

Improving the functioning of the internal market and the public health in the EU

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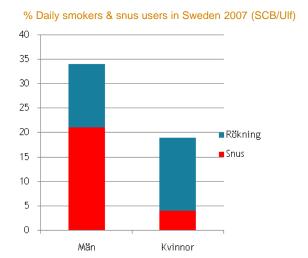
"The Swedish snus case" – a summary

- Swedish snus, a commonly used smokeless tobacco product predominately used in Scandinavia, especially in Sweden, is defined as an oral product and prohibited in the EU since 1992 with the permanent exemption of Sweden (2001/37/EC).
- Cigarettes and other types of smokeless tobacco products (including Asian/African-types) are allowed while Swedish snus, considered to be among the least harmful tobacco products, is prohibited.
- This discrimination and ultimate violation of the founding principle of free movement of goods within the EU is difficult to explain based on the established health risks associated with the long term use of Swedish snus.
- The Swedish Government questions the ban based on proportionality and discrimination.
- The ban is unpopular among the public in Sweden and has been a recurring issue in Swedish EU-elections
- The growth of the snus-category correlates with the record low smoking rate among men in Sweden.
- Several scientific studies attributes the record low incidence of tobacco related diseases and death among Swedish men (including oral cancer) to the availability of Swedish snus

"The Swedish snus case" – a summary

- The current regulation on tobacco causes severe distortions of competition between ferries on the Baltic Sea as well as significant economic losses for the autonomous island of Åland
- Manufacturers of snus employ more than 1 200 persons in Sweden
- It is estimated that approx. 200 million EUR have been invested in production and R&D in Sweden since 2000
- The tobacco tax on snus in Sweden generates annually 200 million EUR
- The consumer value of snus within Swedish trade is worth 660 million EUR
- Swedish Match welcome a non-competitive product regulation based on consumer protection and the principle of food standards i.e.. maximum permissible levels for certain compounds

Swedish snus

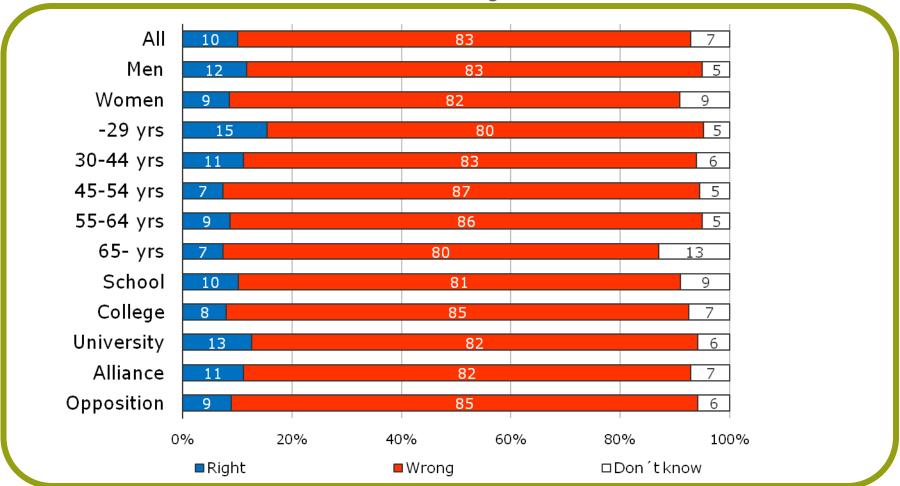




- Has been consumed since the mid 1800s
- Is "pasteurized", made up of air-cured tobacco, salt and water
- Regulated in Sweden by the Food Act
- Also referred to as "low nitrosamine smokeless tobacco"
- Commonly used in Scandinavia (more commonly used than cigarettes in Sweden)
- Used daily by approximately 1 million Swedes
 - About 50 percent of current snus users are former cigarette smokers
 - More than 20 percent of the male population use snus daily
 - Among women, about 4 percent use snus daily
 - A significant number of scientific studies suggests that the record low smoking prevalence among Swedish men is due to the availability of Swedish snus

Opinion in Sweden against the prohibition

Is it right or wrong that the trade with snus within the EU is treated differently than with wine and cigarettes?



Current EU Legislation – the Framework

- The internal market shall comprise an area without internal frontiers in which the free movement of goods, persons, services and capital is ensured in accordance with the provisions of the Treaties. (art. 26.2)
- ...shall not preclude prohibitions or restrictions on imports, exports or goods in transit justified on grounds of public morality, public policy or public security... Such prohibitions or restrictions shall not, however, constitute a means of arbitrary discrimination or a disguised restriction on trade between Member States. (art. 36)
- A high level of human health protection shall be ensured in the definition and implementation of all Union policies and activities...(art. 168)

Current EU Legislation - 2001/37

The Tobacco Product Directive 2001/37

- Article 2.4, Definitions: "Tobacco for oral use" defined as "all products for oral use, except those intended to be smoked or chewed, made wholly or partly of tobacco, in powder or particulate form or in any combination of these forms particularly those presented in sachet portions or porous sachets or in a form resembling a food product"
- Article 8, Tobacco for oral use states that "Member States shall prohibit the placing on the market of tobacco for oral use....."
- Art 11, oblige the Commission to review "tobacco products which may have the potential to reduce harm"

Health effects of Swedish snus are well analysed

- In 2001 the EU changed the warning text on snus from "Causes Cancer" to "This tobacco product can damage your health and is addictive"
- The EU's Scientific Committee (SCENIHR) in February 2008 published an evaluation of the health effects of smoke-free products and Swedish snus:
 - Snus use is significantly less harmful to health than smoking
 - Snus use has been beneficial to Swedish public health
 - No link can be found between snus and oral cancer.
 - Snus can help smokers to quit smoking
 - Snus is not a gateway to smoking
- Public Health Statistics from Sweden support the above conclusions
- "For every snus user who takes up smoking there are four smokers who switch to snus when they give up smoking." ... "These results indicate that the net effects of the changed tobacco habits are positive in public health terms, since smoking is so much more dangerous to health than snus". Public Health Report 2005, Swedish National Board on Health and Welfare (Socialstyrelsen).

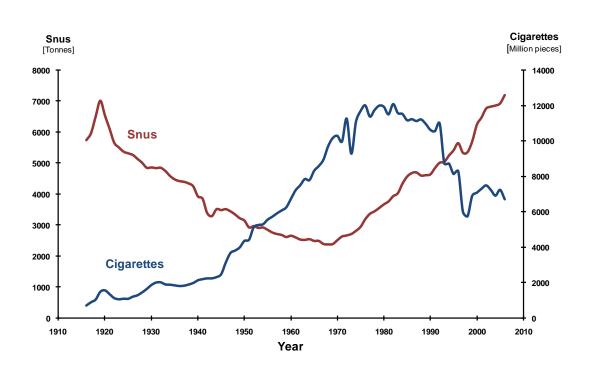
"The Swedish Experience"

Swedish men the past fifty years....

- Europe's highest per capita consumption of smokeless tobacco (snus).
- Lowest cigarette consumption in Europe.
- Lowest lung cancer mortality in Europe.
- Lowest percentage of smoking-related deaths among developed countries.
- Lowest oral cancer mortality rate in Europe.
- The Swedish females constitute the "control group".
- This paradox has often been referred to as the "Swedish Experience" in the scientific community.

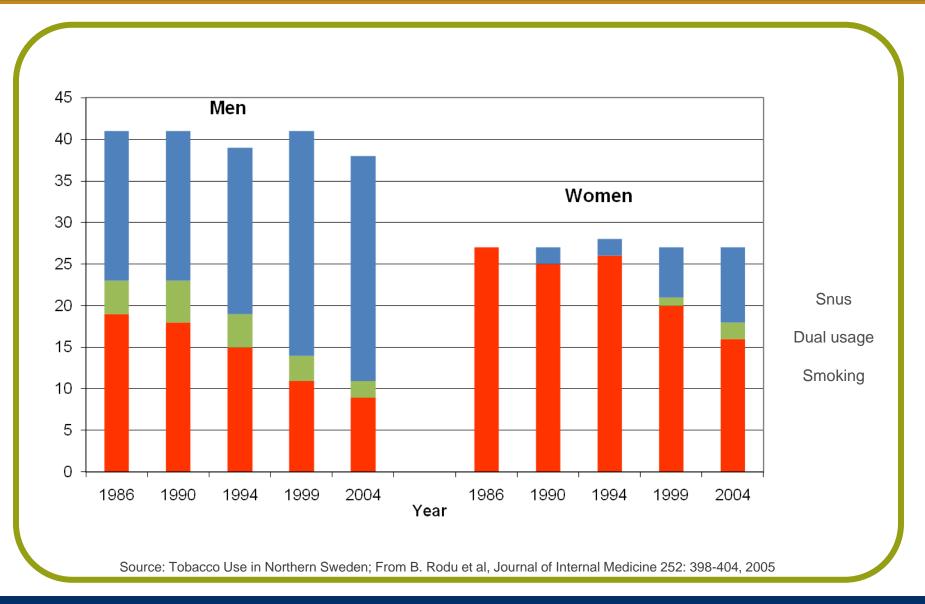
Snus vs. cigarettes in Sweden

Sales of snus and cigarettes in Sweden 1916-2007

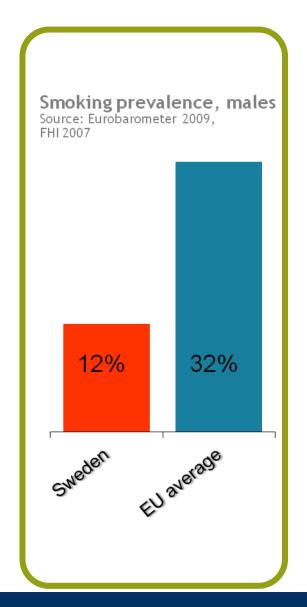


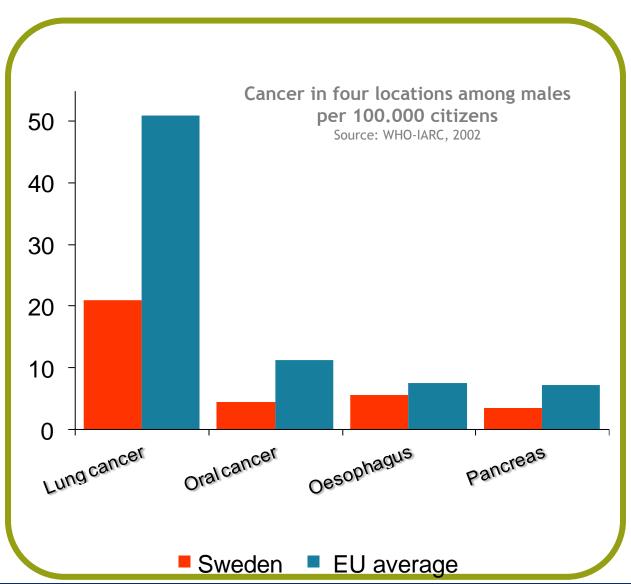
- 43 percent of all daily snus users are exsmokers
- ~ 40 percent of all male daily snus users are ex-smokers
- ~ 60 percent of all female daily snus users are ex-smokers

The movement from cigarettes to snus in Sweden

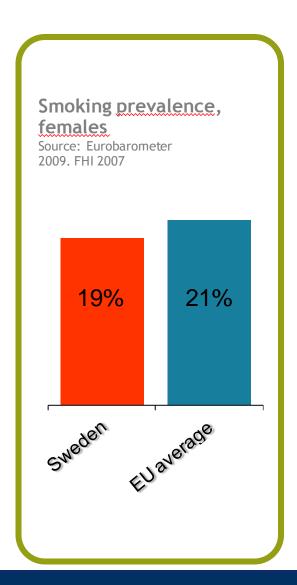


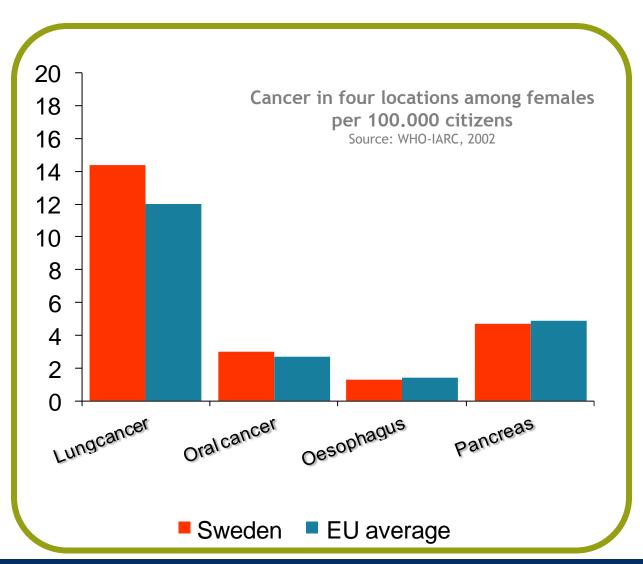
Smoking- and cancer incidence, males

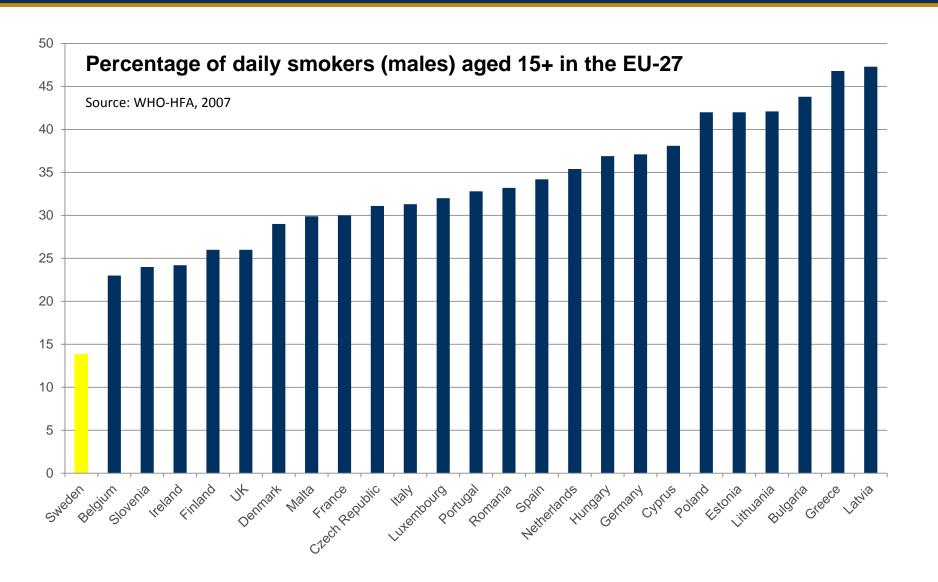


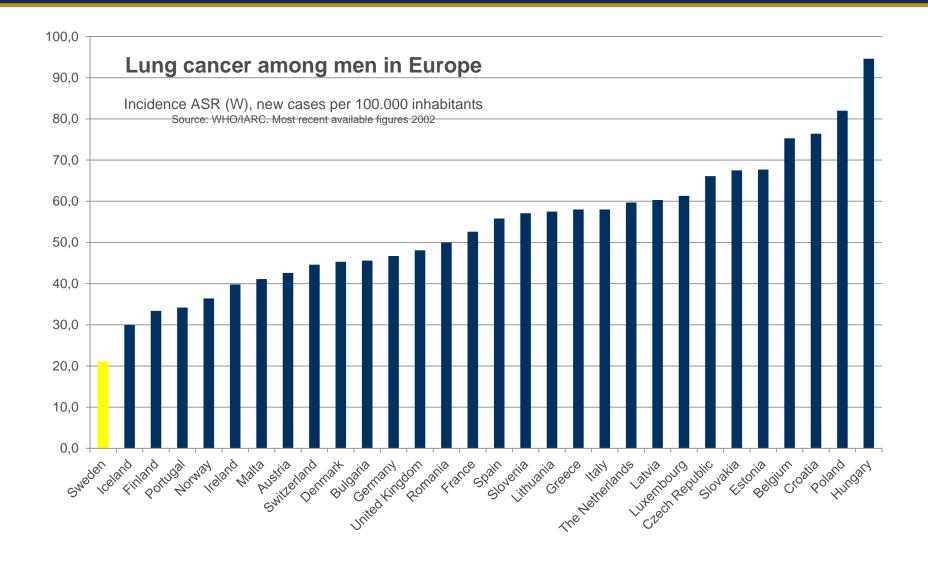


Smoking- and cancer incidence, females

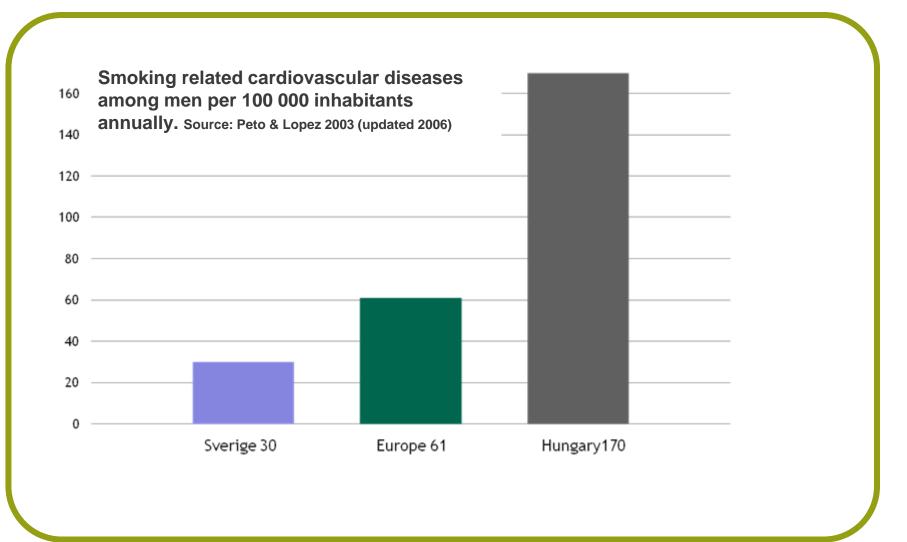








Incidence of cardiovascular diseases, males



WHO Tob.Reg. Report

"Cigarette smoke is the most hazardous form of nicotine intake, and medicinal nicotine is the least hazardous. Among the smokeless tobacco products on the market, products with low levels of nitrosamines, such as Swedish snus, are considerably less hazardous than cigarettes, while the risks associated with some products used in Africa and Asia approach those of smoking."

"The differences in risks 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."

In the era of better regulation...

- The Commission (Sanco) is reviewing the directive:
 - ¬ Scenihr report on "Health effects of smokeless tobacco products" was published in 2008
 - Impact Assessment being finalised
 - Public and stakeholder consultations is expected end of September 2010
- The Commission published 27 May 2010 a Q/A on the fight against tobacco in the EU, question 7 jumps out:
 - Q: Will the Commission propose lifting the ban on oral tobacco/snus?
 - A: Snus is a smokeless tobacco product. It is a moist snuff which is placed under the lip for extended periods of time. The sale of snus is illegal in the European Union. Sweden is the only country in the EU that is exempt from this ban. The derogation was granted on condition that Sweden shall take all the necessary measures to ensure that snus is not placed on the market in other Member States.

The opinion of the Scientific Committee on Emerging and Newly Identified Health Risks (SCENIHR) of February 2008 states that snus is a harmful product. This opinion calls for a very cautious approach; there are currently no plans to lift the ban.

Unclear rational for maintaining a total ban

Replacing the ban with a Smokeless Tobacco Regulation

Swedish Match proposes a <u>science based non-competitive</u> product regulation. The guiding principles for such a regulation should be based on <u>common food standards</u>, <u>product quality</u> and <u>consumer protection</u>. The proposed regulation includes (but not limited to):

Maximum permissible levels of certain compounds that are perceived to be harmful to health

- Reporting requirements for nicotine
- Food approved flavouring substances only
- Reporting requirements for non-tobacco materials
- Packaging materials according to food standards
- Certain labelling and consumer information requirements
- Ingredients reporting system

"The moist snuff (snus) currently manufactured, marketed and used in Sweden has been well studied and is produced to a standard that results in a lower nitrosamine content"

WHO Study Group on Tobacco Product Regulation, WHO Technical Report Series 955, 2010