WHAT'S NEXT?

The world's leading regulatory agencies are deciding how to deal with potentially reduced-risk tobacco products.

By Jeannie Cameron

Three significant health regimes are presently considering reduced-risk tobacco products, which include noncombustibles and nicotine-delivery products. The outcome of these regulatory reviews will likely drive forward future policy in these areas, and it is worth knowing what, specifically, is on the agenda.

At the fifth Conference of the Parties to the World Health Organization's Framework Convention on Tobacco Control (CoP5) in November 2012, participants agreed to further develop the partial guidelines for the implementation of articles 9 and 10 of the FCTC. These articles deal with the contents of tobacco products and tobacco product disclosure. In addition, the CoP parties agreed to consider the control and prevention of smokeless tobacco products and electronic nicotine-delivery systems.

In December 2012, the European Commission released its review of the European Tobacco Products Directive of 2001, which is to include smokeless, oral, novel and nicotine-delivery devices.

Also in December 2012, the U.S. Food and Drug Administration called for comments and scientific evidence for its consideration of smokeless tobacco product warning statements. Submissions must be made before April 1, 2013.

The WHO

The FCTC defines tobacco products as: "... products entirely or partly made of the leaf tobacco as raw material, which are manufactured to be used for smoking, sucking, chewing or snuffing." This includes cigarettes, smokeless and oral tobacco—in a sense, "tobacco in all its forms." The 193 FCTC negotiating governments adopted this definition, but things have moved on since then.

E-cigarettes were first discussed in 2008, during the second session of the Intergovernmental Negotiating Body (INB) on the Protocol on Illicit Trade in Tobacco Products. At the time, the chair of the illicit trade negotiations, Ian Walton George, asked for the INB to receive a brief description of e-cigarettes so the negotiators could understand what they were, even though e-cigarettes were not officially part of the discussions.

However, by the time of CoP3, in 2009, the WHO was asked to produce a report on smokeless tobacco and e-cigarettes on the basis that the FCTC related to all tobacco products, even though the focus had been only on cigarettes.

At CoP4, in 2010, the CoP secretariat and the WHO Tobacco Free Initiative were asked to prepare a comprehensive report on these topics, based on the experience of the parties, for presentation at CoP5 in 2012. This was provided by the WHO Study Group on Tobacco Product Regulation and subsequently in two reports of the CoP: "Control and prevention of smokeless tobacco products" and "Electronic nicotine-delivery systems including e-cigarettes."

The report on smokeless tobacco called for more research because of the great diversity in appearance, composition and toxicity levels among products. The report recommended regulating all products that deliver nicotine for human consumption, and regulating smokeless tobacco products by controlling the contents of the products.

The report on electronic nicotine-delivery systems concluded that the safety and efficacy of e-cigarettes had not been established, and, therefore, a regulatory framework was needed to address the concerns. The major issues related to whether e-cigarettes "imitated" smoking,

whether the vapor was toxic to lungs, and whether they should be regulated as tobacco products or pharmaceuticals, or be banned.

In order to address these concerns, CoP5 agreed the CoP secretariat would invite the WHO to:

- identify, examine and collect existing best practices on prevention and control of smokeless tobacco products
- collate existing research, explore the research gap and identify the research areas that need to be focused upon
- identify options for the prevention and control of smokeless tobacco products and electronic nicotine-delivery systems
- examine emerging evidence on the health impacts of electronic nicotine-delivery systems use and report on the outcome of these findings to CoP6 (scheduled to take place in Moscow in December 2014)

In addition to being considered by the WHO in the run-up to CoP6, these areas are also going to be considered in the context of further development of the FCTC guidelines for the implementation of articles 9 and 10.

At CoP5, participants agreed to invite the WHO to prepare a comprehensive report in time for CoP6 that identifies measures that would be likely to reduce the toxicity of both smoked and smokeless tobacco products, and describes the evidence supporting the effectiveness of such measures; monitors the evolution of new tobacco products, including products with potentially "modified risks"; and outlines aspects of addictiveness of both smoked and smokeless tobacco products.

It was also decided that the FCTC product working group would identify which analytical chemical methods for the testing and measuring of cigarette contents and emissions should be extended to include tobacco products other than cigarettes. Under the CoP rules of procedure, these draft reports need to be made available to the secretariat for comments by the parties at least six months before the opening day of CoP6, which means this area of future tobacco-product regulation work is currently underway.

The EU

At present, the EU regulates tobacco products under the 2001 Tobacco Products Directive, which defines tobacco products as those for the "purpose of smoking, sniffing, sucking or chewing." Oral tobacco products are defined as "products for oral use, except those intended to be smoked or chewed, made wholly or partly from tobacco, in powder or particulate form ... particularly those presented in sachet portions ... or in a form resembling a food product."

Tobacco products for oral use and smokeless tobacco products are required to carry health warnings stating, "This tobacco product can damage your health and is addictive," in the relevant language or languages. However, oral tobacco products are banned in all EU member states except Sweden, where snus has been used for more than 300 years.

At the request of the EU, the EU Standing Committee on Emerging and Newly Identified Health Risks (SCENIHR) investigated whether smoke-free products, including Swedish snus, have a potentially risk-reducing effect.

In its final report, published on Feb. 18, 2008, SCENIHR confirmed Swedish snus has scientifically substantiated risk-reducing effects and established there is no scientific support for a continued ban on the product within the EU. Specifically, the expert committee confirmed that using snus is significantly less harmful than smoking; that a smoker who switches to snus will significantly reduce his/her risk of contracting tobacco-related illnesses; and that access to snus has had positive effects on Swedish public health.

The SCENIHR committee was asked to pay particular attention to tobacco for oral use, moist snuff and Swedish snus, but it considered other smokeless tobacco products as well. The report states that different types of smokeless tobacco products are used around the world and that their health risks vary considerably. It states that smokeless tobacco comes in two main forms—snuff and chewing tobacco. Snuff comprises finely ground or cut tobacco leaves that can be dry or moist and are packed either loose or in sachets. It is administered either to the mouth or to the nose. Chewing tobacco comprises loose leaf or pouches of tobacco leaves in "plug" or "twist" form.

The report found smokeless tobacco delivers quantities of nicotine comparable to those typically absorbed from cigarette smoking. However, smokeless tobacco products deliver nicotine slower than do cigarettes and may therefore have less potential to addict their users.

Nicotine levels obtained from smokeless tobacco are generally higher than those typically obtained from nicotine-replacement therapy, which is considered to have a low-addiction potential. The general conclusion of SCENIHR is that smokeless tobacco products are addictive and their use is hazardous to health. Smokeless tobacco products contain various levels of toxic substances. Evidence on the effectiveness of smokeless tobacco as a smoking cessation aid is insufficient. Trends in the progression from smokeless into, and away from, smoking differ between countries. Societal differences make it impossible to extrapolate the patterns of tobacco use from one country to another.

SCENIHR reported that, for an individual, substitution of smoking by the use of smokeless tobacco products would probably decrease the incidence of some tobacco-related diseases. There is, however, insufficient evidence available on smokeless tobacco's efficacy as a quit-smoking aid. There are concerns smokeless tobacco can cause dependence, which may lead to subsequent cigarette smoking.

At the end of 2012, the EU announced a review of its EU 2001 Tobacco Products Directive. Like the WHO, it is beginning to establish regulatory frameworks for smokeless

tobacco and electronic nicotine-delivery systems. The rationale for the revision is that, since the adoption of the directive in 2001, the tobacco products market has increasingly diversified, and the directive does not cover electronic nicotine-delivery systems despite them being generally marketed as alternatives to smoking.

Some member states classify e-cigarettes that contain nicotine as pharmaceutical products. This means they cannot be put on the market unless they have proven efficacy, safety and quality as pharmaceutical products. However, in other member states, electronic nicotine-delivery systems are marketed as consumer products without prior authorization or safety checks. Nicotine drinks and sweets fall under food regulations, and the directive excludes cigarette-like products that do not contain tobacco, such as herbal cigarettes, yet have harmful effects similar to those of regular cigarettes. In addition, the current regulatory framework bans some smokeless tobacco products (snus) while others (chewing tobacco) are freely available in many member states. The legislation of member states to classify or regulate these products varies and all this has led to uncertainty, requiring a revision.

Article 1 of the new draft calls for the prohibition of oral tobacco, thereby effectively continuing the ban on Swedish snus outside of Sweden. Tobacco for oral use is defined as "all tobacco products for oral use, except those intended to be inhaled or chewed, made wholly or partly of tobacco, in powder or in particulate form or in any combination of those forms, particularly those presented in sachet or porous sachets."

Another aim is to create a "notification obligation" for new tobacco products, thereby opening a window of opportunity for these products, so long as member states are notified. A novel tobacco product is defined as "a tobacco product other than a cigarette, roll-your-own tobacco, pipe tobacco, water-pipe tobacco, cigar, cigarillo, chewing tobacco, nasal tobacco or tobacco for oral use."

A further aim is to regulate the marketing and labeling of certain tobacco-related products—namely nicotine-containing products and herbal products for smoking. Nicotine-containing products are defined as products "usable for consumption by consumers via inhalation, ingestion or in other forms, and to which nicotine is either added during the manufacturing process or self-administered by the user before or during consumption."

Regardless of the product definition, health warnings on tobacco products are to be determined by whether a tobacco product is combustible or smokeless. A smokeless tobacco product is defined as "a tobacco product not involving a combustion process, including chewing tobacco, nasal tobacco and tobacco for oral use." Therefore, even in member states allowing oral tobacco (Sweden), the product must carry a health warning stating it can damage health and is addictive.

Novel tobacco products are also required to carry health warnings on the basis of whether they are combustible or smokeless. Nicotine-containing products are required to carry the health warning, "This product contains nicotine and can damage your health."

The FDA

The FDA obtained regulatory authority over tobacco in 2009. The FDA definition of smokeless tobacco is narrower than that of the EU: The agency defines smokeless tobacco as any tobacco product that consists of cut, ground, powdered or leaf tobacco and that is intended to be placed in the oral or nasal cavity. Just recently, the FDA called on interested parties to provide input by April 1, 2013, regarding smokeless tobacco product warnings.

The objective is to ascertain what changes would promote a greater public understanding of the risks associated with the use of smokeless tobacco products. At present, e-cigarettes that are marketed for therapeutic purposes are regulated by the FDA Center for Drug Evaluation and Research. The FDA Center for Tobacco Products intends to regulate other nicotine-containing products, including e-cigarette products that do not make a therapeutic claim, in the future.

Unlike the WHO and the EU, the FDA recognizes modified risk. While certain provisions must be met, the Tobacco Act accepts tobacco harm reduction conceptually. Section 911 defines a modified-risk tobacco product as any tobacco product that is sold or distributed for use to reduce the harm or the risk of tobacco-related disease associated with commercially marketed tobacco products.

Such a product would have to meet certain criteria, such as present a lower risk of tobacco-related disease or be less harmful than one or more other commercially marketed tobacco products; contain a reduced level of a substance or present a reduced exposure to a substance; or be free of a given substance altogether.

Prior to marketing such products, manufacturers are required to demonstrate that such products will meet a series of rigorous criteria and will benefit the health of the population as a whole, taking into account both users and non-users of tobacco products.

Tobacco policy and regulation has come a long way in the 10 years since the adoption of the FCTC, but it still has a long way to go. Certainly there are political influences at play when there should be more science involved. For example, why are e-cigarettes permitted while snus has been banned in most jurisdictions—even though there's little known about the health risks of e-cigarettes, but significant evidence suggesting snus use is less harmful than tobacco smoking?

What is needed is a full-risk continuum for tobacco and nicotine products in order to demonstrate harm-reduction strategies and develop a global regulatory regime. The FDA recognizes the concept and the EU keeps the door cracked in terms of the proposal for notification for novel products. While not budging from its tobacco-is-harmful-in-all-forms mantra, the WHO, at least, has discussion pending for CoP6. TR