Scientific Advisory Committee on Tobacco Product Regulation (SACTob) Recommendation on Tobacco Product Ingredients and Emissions

Background

Historically, cigarettes and other tobacco products have been exempt from health and safety standards for ingredients and emissions that are typically applied to other consumed products including foods, beverages and drugs (1, 2, 3). Although some countries have begun to develop and apply standards for allowable ingredients, there are no globally accepted standards or guidelines (2). Presently limits on emissions from tobacco products have not been implemented with the exception of estimates of tar, nicotine and carbon monoxide (2). An important consideration in the regulation of ingredients is that when the cigarette is used as intended, the ingredients can be modified and emission profiles altered during the processes of combustion ("burning") and pyrolysis ("modification by heat"). Therefore, the focus of this document is on the importance of evaluating *tobacco product emissions* as well as their *ingredients* under the conditions in which these products are actually used. The purpose of the document is to provide recommendations to support the development of protocols for assessing tobacco product ingredients and associated emissions with the intent to reduce tobacco caused disease.

The central premise is that tobacco product ingredients and emissions thereof, including nicotine, should be regulated. Ingredients include all product components, materials used to manufacture those components, residual substances from agricultural practices, storage and processing, and substances that can migrate from packaging into the product. [The term *ingredients* is preferred to terms such as "additives" and "processing aids"]. Emissions comprise what is actually delivered to the user and are the product responsible for most tobacco-attributable death and disease. Emissions are substances that are produced when the product is used and this is distinguished from "exposure", a term that in this context refers to the fraction of emissions that is actually absorbed by the user.

In the case of smokeless tobacco products, emissions refer to substances released during the process of oral use ("chewing"). In the case of the cigarette and other smoked products, the term refers to the constituents of the smoke. This includes those emissions directly inhaled by the user of the product ("mainstream smoke") and those inhaled by nonusers and users alike ("secondhand tobacco smoke").

The preferred focus for regulation is the emission from the product when it is used as intended [exceptions may include certain cigarette ingredients such as nicotine and ammonia]. These principles apply to all smoked products including novel cigarette substitutes and smokeless tobacco products (4), recognizing that all tobacco products have ingredients and emissions.

This focus on emissions as the critical point for regulation does not exclude consideration of allowable ingredients and design features. This is consistent with the emphasis that the tobacco industry itself places on the nature and acceptability of the emissions in their product development and evaluation (1, 2, 5, 6). This includes industry research on the

physical nature of the smoke ("smoke chemistry" and appearance) and its acceptability to potential consumers (5, 7). The physical design characteristics of the tobacco product interact with its chemical make-up to influence its function and effect (2, 5). For example, the size of the cuttings of the tobacco in cigarettes and smokeless tobacco, its level of acidity (pH), and the presence of other substances interact to influence the release of nicotine from the product (3, 5). Similarly, physical and chemical characteristics of cigarettes interact to alter the size distribution of the aerosol particles that convey nicotine and other chemicals and establish the degree of absorption (5).

The emphasis on both ingredients and emissions recognizes that actual health effects of tobacco products depend on their physical nature, their chemical make-up and how they are used (2, 3, 8, 9, 10). For example, more frequent or longer use of a product delivering lower levels of toxins per unit may result in greater risks to health than less frequent use or fewer years of use of a product that is more toxic per unit (11, 12, 13). Because the tobacco industry has a history of marketing its products on the basis of apparent reductions in toxicity with the intent being to increase consumption of their products, a regulatory strategy to reduce toxins must be accompanied by oversight of marketing and by surveillance of consumer use to detect such effects (3, 13).

It should be recognized that tobacco is a unique consumer product which could not be introduced into the market today under any known consumer regulations if it were not already established world-wide among a variety of substantially addicted populations. Therefore, its regulation requires a radical approach that will deviate substantially from the regulatory norms applied to other consumer products such as foods, cosmetics, and drugs. Given that tobacco product emissions are known to vary greatly and can consist of thousands of toxicants, there is no alternative but to establish upper limits for selected constituents, based on toxicity profiles, as a means of progressive toxicant reduction in order to begin progress towards reduced toxicity and addictiveness (14, 15).

It is important to note that for many products, regulatory limits are set on the basis of defining safe limits on exposure. The level of toxicants in tobacco products is so high that no regulatory strategy could be based on either safe levels or product safety. However a large number of toxic constituents have been identified in the tobacco smoke and substantial variability exists in the levels of individual constituents across brands of cigarette and other products. This variability suggests that performance standards for the emissions of tobacco products could be set by establishing upper limits for individual toxic constituents based on what appears to be technically feasible.

It is acknowledged that standards for upper limits of ingredients or emissions will not necessarily result in decreased health risks even though that is the intent. These recommendations must not form the basis for the development of product descriptors and claims that would imply health benefits or claims about the health effects of the products. Health effects include all forms of tobacco-related diseases, including addiction.

Observations and Principles

- Tobacco products have the capacity to cause addiction, due to their nicotine content and other substances in the emissions.

- Manufacturing processes can further add to the toxicants and can make nicotine more readily available for absorption into the body (for example, through the manipulation of pH, selection of aerosol particle size, the addition of chemicals and changes in other physical parameters of the materials such as paper porosity and size of the cut tobacco material).

- Combustion and pyrolysis of tobacco material in tobacco products, such as cigarettes [both manufactured and hand-made], pipes, cigars, and bidis, result in the formation of additional toxicants and can increase the addictive effects of nicotine

- Cigarette ingredients and emissions regulation are intended to support tobacco control efforts to prevent initiation and to stimulate cessation.

- One of the purposes of this regulation of tobacco products is a progressive reduction in the level of toxic chemicals in tobacco product ingredients and emissions, through periodic setting of standards. The upper limits set by the regulations do not in any way indicate an acceptable level of safety for any tobacco product and its emissions.

- The development of ingredient and emissions regulation should aim to reduce health risks, although there is no expressed or implied measure of disease reduction.

- Smokeless tobacco products also produce emissions that are addictive and toxic.

Recommendations

1. Regulations in terms of setting upper ingredients and emissions limits for toxicants need to be developed for all tobacco products whether they are intended for smoking or non smoking methods of consumption. Variation in the ways in which tobacco products are used needs to be considered in establishing performance standards.

2. For tobacco products intended to be smoked, the manufactured product needs to be differentiated from the product actually intended for consumption which is its emission ("smoke"), and the critical focus of regulation must be on the emissions.

3. Ongoing surveillance and research must be instituted to assess the consequences of regulation on initiation, cessation and health effects in order to modify the regulatory process on a regular basis.

4. With respect to nicotine, it remains uncertain at this time whether public health would be better served by increased or decreased levels of nicotine per unit (e.g., cigarette) and further study of this issue is required.

5. No health claims can be permitted based on the level of ingredients or emissions or whether the products meet regulatory standards for ingredients and emissions.

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