

THE WHO FRAMEWORK CONVENTION ON TOBACCO CONTROL AND THE PROTOCOL TO ELIMINATE ILLICIT TRADE IN TOBACCO PRODUCTS

Introduction to the WHO FCTC and the Protocol

The WHO Framework Convention on Tobacco Control (WHO FCTC) is an evidence-based treaty that reaffirms the right of all people to the highest standard of health. Adopted in 2003 by WHO Member States, it provides a framework for tobacco control measures to be implemented by its Parties in order to reduce continually and substantially the prevalence of tobacco use and the exposure to tobacco smoke. It is among the most widely embraced treaties in the UN's history, with 182 Parties that together comprise more than 90% of the world's population. Since its entry into force in 2005, the WHO FCTC has been an unambiguous success and remains the organizing principle for progress and cooperation on tobacco control locally, nationally, regionally, and globally.

In becoming a Party to the WHO FCTC, countries assume mutually reinforcing obligations to reduce the demand for, and supply of, tobacco products. The MPOWER technical package – developed by WHO – helps countries implement most of these demand-reduction measures by providing a measurable gold standard for their achievement and monitoring progress towards it. While the MPOWER package's cost-effectiveness justifies this focus, supply-reduction measures are also needed for a comprehensive, synergistic approach and for supporting the political economy of tobacco control.

The Convention also contains general obligations that are crucial to these demand- and supply-reduction measures (and especially those in the MPOWER package). Article 5 provides the basis for the governance of tobacco control, with Paragraph 1 and Paragraph 2 calling for a multisectoral, whole-of-government approach and the development of appropriate national legislation and strategies.

Paragraph 3 of Article 5, together with the guidelines for implementation of Article 5.3, provides the basis for protecting tobacco control public health policies from the influence of the tobacco industry and those who work to further its interest. Those measures, together with Article 19 on tobacco industry liability, make the Convention innovative in its ability to target an industry known for using deceptive means to prioritize profits over public health.

The WHO FCTC governing body, the biennial Conference of the Parties (COP), is the leading global forum for discussing and reaching consensus on Convention implementation and any emerging tobacco control issues, and is the sole body for authoritative interpretations of the Convention's provisions. In 2012, at the Fifth Session of the COP in the Republic of Korea, Parties adopted a new international treaty: the Protocol to Eliminate Illicit Trade in Tobacco Products. The Protocol builds on Article 15 of the Convention that addresses illicit trade in tobacco products, but the complexity of transboundary cooperation to prevent illicit trade required a more extensive

and finely tuned set of obligations. Illicit trade in tobacco products poses a significant threat to key demand-reduction measures, in particular price measures and health warnings.

The Protocol came into force in September 2018 and currently counts 63 Parties as of 25 May 2021. It aims at the elimination of all forms of illicit trade in tobacco products and its obligations encompass tools for preventing illicit trade, and numerous mechanisms for promoting cooperation between countries. Parties to the Protocol assume substantive obligations to: control the supply chain for tobacco products; make it an offence to have any involvement with illicit trade; and cooperate with other countries in the prevention of illicit trade. The Protocol also has its own governing body, the Meeting of the Parties (MOP), which, like the COP, convenes biennially.

The WHO FCTC also mandated the COP to establish a Convention Secretariat to provide policy support to Parties in implementing the Convention, as well as to support the functioning of the COP and other subsidiary body meetings. The Protocol established that the Convention Secretariat is also its Secretariat, with similar functions. WHO cooperates with the Convention Secretariat to support Parties to the WHO FCTC and to the Protocol in their substantive and reporting requirements, and also advocates to increase the number of Parties to the WHO FCTC and the Protocol.

KEY WHO FCTC PROVISIONS

Demand-reduction measures	<p>Article 6: Price and tax measures to reduce the demand for tobacco</p> <hr/> <p>Article 8: Protection from exposure to tobacco smoke</p> <hr/> <p>Article 9: Regulation of the contents of tobacco products</p> <hr/> <p>Article 10: Regulation of tobacco product disclosures</p> <hr/> <p>Article 11: Packaging and labelling of tobacco products</p> <hr/> <p>Article 12: Education, communication, training and public awareness</p> <hr/> <p>Article 13: Tobacco advertising, promotion and sponsorship</p> <hr/> <p>Article 14: Demand-reduction measures concerning tobacco dependence and cessation</p>
Supply-reduction measures	<p>Article 15: Illicit trade in tobacco products</p> <hr/> <p>Article 16: Sales to and by minors</p> <hr/> <p>Article 17: Provision of support for economically viable alternative activities</p>
General obligations	<p>Article 4: Guiding principles</p> <hr/> <p>Article 5: General obligations</p> <ul style="list-style-type: none"> ■ 5.1: Comprehensive multisectoral national tobacco control strategies, plans and programmes ■ 5.2: National coordinating mechanism or tobacco control focal point ■ 5.3: Protecting tobacco control policies from the tobacco industry's commercial and vested interests
Other measures	<p>Article 18: Protection of the environment and the health of persons</p> <hr/> <p>Article 19: Liability</p> <hr/> <p>Article 20: Research, surveillance and exchange of information</p> <hr/> <p>Article 21: Reporting and exchange of information</p> <hr/> <p>Article 22: Cooperation in the scientific, technical and legal fields and provisions of related expertise</p>

The Conference of the Parties has provided guidance on the regulation of novel and emerging tobacco products and nicotine products since 2008.

COVID-19's effect on WHO FCTC / Protocol Implementation

The devastation caused by the COVID-19 pandemic starkly illustrates the need for accelerated implementation of the WHO FCTC and the Protocol, with a particular focus on scaling up achievement using the MPOWER technical package. There is irrefutable evidence of a deadly interplay between COVID-19 and tobacco use, both past and present: those infected with the virus and who are tobacco users have suffered more severe disease progression than non-tobacco users; the vulnerability of health systems has been exacerbated; and tobacco use has increased the pandemic's human and economic costs (1–6). Accordingly, global and national efforts to build back better will be incomplete unless the “tobacco pandemic”, alongside other vulnerabilities underlying the crisis, are addressed.

More broadly, the COVID-19 pandemic and accompanying global economic recession have disrupted political agendas. This has, in certain cases, come at the expense of activities such as tobacco control, that may appear less pressing or uneconomical. This has challenged progress on implementation of the WHO FCTC and the Protocol. Most strikingly, the Ninth Session of the COP (COP9) and the Second Session of the MOP (MOP2), originally scheduled for November 2020, were postponed until November 2021.

But the COVID-19 pandemic has also provided opportunities for advancing tobacco control measures. For example, 17 countries in the Eastern Mediterranean Region have banned the use of waterpipes (shishas) in public places, and South Africa temporarily banned tobacco sales under a general ban on the sale of “non-essential” products during the country's pandemic response. Similarly, other countries such as South Africa and the Russian Federation have raised tobacco taxes in an effort to save lives while mobilizing

revenue to fight the pandemic and its associated economic crisis.

The tobacco industry has taken advantage of the situation by muddying the science on tobacco's link with COVID-19 and positioning itself as an economic and development partner for national COVID-19 recovery efforts. Many of the major tobacco industry actors have – under the banner of so-called corporate social responsibility – used a small portion of their immense resources on heavily publicized COVID-19-related charity programmes. As the Guidelines for implementation of Article 13 of the WHO FCTC note, these activities are a form of sponsorship.

The COP9 (8–13 November 2021) and MOP2 (15–18 November 2021)

The COVID-19 pandemic means that the forthcoming sessions of the COP and MOP will be held virtually. At the sessions, delegates will note the implementation progress attained and identify challenges and possible opportunities for advancing and strengthening the comprehensive implementation of the respective treaties. Parties will adopt new decisions to guide the future direction of implementation for both treaties by, inter alia, establishing new subsidiary bodies, clarifying the interpretation of obligations and requesting the Convention Secretariat and/or inviting WHO to undertake some tasks and report on specific matters.

After nearly 2 years of pandemic-related disruption to the tobacco control agenda and despite an abridged Provisional Agenda, both COP9 and MOP2 will feature important items for consideration, such as a proposed investment fund for the WHO FCTC and the Protocol – an innovative financing mechanism that aims to provide much-needed resources for the implementation of both treaties.

A highlight of the MOP2 Provisional Agenda is the consideration of a report

from a subsidiary body established by MOP1 on tracking and tracing systems for tobacco products. Under Article 8 of the Protocol, Parties agreed to establish a global tracking and tracing regime by September 2023. This global regime will comprise national and regional systems intended to ensure that Parties can secure the supply chain of tobacco products, and a global information-sharing focal point located at the Convention Secretariat that will enable Parties to exchange information in order to better tackle illicit trade. The MOP's deliberation on this matter will be crucial for guiding and promoting timely implementation of this technically complex obligation.

Novel and emerging tobacco products and nicotine products

The COP has provided guidance on the regulation of novel and emerging tobacco products and nicotine products since 2008, with a particular focus on heated tobacco products (HTPs), electronic nicotine delivery systems (ENDS) and electronic non-nicotine delivery systems (ENNDS) (7). The COP has defined the landscape as follows. HTPs are tobacco products, which produce aerosols containing nicotine and other chemicals, by heating tobacco units; they are subject to the provisions of the WHO FCTC. By contrast, ENDS and ENNDS do not contain tobacco and instead vaporize a solution composed of numerous compounds, which include nicotine in the case of ENDS, or may not contain nicotine in the case of ENNDS. Regarding the latter products, COP6 invited Parties “to consider prohibiting or regulating ENDS/ENNDS, including as tobacco products, medicinal products, consumer products, or other categories, as appropriate, taking into account a high level of protection for human health” (8). At COP7, Parties were also invited to apply regulatory measures to prohibit or restrict the manufacture, import, distribution, presentation,

sale and use of ENDS/ENNDS, as appropriate (9). As noted in a WHO report submitted to COP8, the tobacco industry's promotion of products in each category can be considered a response to declining sales of cigarettes in high-income countries (10).

Work on addressing ENDS at the COP to date

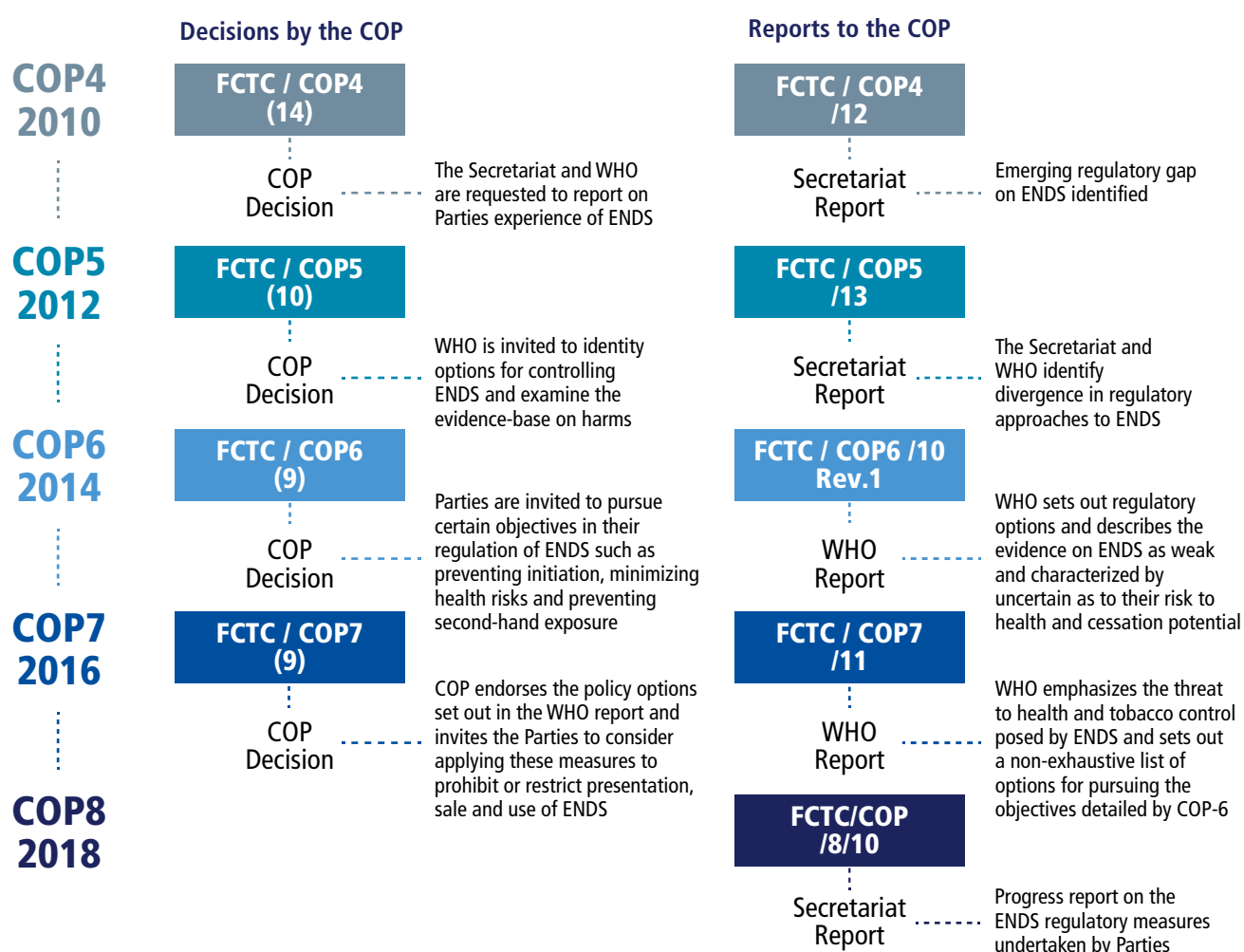
At COP3, the Convention Secretariat was requested to invite WHO to submit a report to COP4, identifying best practices in reporting to regulators on the contents, emissions, and product characteristics, including for electronic systems. Since then, multiple reports and decisions have addressed the matter.

The most relevant decisions are from COP6, which set out basic objectives

that Parties were invited to pursue when addressing ENDS/ENNDS, including: (a) preventing initiation by non-smokers and youth with special attention to vulnerable groups; (b) minimizing as far as possible potential health risks to users and protecting non-users from exposure to emissions; (c) preventing unproven health claims being made about ENDS/ENNDS; and (d) protecting tobacco-control activities from all commercial and other vested interests related to these products, including interests of the tobacco industry. Parties were also invited to consider prohibiting or regulating ENDS/ENNDS, including as tobacco products, medicinal products, consumer products, or other categories as appropriate, taking into account a high level of protection for human health (8).

This was followed, in 2016, by a COP7 decision inviting Parties to consider prohibiting or restricting the manufacture, import, distribution, presentation, sale and use of ENDS/ENNDS, as appropriate to their national laws and public health objectives. Parties that have not totally banned those products were invited to follow a non-exhaustive list of regulatory options for pursuing the objectives set out in the COP6 decision – provided in a report prepared by WHO – that were endorsed for consideration by the Parties (8). Such regulation entails the application of most of the WHO FCTC demand and supply reduction measures to ENDS/ENNDS, as well as the concerted application of Article 5.3 (11).

TIMELINE OF ENDS-RELATED DECISIONS AT, AND REPORT TO, THE COP



Work on addressing HTPs at the COP to date

Since their emergence, HTPs have been marketed with health and cessation claims that are not supported by independent, solid evidence (12). Cessation is defined in the Guidelines for implementation of Article 14 of the WHO FCTC as “the process of stopping the use of any tobacco product...” and it is, therefore, implausible to claim this may be done by switching to another tobacco product. In 2016, the COP7 requested the Convention Secretariat to invite WHO to report on specific questions related to HTPs at the subsequent session (13).

Following this report, in 2018, COP8 defined HTPs as tobacco products, and “therefore subject to the provisions of the WHO FCTC”. Parties were invited to prioritize certain measures in addressing the challenges posed by novel and emerging tobacco products such as HTPs, and the devices designed for consuming such products. Such measures included: (a) preventing initiation into use of novel and emerging tobacco products; (b) protecting people from exposure to their emissions and explicitly extending the scope of smoke-free legislation to these products in accordance with Article 8 of the WHO FCTC; (c) preventing health claims from being made about these products; (d) applying measures regarding the advertising, promotion and sponsorship of these products in accordance with Article

13 of the WHO FCTC; (e) regulating the contents and the disclosure of the contents of these products in accordance with Articles 9 and 10 of the WHO FCTC; (f) protecting tobacco-control policies and activities from all commercial and other vested interests related to these products, including interests of the tobacco industry, in accordance with Article 5.3 of the WHO FCTC; (g) regulating – including restriction or prohibition, as appropriate – the manufacture, import, distribution, presentation, sale and use of these products, as appropriate to their national laws, taking into account a high level of protection for human health; (h) applying, where appropriate, the above measures to the devices designed for consuming such products (9).

In 2018 the Convention Secretariat, WHO, and the WHO Tobacco Laboratory Network were also invited by the COP to report on various characteristics of novel and emerging tobacco products, in particular HTPs, as well as to monitor market developments and the use of these products. Despite HTPs unambiguously being tobacco products, some of their product characteristics pose regulatory challenges for their definition and classification, as well as for the comprehensive application of the WHO FCTC. For that reason, the COP requested the Convention Secretariat and invited WHO to provide more information on novel tobacco products, in particular HTPs, to COP9 (9).

Contextualizing the WHO report on the global tobacco epidemic, 2021

The focus of this report – addressing new and emerging products – is important at a time when the tobacco industry is using new strategies to position itself as a development partner. The foundation for the regulation of ENDS and HTPs, laid down by the COP, has been crucial for translating technical recommendations into political action at the national level.

The documents analysed in this chapter are the political decisions made by Parties to the WHO FCTC in relation to the regulation of ENDS and HTPs. Until solid and independent science present a different scenario for consideration of the Parties, these provide the regulatory options that Parties to the WHO FCTC are invited to follow.

They are markers of global sentiment capable of cutting through the commercially interested noise and tobacco industry obfuscation that surrounds these products. Such decisions are influential in national regulation and can also contain legally authoritative interpretations of the WHO FCTC’s provisions.

In 2018, COP8 defined heated tobacco products as tobacco products, and are therefore subject to the provisions of the WHO FCTC.

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