Progress on further development of the partial guidelines for implementation of Articles 9 and 10 of the WHO FCTC

Report by the working group

1. At its fifth session (Seoul, Republic of Korea, 12–17 November 2012), the Conference of the Parties (COP) adopted further partial guidelines for implementation of Article 9 (Regulation of the contents of tobacco products) and Article 10 (Regulation of tobacco product disclosures) of the WHO FCTC. The COP also decided to mandate the working group on Articles 9 and 10 to:

(a) continue to monitor areas such as dependence liability and toxicology;
(b) continue its work in elaborating guidelines in a step-by-step process, and to submit draft partial guidelines or a progress report on the testing and measuring of contents and emissions using the analytical chemical methods validated by WHO to the next session of the Conference of the Parties;
(c) identify which other analytical chemical methods for the testing and measuring of cigarette contents and emissions, or ingredients, need to be validated and/or to identify the methods for which validation should be extended to include tobacco products other than cigarettes;
(d) continue work on definitions in the area of product regulation;
(e) examine how Parties may address possible false, misleading or deceptive conduct and/or representations with respect to tobacco products contents, characteristics and/or performance, and possibly produce text on this matter to be included in the partial guidelines.

1 Decision FCTC/COP5(19) provided for “one meeting of Key Facilitators, and up to two representatives per region, in combination with intersessional work of the Convention Secretariat and online communication with the members of the working group”. This report presents the views and deliberations of those working group members who participated in the eighth meeting of the working group.

2 See decision FCTC/COP5(6).
2. The eighth meeting of the working group (Geneva, Switzerland, 28–30 January 2014), was attended by 11 Parties and four Key Facilitators in line with the workplan and budget adopted by the COP. WHO and the WHO Tobacco Laboratory Network also attended at the invitation of the Convention Secretariat and representatives of civil society participated in an observer capacity. The participants came from the WHO African Region, the Region of the Americas, the South-East Asia Region, the European Region and the Western Pacific Region.

3. During the meeting the working group discussed all matters falling within its mandate. In particular, it examined draft text proposed by the Key Facilitators for inclusion in the partial guidelines in relation to the testing and measuring of contents and emissions using the analytical chemical methods validated by WHO, as well as a definition of “constituents”; discussed proposals for other analytical chemical methods for the testing and measuring of contents and emissions of cigarettes and other tobacco products for which validation should be extended, and ways Parties may address false, misleading or deceptive tobacco product characteristics; and considered updates from WHO in the areas of dependence liability and toxicology.

4. In addition to deliberating on topics within its own mandate, the working group also discussed with WHO the ongoing work the Organization had been invited to undertake, as requested by the COP. In this context the working group provided feedback on the draft fact sheets prepared by WHO.

5. The Key Facilitators prepared the present report based on the deliberations at the eighth meeting of the working group. A draft was made available to the Parties on 8 April 2014. Comments from nine Parties were received and considered by the Key Facilitators.

**ISSUES FOR CONSIDERATION BY THE CONFERENCE OF THE PARTIES**

6. At its third session (Durban, South Africa, 17–22 November 2008), the COP requested the Convention Secretariat to invite WHO’s Tobacco Free Initiative, among other work, to validate, within five years, the analytical chemical methods for testing and measuring the cigarette contents and emissions identified as priorities in the progress report of the working group. At its fifth session, the COP mandated the working group to submit draft partial guidelines or a progress report on the testing and measuring of contents and emissions using the analytical chemical methods validated by WHO (which at the time of the eighth meeting of the working group applied to methods for nicotine and tobacco specific nitrosamines (TSNAs)).

7. The working group reviewed draft text proposed by the Key Facilitators for insertion into the partial guidelines that focused on the testing and measuring of nicotine and TSNAs. However, consensus could not be reached. Reasons for the lack of consensus included disagreement on the level of detail to provide on testing and measuring, as well as the preference of some Parties to develop

---

1 Australia, Benin, Burkina Faso, China, Colombia, Germany, India, Nicaragua, Nigeria, Norway and Thailand.
2 Brazil, Canada, European Union and Turkey.
3 See decision FCTC/COP5(19).
4 See document FCTC/COP/6/14 for WHO’s report on work requested by the COP (forthcoming).
5 See decision FCTC/COP5(6), paragraph (3)(b)(v).
6 See decision FCTC/COP3(9).
7 Document FCTC/COP/3/6.
guidance on disclosure before recommending validated analytical chemical methods. The COP is invited to note the latest versions of the text prepared by the Key Facilitators (Annexes 1 and 2) subsequent to the discussions of the working group, and to provide direction to the working group should its mandate be extended.

8. At its fifth session the COP also mandated the working group to continue work on definitions in the area of product regulation. The working group discussed draft text proposed by the Key Facilitators but did not reach consensus on a definition of “constituents” for section 1.3 (Use of terms) of the partial guidelines. The COP is invited to note the versions discussed by the working group (Annex 3). The working group will reconsider this matter at a future meeting, if it receives the mandate to do so.

9. The working group noted the progress made by WHO to date in validating the analytical chemical methods for testing and measuring the cigarette contents and emissions identified as priorities and appreciated the high quality of the corresponding standard operating procedures presented so far. A current description of progress of validation of analytical chemical methods can be found in the report of WHO to the COP. The working group invites the President of the COP to appropriately recognize the meaningful and significant contribution of the laboratories that contributed to the validation of the analytical chemical methods through the WHO Tobacco Laboratory Network. The working group also invites the COP to ask the Convention Secretariat to make these standard operating procedures and related documentation accessible via the WHO FCTC website.

10. In considering the need for validation of other analytical chemical methods for the testing and measuring of cigarette contents and emissions, or methods for which validation should be extended to include tobacco products other than cigarettes, the working group expressed a strong interest in validation of analytical chemical methods for smokeless tobacco products. However, it was noted that the diversity among smokeless tobacco products may impede validation of generally applicable analytical chemical methods. Based on the discussions of the working group, the Key Facilitators sought advice from the WHO Tobacco Laboratory Network, through WHO, about the validation of analytical chemical methods for testing and measuring nicotine and TSNAs in smokeless tobacco products. The recommendation received was to first investigate whether the existing validated method for testing and measuring nicotine in tobacco products is applicable to other tobacco products, prioritising validation of a range of smokeless tobacco products.

11. Discussions of the working group on false, misleading or deceptive product characteristics focused on Parties’ experiences with regard to slim/super slim cigarette designs, filter ventilation, and flavour-delivering mechanisms such as capsules. These discussions revealed a clear interest of the working group to engage in further work in this area, should it receive the mandate to do so.

12. The working group noted updates provided by WHO with respect to the toxicity of tobacco products and aspects of addictiveness (or dependence liability), based on a review of the scientific and medical literature. While it acknowledged the recent developments in these areas, the working group recognized the long-term challenges these issues represent and the resulting need to examine them further within the working group.

13. The working group invites the COP to encourage Parties, international, regional and subregional organizations, international financial institutions and/or other development partners to coordinate

---

1 See document FCTC/COP/6/14 (forthcoming).
research activities that would support Parties in implementing Articles 9 and 10. The COP could also encourage Parties to address infrastructure and capacity issues for laboratories, including on a regional basis, and share best practices and tools used in the disclosure of contents and emissions of tobacco products.

PROPOSED FUTURE WORK

14. Should the COP decide to continue the mandate of the working group in relation to the testing and measuring of constituents and emissions of tobacco products, the working group would recommend that its mandate also include developing proposals with respect to their disclosure, taking Annexes 1 and 2 of the present document into consideration, with a view to presenting draft partial guidelines or a progress report to the COP at its seventh session. In this context it is suggested that the working group’s mandate could also include continuing to explore possibilities for defining “constituents” in a way that is meaningful and acceptable to all Parties, taking into consideration the alternative definitions outlined in Annex 3.

15. Should the COP decide to extend the mandate given to the working group to “continue to monitor areas such as dependence liability and toxicology” the working group would recommend that its mandate include taking stock of information obtained so far from WHO in relation to these two areas and examining relevant issues, in order to report back to the COP at its seventh session.

16. On the basis of the interest expressed by the working group, the COP could mandate the working group to consider tobacco product characteristics from the perspective of increased attractiveness and misleading or deceptive impressions with a view to submitting further draft partial guidelines or a progress report in relation to these issues to the COP subsequently. As a starting point, the focus could be on the following cigarette characteristics: slim/super slim designs, filter ventilation, and innovative filter design features including flavour-delivering mechanisms such as capsules.

17. In order to support the possible future work outlined above, the COP could also consider requesting the Convention Secretariat to invite WHO to:

(a) prepare a report on specific cigarette characteristics (slim/super slim designs, filter ventilation, and innovative filter design features including flavour-delivering mechanisms such as capsules), as well as other tobacco product characteristics of interest, from the perspective of increased attractiveness and misleading or deceptive impressions, for consideration by the working group at its first meeting following the sixth session of the COP;

(b) finalize, within one year, the validation of the analytical chemical methods already under way (see paragraph 6), for testing and measuring cigarette contents and emissions identified as priorities in the progress report\(^1\) presented to the COP at its third session, while recognizing that the difficulties experienced may impede completion of the validation of a method for ammonia; and

(c) assess whether or not the recently developed standard operating procedures for nicotine and TSNAs are applicable to tobacco products other than cigarettes, such as smokeless tobacco.

---

\(^1\) Document FCTC/COP/3/6.
ACTION BY THE CONFERENCE OF THE PARTIES

18. The COP is invited to note the report of the working group, to review Annexes 1 and 2 (relating to the testing and measuring of contents and emissions using the analytical chemical methods validated by WHO) and Annex 3 (in relation to possible definitions of “constituents”) and to provide further guidance.
ANNEX 1

CONSTITUENTS – DISCLOSURE

PROPOSAL FOR CONSIDERATION IN RELATION TO POSSIBLE FUTURE WORK ON THE PARTIAL GUIDELINES FOR IMPLEMENTATION OF ARTICLES 9 AND 10 OF THE WHO FCTC

INSERT after “3.1.3 Constituents (Disclosure)”

This section outlines measures that Parties could introduce to require the disclosure by manufacturers and importers of tobacco products of information on the constituents of these products.

3.1.3.1 Background

Considering the complexity of tobacco products, the addictive and toxic substances they contain, understanding their constituents profile at a national level could support the development of better policies and regulations to regulate tobacco products, and increase the information available to governmental authorities to assess the nature of their tobacco products market.

Guidance on the constituents that may be of interest to governmental authorities is available from various sources, such as a number of health authorities and WHO.

3.1.3.2 Recommendations

(i) Parties should consider requiring that manufacturers and importers of tobacco products disclose information on constituents to governmental authorities at specified intervals, for each brand within a brand family.

(ii) Parties should consider specifying the analytical methods\(^1\) that must be used by manufacturers and importers of tobacco products for the testing and measuring of constituents for the purpose of disclosure.

(iii) Parties should ensure that every manufacturer and importer provides to governmental authorities a copy of the laboratory report that shows the product tested and the results of the testing and measuring conducted on that product. Parties should also consider asking for proof of accreditation of the laboratory that performed the testing and measuring.

---

\(^1\) Analytical laboratory methods are used to collect information on constituents. Such methods have been developed by various governmental authorities and international organizations. A selection of methods for the testing and measuring of constituents in cigarettes, that have been validated and can be easily performed by a wide spectrum of laboratories, are gradually becoming available under the auspices of WHO. See the list of available WHO methods at [www.who.int](http://www.who.int)
ANNEX 2

EMISSIONS – DISCLOSURE

PROPOSAL FOR CONSIDERATION IN RELATION TO POSSIBLE FUTURE WORK ON THE PARTIAL GUIDELINES FOR IMPLEMENTATION OF ARTICLES 9 AND 10 OF THE WHO FCTC

INSERT after “3.2 Emissions”

3.2.1 Disclosure

This section outlines measures that Parties could introduce to require the disclosure by manufacturers and importers of tobacco products of information on the emissions of these products.

3.2.1.1 Background

Considering the complexity of tobacco products, and the addictive and toxic substances they release during their use, understanding their emissions profile at a national level could support the development of better policies and regulations, and increase the information available to governmental authorities to assess the nature of the tobacco products available on their national market.

A key step in obtaining this information is for governmental authorities to select not only the tobacco products intended for disclosure, but also to determine which emissions the manufacturers and importers will be required to report on. Guidance on the emissions that may be of greater public health relevance is available from various sources, such as WHO and a number of health authorities.

An issue to consider with respect to combustible tobacco products is that smoking machines are typically used to generate emissions from cigarettes, and a few other cigarette-like products (e.g. small-diameter cigars, kreteks). Research and development continues with respect to other products (e.g. water pipes).

It is also important to consider the selection of smoking parameters for the smoking machine. The two most often used sets of parameters for cigarettes are known respectively as the “ISO” and the “intense” regimens. It must be cautioned that no machine-smoking regimen can represent all human smoking behaviours; machine smoking is useful in characterizing cigarette emissions for design and for regulatory purposes. Furthermore, disclosing to smokers the yields obtained from different cigarettes can result in misunderstandings or false assumptions about exposure and health risk.

---

1 There are no recognized machines or laboratory methods to generate emissions from smokeless tobacco products, as at the time of completion of the present document.
3.2.1.2 Recommendations

(i) Parties should consider requiring that manufacturers and importers of tobacco products disclose information on emissions to governmental authorities at specified intervals, for each brand within a brand family.

(ii) Parties should consider specifying the analytical methods\(^1\) that must be used by manufacturers and importers of tobacco products for the testing and measuring of emissions for the purpose of disclosure.

(iii) Parties should ensure that every manufacturer and importer provides to governmental authorities a copy of the laboratory report that shows the product analysed and the results of the testing and measuring conducted on that product. Parties should also consider requiring that proof of accreditation be submitted for the laboratory that performed the testing and measuring.

(iv) When implementing recommendation (i) of this paragraph, Parties should consider requiring at a minimum two sets of smoking regimens, such as the “intense” smoking parameters (found in the Standard operating procedure for intense smoking of cigarettes, Tobacco Laboratory Network SOP 01, WHO) and the “ISO” smoking ones (found in Routine analytical cigarette-smoking machine—Definitions and standard conditions, ISO 3308, International Organization for Standardization).

---

\(^1\) Analytical laboratory methods are used to collect information on emissions. Such methods have been developed by various governmental authorities and international organizations. A selection of methods for the testing and measuring of emissions in cigarettes, that have been validated and that can be easily performed by a wide spectrum of laboratories, are gradually becoming available under the auspices of WHO. See the list of available WHO methods at [www.who.int](http://www.who.int).
ANNEX 3

USE OF TERMS – CONSTITUENTS

ALTERNATIVE DEFINITIONS FOR CONSIDERATION IN
RELATION TO POSSIBLE FUTURE WORK ON THE PARTIAL GUIDELINES
FOR IMPLEMENTATION OF ARTICLES 9 AND 10 OF THE WHO FCTC

“Constituents” means substances found in tobacco.

or

“Constituents” means substances found in tobacco (contaminants are not part of the constituents).

or

“Constituents” means endogenous substances found in tobacco leaf.

or

“Constituents” means natural substances found in tobacco leaf.

or

“Constituents” means endogenous substances found in processed tobacco.

= = =