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Preface

In November 2003, the WHO Director-General formalized the Scientific Advisory Committee on Tobacco Product Regulation (SACTob) by changing its status to that of a study group. Following the status change, the SACTob became the "WHO Study Group on Tobacco Product Regulation" (TobReg). It is composed of national and international scientific experts on product regulation, tobacco dependence treatment, and laboratory analysis of tobacco ingredients and emissions. Its work is based on cutting edge research on tobacco product issues. It conducts research in order to fill regulatory gaps in tobacco control. As a formalized entity of WHO, TobReg reports to the Executive Board through the Director-General in order to draw the Member States' attention to WHO's efforts in tobacco product regulation. This recommendation was approved and adopted by TobReg during its first meeting on 26 to 28 October 2004 in Montebello, Canada.

WHO Study Group on Tobacco Product Regulation

Recommendation 1: Guiding Principles for the Development of Tobacco Product Research and Testing Capacity and Proposed Protocols for the Initiation of Tobacco Product Testing

Background and purpose

This recommendation is the first formulated by the WHO Study Group on Tobacco Product Regulation (TobReg).[1] The purpose of this recommendation is to promulgate the principles that should guide the development of the laboratory capacity required to enable implementation of Articles 9, 10 and 11 of the WHO Framework Convention on Tobacco Control and the initiation of tobacco product testing. Such laboratory capacity provides government regulatory authorities with the means to guide and validate tobacco product testing, including any testing that may be carried out by the tobacco industry itself. The considerations and principles discussed in this recommendation are intended to provide guidance for establishing laboratory capacity that meets the highest standards of excellence, transparency, reliability and credibility.[2]

The WHO Framework Convention on Tobacco Control includes three articles that lay the groundwork for the regulation of the contents, disclosures, and packaging and labelling of tobacco products (*1*). They are:

- Article 9: Regulation of the contents of tobacco products
- Article 10: Regulation of tobacco product disclosures
- Article 11: Packaging and labelling of tobacco products.

> **Article 9: Regulation of the contents of tobacco products.** The Conference of the Parties, in consultation with competent international bodies, shall propose guidelines for testing and measuring the contents and emissions of tobacco products, and for the regulation of these contents and emissions. Each Party shall, where approved by competent national authorities, adopt and implement effective legislative, executive and administrative or other measures for such testing and measuring, and for such regulation.

[1] For details of the five recommendations formulated by the former WHO Scientific Advisory Committee on Tobacco Product Regulation (SACTob) , see references 12–16.

[2] The various regulatory strategies and considerations discussed in the publications listed in references *2–10* provide useful background information for the present recommendation. The reports and recommendations previously published by WHO and the publications of other institutions that are listed in references *11–20* form the basis of the present recommendation and therefore make essential background reading.

Article 10: Regulation of tobacco product disclosures. Each Party shall, in accordance with its national law, adopt and implement effective legislative, executive, administrative or other measures requiring manufacturers and importers of tobacco products to disclose to governmental authorities information about the contents and emissions of tobacco products. Each Party shall further adopt and implement effective measures for public disclosure of information about the toxic constituents of the tobacco products and the emissions that they may produce.

Article 11: Packaging and labelling of tobacco products

1. Each Party shall, within a period of three years after entry into force of this Convention for that Party, adopt and implement, in accordance with its national law, effective measures to ensure that:

    (a) tobacco product packaging and labelling do not promote a tobacco product by any means that are false, misleading, deceptive or likely to create an erroneous impression about its characteristics, health effects, hazards or emissions, including any term, descriptor, trademark, figurative or any other sign that directly or indirectly creates the false impression that a particular tobacco product is less harmful than other tobacco products. These may include terms such as "low tar", "light", "ultra-light", or "mild"; and

    (b) each unit packet and package of tobacco products and any outside packaging and labelling of such products also carry health warnings describing the harmful effects of tobacco use, and may include other appropriate messages. These warnings and messages:

        (i) shall be approved by the competent national authority,
        (ii) shall be rotating,
        (iii) shall be large, clear, visible and legible,
        (iv) should be 50% or more of the principal display areas but shall be no less than 30% of the principal display areas,
        (v) may be in the form of or include pictures or pictograms.

2. Each unit packet and package of tobacco products and any outside packaging and labelling of such products shall, in addition to the warnings specified in paragraph 1(b) of this Article, contain information on relevant constituents and emissions of tobacco products as defined by national authorities.

3. Each Party shall require that the warnings and other textual information specified in paragraphs 1(b) and paragraph 2 of this Article will appear on each unit packet and package of tobacco products and any outside packaging and labelling of such products in its principal language or languages.

4. For the purposes of this Article, the term "outside packaging and labelling" in relation to tobacco products applies to any packaging and labelling used in the retail sale of the product.

These three articles are the result of the consensus view that such regulation would serve public health goals by providing a meaningful regulatory oversight of tobacco products and related communications made to consumers. The articles imply the need for an objective, science-based approach to the implementation of the provisions of the Framework Convention. Unfortunately, as indicated in the recommendations and conclusions contained in the reports of the Scientific Advisory Committee on Tobacco Product Regulation (see references *12–16*), the current methods for product testing adopted by the International Organization for Standardization (ISO) and the United States Federal Trade Commission (FTC) are inadequate since they fail to provide the appropriate scientific basis for tobacco product regulation. New laboratory capacity is needed and guidance in initiating the testing of existing and anticipated tobacco products is a critical factor in advancing the regulatory process.

Laboratory capacity: research and testing

Laboratory capacity refers to the physical and human resources needed to conduct research, develop standards for product performance, develop product testing methods, and conduct product testing. A report by the Institute of Medicine on tobacco harm reduction (*18*) summarizes the science base for testing the physical attributes of tobacco products that contribute to addiction, morbidity, and premature mortality. It is useful to distinguish the two main types of laboratory capacity required to enable implementation of Articles 9 to 11 of the Framework Convention: research and testing.

Research

The main goals of research are to understand better the nature of tobacco products, how they work, their effects, and how they might be modified to alter their effects (e.g., by new ingredients and designs). This research can include molecular, *in vitro,* animal, and human research, addressing topics such as the relationship between tobacco-specific nitrosamines (TSNAs) and lung cancer risk, the relationships between ingredients and addiction risk, and the relationships between particle size and lung retention of cigarette smoke toxicants. Research on human patterns of use and how they interact with product characteristics is also essential.

Testing

The repetitive examination and evaluation of products according to standardized methods to assess product performance is generally referred to as testing. Testing can occur at several stages. To aid the regulatory process, it is useful to test products according to a standardized protocol in order to characterize their delivery of substances such as carbon monoxide, nicotine, and nitrosamines. Annex 1 lists the standardized methods for testing tobacco products.

Laboratory research and testing must be coordinated

Although research, testing and performance standards may be distinguished for conceptual and organizational purposes, they are not mutually exclusive; indeed, they must be interactive. Performance standards require the testing of a broad range of product characteristics, conducting research to determine which toxicity-reducing goals are feasible, and developing standardized testing protocols. This process will continually evolve and rapidly expand to address the challenges posed by existing products. As the number of new tobacco products

increases, it is reasonable to assume that the need to develop new performance standards will similarly increase. Research and testing need to include assays of the physical characteristics, the chemical composition and the performance of products, *in vitro* and *in vivo* toxicology testing, and the assessment of human use patterns to determine the interactions between behaviour and product characteristics as well as actual human exposures.

Tobacco product diversity

Tobacco product diversity increases the range of challenges; thus it is essential to consider both existing products and emerging product alterations in establishing laboratory capacity. The various forms and methods of use of tobacco products include orally or nasally administered products (e.g., snuff), smoked cigarettes, which are designed to maximize exposure, and cigars, in the use of which inhalation of smoke is not generally needed for sufficient nicotine absorption *(11, 18, 21, 22)*. The major categories of products include cigarettes as well as extensively modified cigarettes, cigars, bidis, and smokeless tobacco products, including various forms of snuff, chewing tobacco and Swedish snus (*23, 24*) (see Annex 2).

New tobacco products

In addition to a diverse array of conventional tobacco products, new product types and tobacco product substitutes continue to proliferate rapidly (*25*). The development and marketing of new tobacco products by the tobacco industry appear to be in response to the health concerns associated with conventional products. Moreover, the range of new products is expected to expand as the pressures for reduced toxicity implicit in the terms of the Framework Convention increase. New products marketed in the last several years include an electronically heated and computer-controlled cigarette substitute, cigarettes containing a carbon heating element, a fibreglass-packed cigarette substitute, cigarettes that are claimed to contain reduced carcinogens and to be nicotine-free, tobacco lozenges, and tobacco patches.

Non-tobacco nicotine products (medicines)

This recommendation does not address non-tobacco nicotine products (e.g., nicotine water and lollipops) or medicines (e.g., smoking cessation medicines) as it is assumed that drug regulatory authorities will continue to regulate such products. The current regulation of medicinal nicotine products is appropriately stringent and consistent with that of other drug products, whereas tobacco products are regulated much less rigorously (*3, 26, 27*). It is expected that the implementation of the Framework Convention will narrow the regulatory gap between tobacco products and pharmaceutical products by increasing the regulatory oversight of tobacco products. In some countries, the same agency holds regulatory authority for both tobacco and drug products (e.g., Health Canada in Canada and the National Agency for