

## **Reports of expert committees and study groups<sup>1</sup>**

### **TOBACCO PRODUCT REGULATION**

**Report of the fourth meeting of the WHO Study Group on Tobacco Product Regulation<sup>2</sup>  
Stanford, California, United States of America, 25–27 July 2007**

### **HARM REDUCTION AND SMOKELESS TOBACCO PRODUCTS: REGULATORY RECOMMENDATIONS AND RESEARCH NEEDS**

#### **Main recommendations**

1. The WHO Study Group on Tobacco Product Regulation recommended that research be conducted to determine whether and in what conditions smokeless tobacco might be used as an aid under quitting smoking and whether marketing smokeless tobacco as a method for harm reduction would encourage taking up of smoking or smokeless tobacco use.

#### **Significance for public health policies**

2. The evidence that use of smokeless tobacco leads to quitting cigarette smoking was inconclusive, although survey data from Sweden suggested that use of smokeless tobacco smoking has led to smokers quitting. The evidence that recourse to smokeless tobacco use led to a higher prevalence of use of combustible tobacco products was conflicting. In view of the wide diversity in the composition, toxicity and patterns of use by geographical region of smokeless tobacco products, it was inappropriate to consider smokeless tobacco as a single product.

3. All smokeless tobacco products should be subjected to comprehensive regulatory control by an independent, scientific, government agency. The control must include disclosure of ingredients by manufacturers. As claims for reduced exposure might be interpreted as claims for harm reduction, the former must be based on evidence of reduced risk.

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<sup>1</sup> The Regulations for Expert Advisory Panels and Committees provide that the Director-General shall submit to the Executive Board a report on meetings of expert committees containing observations on the implications of the expert committee reports and recommendations on the follow-up action to be taken. The Regulations for Study and Scientific Groups, Collaborating Institutions and other mechanisms of collaboration provide that, in respect to such groups, the Director-General shall follow, whenever applicable and as far as practical, the principles and rules applicable to support committees.

<sup>2</sup> WHO Technical Report Series No. 951, in press.

4. In view of the wide variety of smokeless products with respect to composition, patterns of use, history of use and user characteristics, public health policy must cater for different populations. Continued testing and measurement of the contents and emissions of smokeless tobacco products must be conducted in order to identify regional variations. Careful attention should be paid to product characteristics and risks, the pattern of tobacco use in the population, social and cultural differences and marketing messages, in order to evaluate the potential of specific smokeless tobacco products to reduce harm.

### **Implications for the Organization's programmes**

5. The wide range of smokeless tobacco products and their characteristics meant that WHO should support individual and population-based research on specific products. Better knowledge was needed about the effects of smokeless tobacco products and about what modifications could be made to alter those effects, so that governments could implement the WHO Framework Convention on Tobacco Control. WHO should continue research on the health hazards and risks to individuals and populations that resulted from use of smokeless tobacco products.

## **“FIRE-SAFER” CIGARETTES: APPROACHES TO REDUCING IGNITION PROPENSITY**

### **Main recommendations**

6. The WHO Study Group on Tobacco Product Regulation recommended that standards such as that of the National Institute of Standards and Technology in the United States of America be implemented in Member States.

### **Significance for public health policies**

7. Research was needed to ensure the effectiveness of regulations for reduced ignition propensity and on the effects of changes in cigarette design to provide the basis for further policies. As in countries that already had reduced ignition propensity policies, others should require tobacco manufacturers to test ignition strength, report to the appropriate authority and cover the costs of research and implementation.

8. Monitoring, reporting and archiving were needed on the effectiveness of techniques for reducing ignition propensity in order to reduce deaths, injuries and property damage due to cigarette-induced fires. Such monitoring would increase public confidence and lead to more effective policies.

9. Claims that use of products with reduced ignition propensity would reduce risk should be prohibited, as they could lead consumers to perceive a lowered overall health risk. Public education programmes should be continued, in order to inform consumers that tobacco products were lethal and that smokers should quit. Such programmes should also include education campaigns to teach the public how to prevent fires.

### **Implications for the Organization's programmes**

10. As techniques for reducing ignition potential were available and could be beneficial, Member States should require that cigarettes feature reduced ignition potential based on the National Institute of Standards and Technology standard or any other standard that has been shown to be effective.

Countries and jurisdictions within countries should retain the right to alter the standard on the basis of population-based data on its effectiveness. Policies should require tobacco manufacturers to commission testing by independent laboratories that have been accredited in accordance with the International Organization for Standardization standard 17025, *General requirements for the competence of calibration and testing laboratories*. WHO should facilitate implementation of such policies and support the development of more effective means of reducing the damage due to cigarette-ignited fires.

## **RECOMMENDATION ON MANDATED LOWERING OF TOXICANTS IN CIGARETTE SMOKE: TOBACCO-SPECIFIC NITROSAMINES AND SELECTED OTHER CONSTITUENTS**

### **Main recommendations**

11. A new regulatory strategy was recommended by the WHO Study Group on Tobacco Product Regulation that established product performance standards, required disclosure of emissions, and mandated a lowering of the toxicant levels generated under standardized conditions, by prohibiting the sale of brands that did not meet the established levels of these standards. This approach was similar to the regulation of most consumer products where toxicant levels present in a product were reduced to the extent possible as part of good manufacturing processes. An essential component of this recommendation was the regulatory prohibition of the advertising of these measures to the public as being related to human exposure or risk, and of any ranking of products by their toxicant yields.

12. Toxicant levels would be compared using units per milligram of nicotine in cigarette smoke as a basis, in order to focus on the toxicity of cigarettes under standardized conditions and avoid their use as measures of exposure. Toxicants should be selected based on multiple criteria, the most important of which was evidence of toxicity.

13. The primary goal of the proposed regulatory strategy was to reduce the levels of toxic constituents measured under standardized conditions in the smoke of cigarettes allowed on the market. A secondary goal was to prevent the introduction into any market of cigarettes with higher levels of smoke toxicants than were present in brands already on the market.

### **Significance for public health policies**

14. Regulatory bodies should consider adoption of the new regulatory strategy in order to avoid the continuing harm resulting from the advertising of tar, nicotine and carbon monoxide values per cigarette, and also as a means of reducing the toxicants known to be present in smoke in a manner similar to that used to regulate toxicant levels in other consumer products. The recommended regulatory strategy should be implemented in phases beginning with a period of required annual reporting of toxicant levels by cigarette manufacturers to the regulatory authority. This should be followed by the promulgation of the levels of toxicants above which brands could not be offered for sale. Finally, the established levels would be enforced and violating brands banned.

15. Any regulatory approach based on yields under standardized conditions should prohibit the use of testing results, ranking of brands by testing levels, or statements that the brand had met governmental regulatory standards, as indicators of risk or exposure. Regulatory authorities had an obligation to ensure that the testing results were not used to mislead the public, as had occurred previously.

### **Implications for the Organization's programmes**

16. In view of the harmful effects of the present approach, which allowed advertisement of measurements of emissions per cigarette, WHO should promote prompt replacement of the approach with the recommended regulatory strategy. Mandated lowering of levels of toxicants per milligram of nicotine in cigarette smoke would make regulation of cigarettes consistent with other regulatory approaches that mandated reduction of known toxicants in products used by humans. The WHO Framework Convention on Tobacco Control recognized the need for tobacco product regulation in Articles 9 and 10.

## **RECOMMENDATION ON CIGARETTE MACHINE-SMOKING REGIMENS**

### **Main recommendations**

17. After evaluation of several machine-smoking regimens, the WHO Study Group on Tobacco Product Regulation recommended that the International Organization for Standardization select the Canadian "intense" regimen in establishing a standard for a machine-smoking regimen.

### **Significance for public health policies**

18. Continued misuse of the "per cigarette yields" generated with the current International Organization for Standardization regimen was harmful to public health and resulted in inadequate characterization of the smoke generated by different products. In the Canadian regimen, more intense smoking conditions were tested, resulting in better characterization of cigarette smoke for use in public health. The yields derived from this regimen could be used, for example, to set product performance standards.

19. Machine-smoking testing was useful for characterizing cigarette emissions for design and regulatory purposes; however, it was not intended to be and was not a valid measure of human exposure or risk. Care should be taken that the measures were not misinterpreted by consumers as differences in exposure or risk.

### **Implications for the Organization's programmes**

20. Accurate characterization of tobacco products and disclosure to regulatory agencies were essential for tobacco product control, as outlined in Articles 9 and 10 of the Framework Convention. Machine-smoking regimens that allowed better characterization of the smoke generated by different products were essential for improving public health and could result in reductions in the levels of known toxicants in emissions. WHO must continue to support the WHO Study Group on Tobacco Product Regulation recommendation that a new machine-smoking regimen be standardized.

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