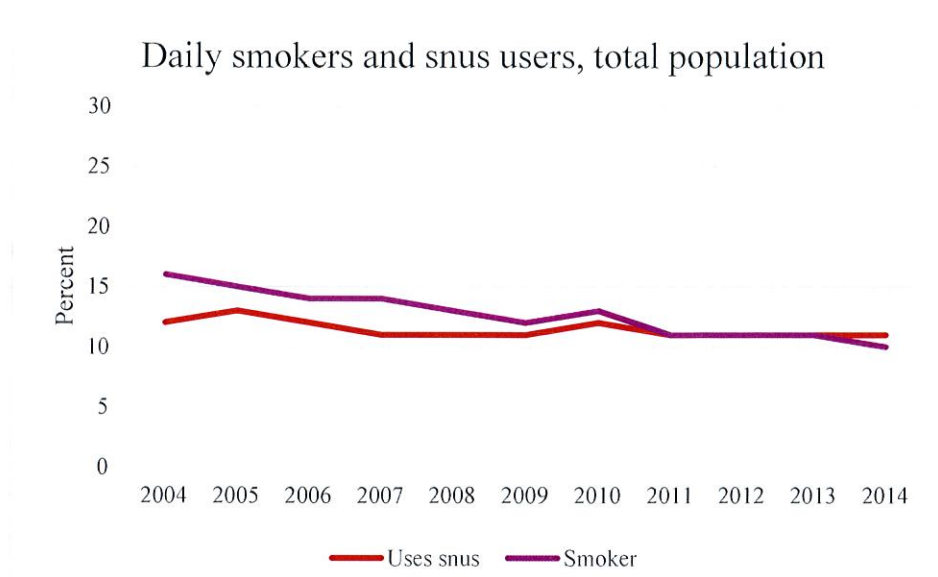


Figure 5. The proportion of the total population that uses snus or smokes at a daily basis 2004-2014.

Table 1. Smoking among daily snus users (2010–2014).

| Smoking habit among daily users of snus (%) | Men | Women |
|---|-----|-------|
| Never smoker                                | 41  | 32    |
| Daily smoker                                | 11  | 12    |
| Occasional smoker                           | 25  | 25    |
| Former smoker                               | 23  | 31    |

Source: National public health survey (“Health on equal terms”), Public Health Agency of Sweden.