

## **Elaboration of guidelines for implementation of Articles 9 and 10 of the WHO Framework Convention on Tobacco Control**

### **Progress report of the working group**

1. In accordance with decision FCTC/COP1(15), the working group requested to elaborate guidelines for the implementation of Article 9 submitted a progress report<sup>1</sup> to the Conference of the Parties at its second session. In addition to giving an overview of the work completed before the second session, the report proposed an outline for future work. The working group suggested that its mandate be extended so that it could, as priorities:

- (a) further examine the issue of smoking regimens (relevant for the testing and measuring of emissions);
- (b) prepare a workplan for the validation of analytical methods, including cost implications, with the assistance of the WHO Tobacco Laboratory Network;
- (c) examine mechanisms of financing for the testing and measuring of tobacco product contents and emissions as well as discuss industry responsibility in this context.

2. At its second session, in July 2007, the Conference of the Parties decided (decision FCTC/COP2(14)) to request the working group established by decision FCTC/COP1(15) to continue its work and to provide a progress report to the Conference of the Parties at its third session. The Conference of the Parties also requested the working group to extend its mandate to Article 10, to include product characteristics such as design features, to the extent that they affect the objectives of the Convention.

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<sup>1</sup> Document A/FCTC/COP/2/8.

3. Pursuant to that decision, the fourth meeting of the working group on Articles 9 and 10 was held from 26 to 28 September 2007 in Brussels, hosted by the European Commission on behalf of the European Community, and the fifth meeting of the working group was held from 5 to 7 March 2008 in Brasília, hosted by the Government of Brazil. Both meetings were attended by representatives of the Key Facilitators<sup>1</sup> and Partners<sup>2</sup> of the working group. The participants also included invited experts in the field of tobacco product regulation, representatives of civil society, the Convention Secretariat and WHO's Tobacco Free Initiative.

4. This report summarizes the progress made by the working group in elaborating guidelines for implementation of Articles 9 and 10 of the WHO Framework Convention. The areas covered were: principles for financing tobacco product regulation programmes, testing and measuring the contents and emissions of tobacco products, regulation of tobacco product disclosures and investigating the elaboration of guidelines for product characteristics, including design features. The report also lists future work and contains the recommendations of the working group to the Conference of the Parties. The report does not prejudge the content of future guidelines.

5. Comments received after the draft report were made available to the Parties through a protected web site in May 2008 were carefully reviewed by the Key Facilitators and will be considered during the next stages of the elaboration of guidelines.

## **PRINCIPLES FOR FINANCING TOBACCO PRODUCT REGULATION PROGRAMMES**

6. Implementing and operating an effective programme for regulating tobacco products requires allocation of significant resources, which may have the undesirable consequence of drawing funding and capacity away from other important tobacco control interventions of high priority. The working group considered that all costs related to tobacco product regulation should be borne by the tobacco industry. This would translate the principle of internalization of external costs into practice.

7. As an example of this principle, the working group considers that the contents and emissions of tobacco products, as part of a Party's tobacco product regulation programme, shall be tested and measured by laboratories approved by competent authorities or according to requirements and templates set up by competent authorities, and the costs shall be borne exclusively by the tobacco industry.

8. The working group intends to look further at means that Parties have at their disposal to finance tobacco product regulation programmes, in conjunction with a monitoring plan and in accordance with Article 5.3 of the WHO Framework Convention, such as:

- (a) designated tobacco taxes;
- (b) manufacturing and/or importing licencing fees;
- (c) product registration fees;

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<sup>1</sup> Canada, the European Community and Norway.

<sup>2</sup> Algeria, Australia, Brazil, Bulgaria, China, Congo, Denmark, Finland, Ghana, Hungary, India, Jordan, Kenya, Mali, Mexico, Netherlands, Thailand, Turkey, Ukraine and the United Kingdom of Great Britain and Northern Ireland.

- (d) tobacco selling licences (distributors and retailers);
- (e) non-compliance fees levied on the industry (for example, administrative monetary penalties).

## **TESTING AND MEASURING THE CONTENTS AND EMISSIONS OF TOBACCO PRODUCTS (ARTICLE 9)**

9. This section outlines the progress made by the working group in elaborating guidelines for testing and measuring the contents and emissions of tobacco products and for regulating those contents and emissions.

### **Contents**

10. Using the criteria for prioritization set at its third meeting (Canada, October 2006), the working group identified the following contents for which methods for testing and measuring (analytical chemistry) should be validated as a priority:

- (a) nicotine
- (b) ammonia
- (c) humectants (propane-1,2-diol, glycerol (propane-1,2,3-triol), triethylene glycol (2,2'-ethylenedioxybis(ethanol))).

11. Measuring the contents on this list will entail three methods: one for nicotine, one for ammonia and one for humectants.

### **Emissions**

12. Using the criteria for prioritization set at its third meeting (Canada, October 2006), the working group identified the following emissions for which methods for testing and measuring in mainstream smoke (analytical chemistry) should be validated as a priority:

- (a) 4-(methylnitrosamino)-1-(3-pyridyl)-1-butanone (NNK)
- (b) *N*-nitrosonornicotine (NNN)
- (c) acetaldehyde
- (d) acrylaldehyde (acrolein)
- (e) benzene
- (f) benzo[*a*]pyrene
- (g) 1,3-butadiene

- (h) carbon monoxide
- (i) formaldehyde.

13. Measuring the emissions on this list will entail four methods: one for tobacco-specific nitrosamines (items (a) and (b)), one for benzo[*a*]pyrene (item (f)), one for aldehydes (items (c), (d) and (i)) and one for volatile organic compounds (items (e), (g) and (h)).

### **Validation of methods**

14. The working group welcomes the proposal of the WHO Tobacco Laboratory Network to validate methods for testing and measuring cigarette contents and emissions.<sup>1</sup> Validation of the three methods for contents and the four methods for emissions by the WHO Tobacco Laboratory Network is estimated to take five and a half years.

### **Cigarette smoking regimens**

15. Smoking regimens are standardized procedures by which machines smoke cigarettes to produce smoke, from which emissions can be analysed.

16. The working group considers that data on cigarette emissions from machine-generated smoke are not intended to be, nor are they, valid measures of human exposure. All machine-smoking regimens have limitations; none can generally represent human smoking patterns, exposure or risk.

17. The working group acknowledges that methods to test and measure emissions should provide for machine smoking of cigarettes to help characterize the smoke and to monitor any change over time.

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<sup>1</sup> *Timeline and costing of method validations*, report of the WHO Tobacco Laboratory Network, submitted to the working group to elaborate guidelines for implementation of Articles 9 and 10 of the WHO Framework Convention.

18. The table below sets out the two smoking regimens for validation of the test methods referred to in paragraph 14.

Smoking regimen	Puff volume (ml)	Puff frequency	Ventilation holes
ISO <sup>1</sup> 3308:2000 <i>Routine analytical cigarette-smoking machine—definitions and standard conditions</i>	35	Once every 60 s	No modifications
Same as ISO 3308:2000, but modified as indicated	55	Once every 30 s	All ventilation holes must be blocked with Mylar adhesive tape.

<sup>1</sup> International Organization for Standardization

## REGULATION OF TOBACCO PRODUCT DISCLOSURES (ARTICLE 10)

19. The following section outlines the progress made by the working group in elaborating guidelines to require manufacturers and importers of tobacco products to disclose to governmental authorities information about the contents and emissions of tobacco products. It also covers the progress made on elaboration of guidelines concerning public disclosure of information about the toxic constituents of tobacco products and the emissions they may produce.

### Objectives and rationale of disclosure

20. Disclosure consists of disclosure to regulators and disclosure to the public. Disclosure requirements should not allow the industry to discharge itself from litigation claims.

21. The working group considers that the main objective of disclosure to governmental authorities is to obtain relevant, precise information on the contents and emissions of tobacco products, the toxicological effects and dependence liability of the contents and emissions, and their composition and design.

22. The working group recognizes that the purpose of disclosing product information to governmental authorities is to give regulators sufficient information to take action and to inform the public about the harmful effects of tobacco use. This information is also useful for the elaboration and implementation of relevant policy, regulations and litigation and for countering tobacco industry arguments.

23. Recognizing the consumer's right to know, the working group considers that the main objective of disclosure to the public is to inform and educate them about the harmful effects of tobacco. By improving public knowledge about tobacco products, consumers' attitudes and behaviour could be influenced, with the final goal of reducing tobacco use.

### Disclosure to regulators

24. The working group realizes that data collection and analysis are a challenge, and guidance is needed on both. There is also a lack of capacity globally to analyse large amounts of data.

25. The working group considers that the following information should be collected from the tobacco industry:

- (a) contents and emissions;
- (b) a list of all ingredients and the quantities thereof used in the manufacture of tobacco products, per brand and type;
- (c) all toxicological information;
- (d) factors influencing attractiveness and addictiveness;
- (e) product characteristics, including design features;
- (f) market data (although this probably falls outside the scope of Article 10 of the WHO Framework Convention).

26. The working group acknowledges that most Parties will lack adequate capacity to collect, verify and manage the data. They will need efficient means of collecting, storing, evaluating and disseminating the data appropriately. Parties might therefore consider setting up a global data repository. The working group carried out an initial analysis of the challenges to creating a global data repository and identified the following issues for special consideration:

- (a) security, protection of the database and confidentiality of information;
- (b) funding mechanisms (development costs, management and ownership of data);
- (c) liability and contractual matters;
- (d) access to and use of data;
- (e) accuracy and validation of data;
- (f) procedure for collecting and managing data.

### **Confidentiality of information**

27. The working group considers that Parties should not accept claims from the tobacco industry concerning the confidentiality of information.

### **Disclosure to the public**

28. In disclosing information about constituents and emissions of tobacco products and their effects, the working group is aware that governmental authorities might have difficulty in translating the complex data collected into objective, understandable information.

## **GUIDELINES FOR PRODUCT CHARACTERISTICS OF INTEREST (ARTICLES 9 AND 10)**

29. This section describes the progress made by the working group in investigating the elaboration of guidelines for product characteristics including design features.

30. The working group notes that the tobacco product characteristics it has reviewed can be grouped as follows:

- (a) characteristics of the ingredients used that do not require testing or measurement in order to be disclosed;
- (b) design features that can be tested or measured with existing, standardized methods and readily available equipment;
- (c) characteristics for which no standardized methods exist and no equipment is readily available.

31. The first group of characteristics that could be part of disclosure requirements for contents (relating to Article 10) comprises:

- (a) type(s) of tobacco used (for example, Virginia, Burley, Oriental);
- (b) percentage of reconstituted tobacco used;
- (c) percentage of expanded tobacco used;
- (d) type of filter (for example, cellulose acetate) and other relevant characteristics, where applicable (for example, charcoal content).

32. The second group comprises the following design features that can be tested or measured with existing, standardized methods and readily available equipment:

- (a) length of the filter;
- (b) length of the tipping paper or overwrap;
- (c) dimensions of the cigarette, including those of the tobacco rod;
- (d) draw resistance of cigarette (ISO 6565. *Tobacco and tobacco products—Draw resistance of cigarettes and pressure drop of filter rods—Standard conditions and measurement*);
- (e) degree of filter ventilation (ISO 9512. *Cigarettes—Determination of ventilation—Definitions and measurement principles*);
- (f) degree of paper ventilation (ISO 9512. *Cigarettes—Determination of ventilation—Definitions and measurement principles*);

(g) type of cigarette paper used and its porosity (ISO 2965. *Materials used as cigarette papers, filter plug wrap and filter joining paper, including materials having an oriented permeable zone—Determination of air permeability*);

(h) product firmness (nominally, a measure of packing density);

(i) pressure drop of the filter (ISO 2965. *Materials used as cigarette papers, filter plug wrap and filter joining paper, including materials having an oriented permeable zone—Determination of air permeability*);

(j) moisture content (AOAC Official Method 966.02. *Moisture in tobacco, gravimetric method*).

33. The third group comprises characteristics for which no standardized methods exist, no equipment is readily available or more research is needed:

(a) aerosol particle size

(b) filter fibre residues.

## **FUTURE WORK**

34. The working group considers that guidelines for the implementation of Articles 9 and 10 of the WHO Framework Convention will be elaborated step-by-step, and proposes to continue its work on a first set of guidelines for possible adoption by the Conference of the Parties at its fourth session.

35. The working group proposes to continue to monitor the areas set out in its previous progress report, which include dependence liability and toxicology.

36. The working group proposes to continue examining the challenges and potential approaches to setting up a global data repository.

## **RECOMMENDATIONS**

37. The working group recommends that the Conference of the Parties, through the Convention Secretariat, request WHO's Tobacco Free Initiative to validate the analytical chemical methods for testing and measuring the cigarette contents and emissions identified as priorities in this report, using the two smoking regimens set out in paragraph 18, and to inform the Conference of the Parties through the Convention Secretariat on a regular basis of the progress made.

38. The working group also recommends that the Conference of the Parties, through the Convention Secretariat, request WHO's Tobacco Free Initiative:

(a) to identify best practices in reporting to regulators as regards contents, emissions and product characteristics, including electronic systems;

(b) to identify best practices in informing the public;

(c) to collect information on legal cases and analyse the legal issues related to tobacco product disclosures;



and to inform the Conference of the Parties at its fourth session, through the Convention Secretariat, of the progress made.

39. The working group recommends that the Conference of the Parties, through the Convention Secretariat, request WHO's Tobacco Free Initiative to monitor scientific progress; when appropriate, to design and validate methods for testing and measuring the product characteristics identified in paragraph 33 of this report; and to inform the Conference of the Parties, through the Convention Secretariat, on a regular basis of the progress made.

40. The working group recommends that the Conference of the Parties mandate the future work set out in paragraphs 34 to 36.

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