



WHO FRAMEWORK CONVENTION
ON TOBACCO CONTROL

Conference of the Parties to the WHO Framework Convention on Tobacco Control

Seventh session
Delhi, India, 7–12 November 2016

12 November 2016

DECISION

FCTC/COP7(14) Further development of the partial guidelines for implementation of Articles 9 and 10 of the WHO FCTC (Regulation of the contents of tobacco products and Regulation of tobacco product disclosures)

The Conference of the Parties (COP),

Taking into account Article 7 (Non-price measures to reduce the demand for tobacco), Article 9 (Regulation of the contents of tobacco products) and Article 10 (Regulation of tobacco product disclosures) of the WHO Framework Convention on Tobacco Control (WHO FCTC);

Recalling its decision FCTC/COP1(15) to establish a working group to elaborate guidelines for implementation of Article 9 and Article 10 of the WHO FCTC, and its decision FCTC/COP2(14) to extend the work of the working group to include product characteristics, such as design features, to the extent that they affect the objectives of the WHO FCTC;

Recalling also its decision FCTC/COP4(10) to adopt partial guidelines for implementation of Article 9 and Article 10 of the WHO FCTC and to mandate the working group to continue its work in elaborating guidelines in a step-by-step process, and to submit draft guidelines on addictiveness and toxicity to future sessions of the COP for consideration;

Recalling further its decision FCTC/COP5(6) to adopt further partial guidelines;

Noting its decision FCTC/COP6(12) to mandate the working group to continue its work in elaborating guidelines in a step-by-step process; to submit draft partial guidelines or a progress report on the disclosure, testing and measuring of contents and emissions, and on specific cigarette characteristics including slim/super-slim designs, filter ventilation and innovative filter design features, to the next session of the COP; to explore possibilities for defining “constituents”; and to continue to monitor areas such as dependence, liability and toxicology, including for smokeless tobacco products and waterpipe tobacco products;

Noting also the report of the working group to the seventh session of the COP (FCTC/COP/7/8) which presents three annexes that the COP is invited to consider for adoption;

Noting further the lack of consensus within the working group in defining constituents as reported at the sixth session of the COP;

Noting also that the working group, as it has done previously, wishes to invite all Parties, the tobacco-related Knowledge Hubs and the World Health Organization (WHO) to continue building capacity to require the tobacco industry to test and disclose the contents and emissions of tobacco products to regulatory authorities, as well as to share their newly acquired knowledge and technical expertise with other Parties; taking note of the publication in 2015 of an *Advisory note: global nicotine reduction strategy*, prepared by the WHO Study Group on Tobacco Product Regulation¹;

1. ADOPTS the further partial guidelines for implementation of Articles 9 and 10 of the WHO FCTC as contained in the Annex 2 and 3 of the present decision;
2. TAKES NOTE WITH APPRECIATION of Annex 1 to the present decision as an important contribution of the working group, as part of work in a step-by-step process;
3. WELCOMES the report of WHO to the COP on the work in progress in relation to Articles 9 and 10 of the WHO FCTC (document FCTC/COP/7/9) and thanks both WHO and the participating laboratories for making such significant progress in the validation of analytical chemical methods for testing and measuring cigarette contents and emissions (document FCTC/COP/7/INF.DOC./1);
4. REQUESTS the Convention Secretariat in cooperation with the WHO to hold a face-to-face meeting with a range of experts and relevant stakeholders from various regions with expertise in different areas, for example experts on addictiveness and dependence, social workers, physicians, public health experts, regulation experts, plant technology experts, agriculture scientists, experts in illicit trade, marketing experts, experts in ethics, scientists from other relevant disciplines and Party representatives and relevant nongovernmental organizations) to study/examine and discuss taking into account the current and emerging knowledge base, including scientific and empirical evidence, on addictiveness reduction measures and report back to the eighth session of the COP on:
 - (a) the potential positive and negative individual and societal consequences of implementing tobacco addictiveness reduction measures as well as the conditions that would support successful implementation of tobacco addictiveness reduction measures;
 - (b) the barriers to implementation of tobacco addictiveness reduction measures;
 - (c) any relevant country experiences;
 - (d) any other related matter that, in the opinion of this diverse group, should be brought to the attention of the COP;
5. REQUESTS the Convention Secretariat to invite WHO to undertake the following work:
 - (a) to continue to monitor and examine market developments and usage of novel and emerging tobacco products, such as “heat-not-burn” tobacco products. This might cover available scientific data on attractiveness, addictiveness and toxicity; health risk impact analysis of the products; their potential role in initiation and cessation of tobacco consumption; and to collect further scientific information, especially in relation to nicotine and other toxicants, including those arising from emissions; and to report progress to the future sessions of the COP;

¹ http://www.who.int/tobacco/publications/prod_regulation/nicotine-reduction/en/

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- (b) to collaborate with the Knowledge Hub on smokeless tobacco by assisting tobacco testing laboratories:
 - i. to collect scientific information on the chemicals in contents and emissions in smokeless tobacco products that contribute to the toxicity, addictiveness and attractiveness and analytical methods used to measure them, and the levels found in products on the market;
 - ii. to finalize the standard operating procedures for measuring nicotine, tobacco specific nitrosamines (TSNAs) as requested by decision FCTC/COP6(12) 2b.ii;
 - iii. to advise on the applicability of WHO Tobacco Laboratory Network (TobLabNet) standard operating procedures to measure humectants and ammonia in smokeless tobacco products;
 - iv. to identify any available technical approaches to reduce toxicants in smokeless tobacco;
 - v. to report progress at the future sessions of the COP;
 - (c) to finalize the validation of the analytical chemical methods for aldehydes and volatile organic compounds in cigarette emissions in accordance with the progress report presented by WHO to COP at its seventh session (FCTC/COP/7INF.DOC.1);
 - (d) to support, in synergy with other WHO FCTC work on implementation/capacity-building, and upon the request of Parties, to strengthen their capacity in testing of tobacco products including through the WHO TobLabNet;
 - (e) to identify, in synergy with other WHO FCTC work on implementation/capacity-building, approaches and strategies to build capacity for Parties wishing to monitor market characteristics and trends through registration, licensing or notification, as well as reporting on tobacco products in order to inform policy-making;
 - (f) to assess the applicability of WHO TobLabNet standard operating procedures to the testing of nicotine and humectants in waterpipe tobacco products;
 - (g) to assess the availability of validated analytical methods on the expanded list of toxicants in contents and emissions of tobacco products, as reported in Table 4 of document FCTC/COP/6/14;
6. DECIDES to mandate the working group:
- (a) to continue its work in elaborating guidelines in a step-by-step process and submit draft partial guidelines or a progress report in accordance with past decisions;
 - (b) to examine the information delivered by the consultation of the range of experts and relevant stakeholders on paragraph 4 and the WHO on paragraph 5 at a future meeting after the eighth session of the COP and submit draft partial guidelines or a progress report to a future session of the COP;
7. DECIDES that within the context of Articles 9 and 10:
- (a) the definition of waterpipe tobacco does not include tobacco-free waterpipe products;
 - (b) future work on “contents and emissions” should take into consideration the characteristics, including the design features, of the waterpipe apparatus and all its components when assessing the emissions from these products;
 - (c) future recommendations should address, where relevant, the impact of the availability and uptake of tobacco-free waterpipe products;
8. INVITES Parties, after notification by the Convention Secretariat, to confirm to the Convention Secretariat their intention to continue as members of the working group or their intention to join the working group by 31 January 2017;
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9. DECIDES, in accordance with decision FCTC/COP4(10):
- (a) to request the Convention Secretariat to provide assistance and make the necessary arrangements, including budgetary arrangements, for the working group to continue its work, and to ensure, in consultation with the Bureau of the COP, that Parties have access to the draft text (for example, via a protected website) and can provide comments before the circulation of the draft guidelines to the COP;
 - (b) to adopt the timeline set out below:

Draft guidelines, if any, made available by the Secretariat for comments by the Parties	At least six months before the opening day of a future session of the COP
Submission of the final report by the working group to the Secretariat	At least three months before the opening day of a future session of the COP
Circulation to the COP	At least 60 days before the opening day of a future session of the COP in accordance with Rule 8 of the Rules of Procedure of the COP

ANNEX 1**OBJECTIVES – ADDICTIVENESS**

REPLACE 1.2.1.2 Addictiveness (dependence liability) with the following

1.2.1.2 Addictiveness

The addictive nature of tobacco products is well established. This is recognized in the WHO FCTC which, in its preamble, clearly states that tobacco products create and maintain dependence. Further, Article 5.2 of the WHO FCTC stipulates that Parties shall “adopt and implement effective legislative, executive, administrative and/or other measures and cooperate, as appropriate, with other Parties in developing appropriate policies for preventing and reducing tobacco consumption, nicotine addiction and exposure to tobacco smoke.

Modifying tobacco products by regulating their contents alone, or both their contents and emissions, may help prevent nicotine addiction/tobacco dependence. Such modifications may also help addicted tobacco users in their cessation efforts.

Any reduction of the addictiveness of tobacco products resulting from the regulation of their contents, or both their contents and emissions, in no way suggests that those tobacco products are less dangerous for human health.

USE OF TERMS – ADDICTIVENESS

INSERT at “1.3 Use of Terms”

“Addictiveness”, sometimes referred to as dependence liability or addiction potential, means the pharmacological potential of a substance or product to cause dependence. Addictiveness is a complex process that varies with the chemical characteristics of the tobacco product’s emissions, with key elements including the dose, speed of absorption, metabolism, and physical and chemical features of the product. Although the concepts of “addictiveness” and “nicotine addiction/tobacco dependence” are linked, they have different meanings¹”.

¹ “Nicotine addiction” is used in Articles 5 and 22 of the FCTC, whereas “tobacco dependence” is used in Article 14. The *Guidelines for implementation of Article 14 of the WHO Framework Convention on Tobacco Control* offer a definition of “tobacco addiction/dependence” which is found in the section entitled “Use of terms.”

ANNEX 2

PRODUCT CHARACTERISTICS – DISCLOSURE

ADD at 3.3.1.1 “Background” after first paragraph

Furthermore, when combined with sales figures, such data will help Parties analyse market trends.

ADD at “APPENDIX 2 Design features of cigarettes”

(n) Description and explanation of function of all innovative components added to the cigarette, such as capsules.

PRODUCT CHARACTERISTICS – REGULATION

INSERT 3.3.2.2 Tobacco Products – Regulation in relation to attractiveness

i. Background

The tobacco industry is continuously aiming at making tobacco products more attractive by modifying existing product design features or introducing new ones. An example is the industry’s manufacture of cigarettes with an ever-smaller circumference (slim, superslim, ultraslim). Another example is the placement of capsules in cigarette filters that release flavour when crushed.

Product design features are used by the tobacco industry to develop strategies making products more attractive to different segments of society, an approach known as market segmentation. These segments can be based for example on age, gender, ethnic or cultural background, socioeconomic status and health concerns. The tobacco industry then targets these segments by developing product design features that meet their expectations and interests with regard to health, glamour, novelty, self-image, weight loss, convenience/ease of use, sensory experience and others.

Regulating product design characteristics to decrease tobacco product attractiveness can contribute to reducing the prevalence of tobacco use.

ii. Recommendations

Consistent with 3.1.2.2., Parties should regulate all tobacco product design features that increase the attractiveness of tobacco products, in order to decrease the attractiveness of tobacco products.

ANNEX 3

CONTENTS – DISCLOSURE

REPLACE 3.1.3 Constituents (Disclosure) WITH the following

3.1.3 Contents (Disclosure to governmental authorities)

This section outlines requirements which Parties could introduce for the disclosure by manufacturers and importers of tobacco products of information on the contents of these products to governmental authorities

3.1.3.1. Background

Given the numerous toxic and addictive substances contained in tobacco products, governmental authorities with access to information on tobacco contents are in a better position to understand the nature of their tobacco product market. Such information can then be used by governmental authorities to inform the development of policies and regulations respecting the attractiveness, addictiveness or toxicity of tobacco products. For example, given that nicotine is the main substance in tobacco involved in the addictive process, Parties may wish to obtain information on the amount of nicotine present in the various tobacco products available in their domestic market.

To help collect such information, governmental authorities can mandate the use of analytical laboratory methods for the testing and measuring of contents of tobacco products developed under the auspices of WHO¹. The WHO Study Group on Tobacco Product Regulation identified a non-exhaustive list of priority toxic contents and emissions of tobacco products for regulation under Articles 9 and 10 of the WHO FCTC². These methods can be easily performed by a wide spectrum of laboratories. Methods have also been developed by various governmental authorities and international organizations.

3.1.3.2 Recommendations

- i. Parties should consider requiring manufacturers and importers of tobacco products to disclose to governmental authorities at specified intervals, information about the contents of their tobacco products by product type, and for each brand within a brand family.
- ii. When requiring the testing and measuring of contents, Parties should consider where it is appropriate specifying that standards agreed by the Parties to the Convention or recommendations by the WHO Tobacco Laboratory Network could be used by the laboratories performing the test on behalf of the manufacturers and importers of tobacco products. On nicotine, Parties should consider specifying that the Tobacco Laboratory Network Official Method SOP 04, entitled *Standard operating procedure for determination of nicotine in cigarette tobacco filler*, World Health Organization³, be used by the laboratories performing the test on behalf of the manufacturers and importers of tobacco products.
- iii. Parties should consider requiring that every manufacturer and importer provides to governmental authorities a copy of the laboratory report that shows the product tested

¹ See the list of available WHO methods at http://who.int/tobacco/publications/prod_regulation/en/

² For the full list, see WHO Technical Report Series, n. 989, WHO Study Group on Tobacco Product Regulation: report on the scientific basis of tobacco product regulation, available at:

<http://apps.who.int/iris/bitstream/10665/161512/1/9789241209892.pdf?ua=1&ua=1>

³ See <http://apps.who.int/fctc/implementation/database/article/article-10/resources>

and the results of the testing and measuring conducted on that product. Parties should also consider asking for proof of accreditation or membership in the WHO Tobacco Laboratory Network or be approved by competent authorities of the Parties in question of the laboratory that performed the testing and measuring.

(Fifth plenary meeting, 12 November 2016)

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