

# Harm reduction needs to be a key element of the FCTC tobacco Product Guideline

## The issue

The World Health Organisation (WHO) has started work on developing guidelines for tobacco product regulation as part of the Framework Convention on Tobacco Control (FCTC) process, and intends to present a progress report at the second meeting of the FCTC Conference of the Parties (COP) in July this year.

British American Tobacco supports public health NGOs, academics, civil society and others that hold the view that the FCTC does not establish pragmatic approaches to harm reduction as a means to reduce the global public health impact of tobacco use and, therefore, that it is essential that the concept of harm reduction become a clearly stated aim of future Product Guideline policy development.

It is remarkable that the world's first international health treaty, which opens with a statement of the need to "give priority to the right to protect public health", fails to include the need to reduce the harm of the product in the protection of public health.

Benjamin Mason Meier, JD, LLM and Donna Shelley MD, MPH at the Centre for Health Policy at Columbia University New York, state in their paper **The Fourth Pillar of the FCTC: Harm Reduction and the International Human Right to Health (October 2006)** "while successful in its execution [the FCTC] fails to acknowledge the harm reduction strategies necessary to help those incapable of breaking their dependence on tobacco" and "... the international right to health supports a harm reduction approach to tobacco control, and that working under the FCTC Framework countries should create international mechanisms to research and regulate harm reduction products and programs."

While there is no doubt that cessation of tobacco product use would deliver the most beneficial impact on public health, it is unrealistic to assume that this will happen. In fact, WHO publications and statistics predict that in coming years the number of smokers worldwide (currently 1.1 billion) will rise despite many years of global anti-tobacco activity. Harm reduction policy recognises that those who choose to continue to smoke despite awareness of the risks are given the opportunity or the right to have the potential harm reduced.

The member governments of the WHO that have ratified or acceded to the FCTC are tasked with developing future international public policy on tobacco product regulation – we add our voice to all of those who believe that product harm reduction concepts and opportunities for research should be placed squarely at the centre of FCTC Product Guideline developments, and we call on them to ensure that this is made possible.

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## Background

It was agreed by the FCTC COP (comprised of the WHO member states that have ratified the FCTC) at its first meeting in 2006 to proceed with elaborating guidelines for governments to meet their obligations for FCTC Articles 9 and 10 – the regulation of the contents and emissions of tobacco products.

The WHO, its relevant internal bodies and representatives of its members have been meeting over the past year to outline progress toward establishing a future regulatory framework for tobacco products to present to the second FCTC COP meeting in Bangkok in June/July 2007.

The FCTC does not deal with the specifics of product regulation or harm reduction. However, the FCTC Preamble (the overriding principles of the treaty) states that the Parties to the Convention are "Determined to promote measures of tobacco control based on current and relevant scientific, technical and economic considerations..."

The FCTC then goes on in Article 1 to define tobacco control as meaning "...a range of supply, demand and harm reduction strategies that aim to improve the health of a population by eliminating or reducing their consumption of tobacco products and exposure to tobacco smoke". Despite this specific reference of direction, the FCTC Product Guideline being developed is being done so in a vacuum of any harm reduction strategy.

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## What is harm reduction?

In a general sense, harm reduction relates to lessening the harm associated with risky products or risk taking behaviour without complete abstinence from that product or behaviour. For example, the giving of clean syringes to heroin addicts, or the provision of condoms to prevent the spread of AIDS, are both controversial and difficult policy areas where governments have moved from considering only a traditional cessation policy approach to a more rational coupling with a harm reduction policy approach in the interests of public health.

In relation to the concept of tobacco harm reduction, Nigel Gray and Jack Henningfield, both leading tobacco control experts, defined it in **The Lancet (Volume 368, September 2006)** as follows: *“In tobacco control, harm reduction can be reasonably defined as any process or programme that reduces harm in continuing users of tobacco. Thus the term can be applied to methods for reducing toxins in tobacco smoke by setting upper limits on them, to programmes promoting the conversion of continuing smokers to smokeless tobacco, or to the long-term complete substitution of nicotine as replacement therapy for tobacco.”*

R.B. Wallace of the **US Institute of Medicine**, in his **Testimony to the US House of Representatives (2003)**, defined tobacco harm reduction as *“decreasing the burden of death and disease, without completely eliminating nicotine and tobacco use.”*

Tobacco harm reduction policy recognises that those who choose to continue to smoke despite awareness of the risks are given the opportunity or the right to have access to potential harm reduced products. Success depends on meeting consumers’ needs for less harmful tobacco products, as well as scientific and public health recognition of the role of such products and regulatory frameworks that support such products.

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## Expanding the Product Guideline remit

The product related articles in the FCTC (Articles 9 and 10) only focus on the regulation of the contents and emissions of tobacco products. Such a narrow focus fails to take into account whether an accepted emission measurement scheme can be correlated to risks and, if so, how such information can be conveyed to consumers to assist in their product selection process.

Extensive epidemiology literature exists that compares the health risks for smokeless products, such as Swedish-style snus, to combustible products. Also, epidemiological evidence correlates a reduction in risk with a reduction in exposure as measured by the International Organisation for Standardisation (ISO) tests. Correlating improved human exposure estimates with risk from studies of tobacco products in use today may provide an important and useful basis for risk communications about the entire range of tobacco products. These communications are important for informed decision making, which underlies a pragmatic harm reduction policy. This is recognised by the **US Institute of Medicine’s** Regulatory Principle 5 in its 2001 report **Clearing the Smoke**.

Along with many public health advocates, British American Tobacco believes that development of future tobacco product regulation taking place through the FCTC process should not be narrowly defined – it should include the full range of tobacco products. Guidelines should include provision for scientific research and evaluations of the range of tobacco products, including evaluations of smokeless categories in terms of potential harm reduction. It is not an option which the WHO or the FCTC COP should ignore.

In terms of reducing the harm from tobacco product use, the FCTC Product Guidelines should focus on reduction of specific constituents in cigarette smoke and the general reduction of harmful smoke exposure, as well as consider evaluations of smokeless categories such as Swedish-style snus. The following information on each of these three areas provides a short explanation of why we believe this is important.

## Smokeless Tobacco (“Swedish-style Snus”)

The inclusion of smokeless tobacco products in a regulatory framework is essential. Swedish-style snus is an example of a smokeless tobacco product. It is comprised of finely ground heat pasteurised tobacco in a mini tea-bag like sachet that is placed into the mouth between the gum and the lip, and which delivers nicotine and flavour to the consumer without any smoke. It has been available and used in Sweden for more than a century. The percentage of tobacco use among Swedes is similar to that in most European countries, yet Sweden has reached the WHO goal of reducing the percentage of smokers in the adult population to below 20%. Sweden has Europe’s highest consumption of smokeless tobacco but Europe’s lowest cigarette consumption, lowest male lung cancer mortality rate, lowest percentage of smoking related deaths among developed countries, and has among the lowest oral cancer mortality rate in Europe.

In 2002, the Tobacco Advisory Group of the **UK Royal College of Physicians** said that Swedish-style snus is “of the order of 10-10,000 times less hazardous than smoking, depending on the product.” In 2005, Nigel Gray noted in the public health journal **The Lancet** “so it is possible (however, reluctantly) to agree with BAT and Swedish Match that snus is a harm reduction product, but only when compared with a cigarette”.

Despite these and many other similar statements from members of the public health community, Swedish style snus is banned for sale in all EU countries apart from Sweden. **Article 8 of the EU Directive 2001/37 /EC** states that “Member States shall prohibit the placing on the market of tobacco for oral use...” However, the Directive review requirement (Article 11 review) obliges the Commission to pay special heed to, amongst other things, “evaluation of tobacco products which may have the potential to reduce harm”.

There are calls to lift the EU ban on smokeless tobacco products from diverse interests. At the UK National Smoking Cessation Conference held in June 2006, Amanda Sandford, **ASH Research Manager**, said “We would welcome a new report by an independent body into the possibility of lifting the ban on snus”. The **UK Royal College of Physicians** has stated “Some manufacturers want to market smokeless tobacco as a ‘harm reduction’ option...and they may find support for that in the public health community”.

It needs to be acknowledged that the use of smokeless products is addictive and not risk free. Nevertheless, independent public health bodies find that using Swedish-style snus is much less harmful than smoking cigarettes. Consumers have a right to know this and should have access to these snus products. Therefore, there needs to be a way for consumers to receive meaningful information in an environment where tobacco advertising is largely prohibited.

## Reduction of specific toxicants in cigarette smoke (“specific reduction”)

In simple terms, if selected harmful toxicants in smoke can be reduced or eliminated then it may be possible to produce a “less risky” cigarette.

This sounds simple enough but it is not. According to the **US Institute of Medicine’s** 2001 report, *Clearing the Smoke*, “...the challenge of potentially reduced exposure products (PREPs) is very demanding”. It goes on to suggest that to establish the science base for tobacco harm reduction the following two criteria need to be met –“(1) a product that results in the substantial reduction in exposure to one or more tobacco toxicants and (2) can reasonably be expected to reduce the risk of one or more specific diseases or other adverse health effects.”

But how can this be measured? There is currently no generally accepted or established methodology for measuring exposure to specific toxicants in tobacco smoke and correlating the exposure to risk.

## General reduction of tobacco smoke exposure (“general reduction”)

Prior to 2001, the public health and scientific consensus was that reduced yield products (cigarettes that reduce the smoke which goes into the smoker’s mouth) were accompanied with reduced risks for many diseases. This consensus was primarily based upon epidemiology studies that repeatedly reported that lower yield cigarettes, as determined by ISO test methodology, were associated with a reduced risk for lung cancer and other diseases.

Although the reductions in risk reported were significant, they were far less than the reductions that were achieved through cessation. For example, while combined analysis of epidemiology studies comparing higher tar cigarettes to lower tar cigarettes have demonstrated lung cancer risk reductions of 35-40%, cessation before middle age will produce 90% reductions in lung cancer risk.

In 2001, the consensus view about the correlation between reduced yield and reduced risk was challenged by the **U.S. National Cancer Institute’s Monograph 13** (*Risks Associated with Smoking Cigarettes with Low Machine-Measured Yields of Tar and Nicotine*). Based largely on a belief that human smoking behaviour eliminated any difference in ISO yield in cigarettes on the U.S. market, Monograph 13 concluded that the risk of lung cancer was not reduced as cigarette yields (as measured by the US Federal Trade

Commission or ISO tests) were reduced. The issue of human smoking behaviour and its relationship with ISO yield differences between products has been researched since 2001 by British American Tobacco and others. British American Tobacco is committed to such research and is using new and refined technologies for measuring human smoking behaviour.

Regardless of the results of the research, the fundamental understanding remains that a dose-response relationship exists between tobacco smoke and disease. The US **Institute of Medicine**, in its 2001 report **Clearing the Smoke**, observed that *“current knowledge of the dose-response relationship is sufficient to support risk reduction through exposure reduction as a goal for the individual through the use of these various products.”*

Therefore, if switching to a lower yield cigarette results in a reduction of daily exposure to cigarette smoke, this is likely to result in a decrease in risk. Accordingly, products that provide smokers with an opportunity to reduce their daily smoke exposure along with information about the risk significance of exposure reduction, approved by regulators, should be integral parts of a pragmatic harm reduction programme.

The proposed FCTC Product Guideline needs to ensure that measurement methodology and priorities on toxicant lists are based on sound science and an understanding of smoking behaviour and, in doing so, all factors need to be considered and all relevant interests included in deliberations, including those of tobacco industry scientists. Tobacco companies have not been included or consulted as part of this process to date, despite the fact that as manufacturers of tobacco products we know a lot about product science and smoking behaviour.

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## Other considerations

The issues associated with developing a future FCTC Product Guideline are many and varied and, while currently the focus is on the regulation of the contents and emissions of tobacco products, if governments are to take up the opportunity to include harm reduction more centrally in the remit then there are other related issues which need to be considered, such as:

- How are less harmful tobacco products to be taxed? Should tax policy surrounding less harmful products be developed with a view to encouraging consumers to choose lower risk products including smokeless products?
- How do consumers get to know about the varying risks among tobacco products without advertising or communications? What will be the process for developing, approving and monitoring consumer communication? Is there a place for existing cigarette brands to encourage consumers to change from one product category to another that is deemed less harmful?
- How do governments ensure that a balance is achieved between cessation and more pragmatic harm reduction policies?
- How do governments prevent their harm reduction policies being undermined by illicit products?

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## Our view

British American Tobacco understands the obligations taken on by governments in ratifying the FCTC to address the public health issues they face – and we support sensible and pragmatic guidelines for the regulation of tobacco products.

We are a commercial entity and we need to continue to deliver value to our shareholders and provide a portfolio of products which consumers want to purchase.

We believe that, where possible, if we can lower or eliminate any health risks without impacting on the valued attributes of our products, it is our duty to do so. At present, British American Tobacco is working on defining exposure methodologies by developing more realistic estimates of human smoking as part of our internal harm reduction approach. But we believe the best outcome could be accomplished if all key stakeholders can work together.

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## What can FCTC COP member governments do?

COP member governments that believe a harm reduction concept and approach is important to include in the development of future tobacco product regulation could ask the WHO working group on the FCTC Product Guideline to include this as an essential part of a regulatory framework.

There are many and varied views on what should be included in the tobacco harm reduction remit. Many tobacco control advocates feel that the FCTC regulatory focus on a prevention, protection and cessation policy misses the fourth important “pillar” or dimension of tobacco control, namely harm reduction.

If the tobacco harm reduction concept and approach were to be included at this stage of the development of the FCTC Product Guideline, it would enable the COP working group to discuss and debate the parameters of what many commentators believe is this missing fourth pillar of the FCTC.

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## Further information

We are happy to elaborate further with any interested party. For further information on British American Tobacco’s views on the FCTC, or to arrange to discuss details of our harm reduction approach with our scientific experts, please contact Jeannie Cameron at [jeannie\\_cameron@bat.com](mailto:jeannie_cameron@bat.com)

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