



WHO FRAMEWORK CONVENTION  
ON TOBACCO CONTROL

CONFERENCE OF THE PARTIES TO THE  
WHO FRAMEWORK CONVENTION ON TOBACCO CONTROL

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# Implementation of Articles 9 and 10 of the WHO FCTC (Regulation of contents and disclosure of tobacco products)

## Report by the Expert Group

### Purpose of the document

In accordance with decision FCTC/COP9(2), the present report is resubmitted to the Conference of the Parties (COP) to the WHO Framework Convention on Tobacco Control (WHO FCTC), without change from document FCTC/COP/9/6. The present document provides an overview of the work, key observations and recommendations of the Expert Group established to examine the reasons for low implementation of Articles 9 and 10 of the Convention in accordance with decision FCTC/COP8(21).

### Action by the Conference of the Parties

The COP is invited to note the present report and provide further guidance.

Contribution to the Sustainable Development Goals (SDGs): All SDGs; in particular, SDG 3 and Targets 3.a and 3.4.

Link to Workplan and Budget item: None.

Additional financial implications if not included in the Workplan and Budget: None.

Related document(s): FCTC/COP/9/6 and report *Meeting of the Expert Group on Articles 9 and 10 of the WHO FCTC* (COP9 supplementary information); FCTC/COP/10/5 and FCTC/COP/10/7.

## BACKGROUND

1. Articles 9 and 10 of the WHO Framework Convention on Tobacco Control (WHO FCTC) set obligations for Parties in relation to the regulation of the contents of tobacco products and of the tobacco product disclosures, respectively. A Working Group to develop guidelines for implementation of Articles 9 and 10 of the Convention was established by the First and Second sessions of the Conference of the Parties (COP) to the WHO FCTC in decisions FCTC/COP1(15) and FCTC/COP2(14). The guidelines developed by the Working Group were adopted by the Fourth session of the COP in decision FCTC/COP4(10) in 2010, but they were labelled as “partial” since some parts of the guidelines were not complete. The Working Group proposed to the COP that additional text be added through decisions FCTC/COP5(6) in 2012 and FCTC/COP7(14) in 2016, but still some sections are not complete.
2. Through decision FCTC/COP8(21), the COP suspended the mandate of the Working Group until the Ninth session of the COP and requested the Convention Secretariat to establish an Expert Group to examine the reasons for low implementation of Articles 9 and 10 of the Convention, and related partial guidelines, by Parties. Since the entry into force of the Convention, an increasing number of Parties have made progress in implementing Articles 9 and 10; however, these articles have remained among the most challenging to implement.<sup>1</sup>

## OPERATION OF THE EXPERT GROUP: METHODOLOGY, PROCESS AND LIMITATIONS

3. The Expert Group established in accordance with decision FCTC/COP8(21) was requested: (a) to provide a detailed analysis of factors that impede implementation of Articles 9 and 10, and related their partial guidelines, including adoption of the test methods referenced therein; (b) to describe the methodology used to arrive at their findings and the limitations to their study; (c) to identify and present positive experiences from Parties in addressing barriers to their implementation of these articles and their related partial guidelines, and examples of successful international cooperation in this regard; and (d) to prepare a report to be submitted to the Ninth session of the COP covering the above points as well as recommending ways the COP could use the findings.
4. The Convention Secretariat, under the guidance of the Bureau, established the Expert Group, composed of 12 experts nominated by Parties. Other participants included five key informants; the chairs of the World Health Organization (WHO) Tobacco Laboratory Network (TobLabNet) and the WHO Study Group on Tobacco Product Regulation (TobReg), and a representative from WHO; and two representatives of civil society organizations accredited as observers to the COP. The Expert Group carried out its work mostly at its meeting in the Netherlands on 21–22 November 2019.
5. Regarding the methodology used by the Expert Group, in order to facilitate deliberations, a report was commissioned by the Convention Secretariat focused on the barriers that impede implementation of Articles 9 and 10 of the WHO FCTC and on identifying best practices and positive experiences from Parties in addressing those barriers. That analysis was based on the information reported by the Parties in the 2018 reporting cycle and more recently, as well as through an ad hoc questionnaire and other

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<sup>1</sup> 2018 Global Progress Report on Implementation of the WHO Framework Convention on Tobacco Control, available at <https://fctc.who.int/publications/m/item/2018-global-progress-report>.

available resources. The Expert Group used the report as a background document for its meeting. The Expert Group discussed the findings and its deliberations contributed to the updating of the report.

6. In preparation for the meeting, the members of the Expert Group were requested to prepare a presentation on the implementation experiences and challenges related to Articles 9 and 10 of the WHO FCTC in the countries and the regions the members represent. Key informants and the other participants were also invited to prepare interventions. The working methods of the meeting included presentations and discussions in small groups and plenary sessions.

7. The experts encountered a few limitations while carrying out their work. First, experts identified the need for more information on implementation of Articles 9 and 10 of the WHO FCTC to enable a broader assessment. Parties should be encouraged to submit responses to additional questions on the use of implementation guidelines adopted by the COP. Particularly, more information is needed to better understand how and at what level countries are developing laws or regulations, and how they are implementing/enforcing/monitoring those laws. Second, in order to reflect on the most recent developments, the elaboration of ad-hoc questionnaires might be considered.

## **FACTORS THAT IMPEDE IMPLEMENTATION OF ARTICLES 9 AND 10 OF THE WHO FCTC**

8. The Expert Group considered the factors that impede implementation of Articles 9 and 10 of the WHO FCTC and those that impede the usage of the related partial guidelines. The barriers for implementation were classified by the experts in five categories, as follows:

(a) *Understanding requirements under Articles 9 and 10 of the WHO FCTC:* Firstly, a lack of awareness and understanding of the potential impact and contribution of Articles 9 and 10 of the WHO FCTC on a comprehensive tobacco control strategy exists among regulators, policy-makers and nongovernmental organizations, resulting in less attention given to these articles. A prevailing misunderstanding is that implementation of these articles is only about laboratory testing. Practical information on how to implement tobacco product regulation is also inadequate. Secondly, certain provisions under Articles 9 and 10 are perceived as very complex, and their interpretation and subsequent communication are considered a challenge. The same perception is widespread among WHO FCTC focal points and government officials. Finally, the lack of understanding of complex technical information hinders the implementation of existing standards and testing methods, which are still to be recommended, developed and made part of the partial guidelines, as appropriate.

(b) *Technical capacity and human resources:* Inadequate training, knowledge and experience of tobacco control staff, and reduced headcount in tobacco control are barriers in implementing these articles. Many countries report the lack or insufficient qualified personnel to test tobacco products and the lack of testing laboratories. When no national laboratory is available, Parties also feel that access to laboratories in other countries is difficult. Furthermore, the lack of testing capacity for non-cigarette products and novel tobacco and nicotine products is a new problem.

(c) *Financial needs:* In general, insufficient and irregular funds dedicated to tobacco control in some countries have implications on the implementation of Articles 9 and 10 of. Implementation costs and the lack of technical capacity devoted to these areas in many Parties are considered important barriers. Specifically, the high cost of setting up a national laboratory

could be a barrier to monitoring existing legislation, including reviewing information received from the tobacco industry.

(d) *Legal and political challenges:* Tobacco product regulation is an area where the tobacco industry often threatens legal action and lawsuits. Also, all of the challenges listed in items (a) to (c) might contribute to the lack of political will to implement Articles 9 and 10, resulting in a lack of national legislation or regulations and implementation rules. In addition, the lack of knowledge of legislators and judges of the public health impact of tobacco use – and of the tobacco industry tactics to jeopardize tobacco control measures – lead to less efficient policies and court decisions that do not favour tobacco control.

(e) *Interference by the tobacco industry:* It is a challenging factor, especially due to the lack of experience of government officials to address attempts at interference in such a complex and low-awareness area. Parties repeatedly experience difficulties in getting information from the tobacco industry, especially on aspects that could facilitate implementation of product regulation measures. The tobacco industry and its front groups continue to engage in lobbying of decision-makers to oppose legislation in tobacco product regulation.

## KEY OBSERVATIONS AND POSITIVE EXPERIENCES

9. To address challenges presented in paragraph 8 above, the Expert Group discussed and identified positive experiences, with proposed potential solutions to improve implementation of Articles 9 and 10. Specific proposals were developed to address the challenges described above that could help the COP to develop future actions to promote implementation of these articles.

(a) *Understanding requirements under Articles 9 and 10 of the WHO FCTC:* Clarity on the requirements of these articles is critical to avoid misperceptions and misconceptions. Promoting implementation and advocacy should be accomplished through campaigns, workshops, webinars and simple policy briefs. In addition, a list of Parties that have implemented the specific measures under Articles 9 and 10 of the WHO FCTC and those that used the related partial guidelines should be regularly updated and disseminated.

(b) *Technical capacity and human resources:* Additional practical tools to raise awareness and improve technical capacity on product regulation are needed, as well as efforts to publicize and facilitate utilization of existing tools and the creation of a practical implementation guide. Since not all Parties need to have their own national laboratories, more coordination is needed in the regions, which might be provided by the existing networks (WHO TobLabNet). The cost of testing and transporting samples should be addressed in the regulations and borne by the industry.

(c) *Financial needs:* There needs to be clarity on the costs associated with implementation of Articles 9 and 10, and a budgeted roadmap on their implementation should be developed. Lessons derived from implementation of these articles and documented practices, including their costs and on how these costs could be placed on the tobacco industry and retailers, should be made available. The tobacco industry should bear the costs of implementing these articles, through – among other means listed in Appendix 1 of the partial guidelines – a specific fee as a potential solution. Dedicated financial contributions from Parties and donors for implementation of Articles 9 and 10 of the WHO FCTC should be made available.

(d) *Collaboration between the Convention Secretariat, WHO and Parties:* WHO TobLabNet testing methods for tobacco products should be further disseminated and promoted by the COP. Work is currently ongoing to develop methods for the contents in liquids for electronic cigarettes, and both contents and emissions in heated tobacco products. This network and its members could help in developing new or strengthening existing national testing capacity. WHO should develop standard operating procedures to test smokeless tobacco products. And a business model for sustainable financial solutions to support work on Articles 9 and 10 of the WHO FCTC should be developed in accordance with decision FCTC/COP7(25) and the *Global Strategy to Accelerate Tobacco Control: Advancing Sustainable Development through the Implementation of the WHO FCTC 2019–2025* adopted by COP8.

(e) *International collaboration:* A needs assessment on testing capacity and laboratories should be conducted by either WHO, the Convention Secretariat, WHO TobLabNet or a combination of these actors. Collaboration and knowledge sharing among Parties and regions through promoting strong examples of implementation are essential. Regional economic integration organizations should be involved in developing regional policies for implementation of these articles. Implementation of the Sustainable Development Goals should be used as a platform to integrate WHO FCTC implementation with strengthening the control of noncommunicable diseases. Parties should partner to visit various laboratory sites to learn and share operating models.

10. During the discussions at the Expert Group meeting a few other issues regarding the implementation of Articles 9 and 10 of the WHO FCTC were also discussed. As both the challenges and the proposed solutions include needs and opportunities concerning data collection, data sharing, communication, technical assistance, capacity-building and other types of engagements among the Parties, the members of the Expert Group suggested that setting up a knowledge hub for Articles 9 and 10 of the WHO FCTC could be beneficial. A knowledge hub focusing on product regulation could act as a central point for data collection and knowledge generation, and support in capacity-building and addressing the challenges associated with the implementation of the Articles 9 and 10.

11. Taking into account the existing capacity of WHO collaborating centres to provide support on questions related to product regulation, together with global networks such as WHO TobReg, WHO TobLabNet and the Global Tobacco Regulators Forum (GTRF), there will need to be increased coordination among various stakeholders to ensure synergy and improve efficiency.

## **RECOMMENDATIONS BY THE EXPERT GROUP**

12. Based on the above, a summary of key observations and recommendations that the Expert Group wishes to propose to COP for its consideration are described below.

(a) Tobacco product regulation is a powerful tool that could help reduce tobacco use by making the products less attractive and palatable. Product regulation should be part of any comprehensive tobacco control strategy, plan or programme.

(b) The documentation of best practices and lessons learnt from Parties on their implementation work – also on addressing gaps and barriers – can further advance tobacco product regulation.

(c) Advancing and assisting with implementation of Articles 9 and 10 of the WHO FCTC needs a multipronged approach and requires good coordination among various stakeholders that could provide such assistance, including the Convention Secretariat, its relevant knowledge hubs, WHO, WHO TobReg, WHO TobLabNet, WHO collaborating centres (through WHO), GTRF and civil society.

(d) Parties need an all-encompassing understanding of Articles 9 and 10 of the WHO FCTC, and their relevance to the changing tobacco market and regulatory environment, where new ingredients, constituents, emissions and sometimes entirely new products are launched so frequently.

(e) Setting up a knowledge hub devoted to product regulation could raise the visibility of Articles 9 and 10 of the WHO FCTC, offer its knowledge and advice to Parties in need, and facilitate and provide a platform for international cooperation and contribute to the existing network of WHO FCTC Knowledge Hubs, including the ones that are heavily dependent on tobacco product regulation know-how by working in the areas of smokeless tobacco products and water pipes. Given the knowledge on and the status of implementation of Articles 9 and 10, a knowledge hub would benefit Parties, bringing leadership on the topic and providing expertise and guidance.

#### **ACTION BY THE CONFERENCE OF THE PARTIES**

13. The COP is invited to note the present report and provide further guidance.

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