

CS/NV/20/13

Decision on heated tobacco products by the United States Food and Drug Administration

The Convention Secretariat, which serves as the Secretariat of both the WHO Framework Convention on Tobacco Control (WHO FCTC) and of the Protocol to Eliminate Illicit Trade in Tobacco Products (Protocol), presents its compliments to the Permanent Missions to the United Nations Office and other international organizations in Geneva and to the Parties to the WHO FCTC and has the honour to draw their attention to a recent decision of the United States Food and Drug Administration (FDA).

On 7 July 2020, the FDA authorized the marketing of the IQOS Tobacco Heating System, including the IQOS device to be used with Marlboro HeatSticks, Marlboro Smooth Menthol HeatSticks and Marlboro Fresh Menthol HeatSticks. This means that, in the United States of America, Philip Morris Products S.A. is authorized to use the following information in the advertising and marketing of the IQOS Tobacco Heating System:

Available evidence to date:

- *The IQOS system heats tobacco but does not burn it.*
- *This significantly reduces the production of harmful and potentially harmful chemicals.*
- *Scientific studies have shown that switching completely from conventional cigarettes to the IQOS system significantly reduces your body's exposure to harmful or potentially harmful chemicals.*

The FDA has also provided the following statement in relation to the authorization:

Even with this action, these products are not safe nor "FDA approved" – there are no safe tobacco products. The exposure modification orders do not permit the company to make express or implied statements that convey or could mislead consumers into believing that the product is endorsed or approved by FDA, or that FDA deems the product to be safe for use by consumers.

Media articles worldwide are reporting this issue, and tobacco industry is trying to encourage other governments to also allow the IQOS Tobacco Heating System to be marketed and sold in their jurisdictions. Philip Morris is also reported to be seeking regulations for the product that would be less onerous than for other tobacco products.

Considering this development and taking into account the statement published by the World Health Organization on 27 July 2020,¹ the Convention Secretariat wishes to bring to the attention of Parties to the WHO FCTC the following:

¹ WHO statement on heated tobacco products and the FDA decision regarding the IQOS Tobacco Heating System can be found at: <https://www.who.int/news-room/detail/27-07-2020-who-statement-on-heated-tobacco-products-and-the-us-fda-decision-regarding-iqos>

- Decision FCTC/COP8 (22) adopted at the Eighth Session of the Conference of the Parties to the WHO FCTC states that:² “...heated tobacco products are tobacco products and are therefore subject to the provisions of the WHO FCTC”. The decision also reminds Parties, inter alia:
 - to “prevent the initiation of novel and emerging tobacco products”;
 - to “prevent health claims from being made about novel and emerging tobacco products”; and
 - to “apply measures regarding advertising, promotion and sponsorship of novel and emerging tobacco products in accordance with Article 13 of the WHO FCTC”.
- Article 13 of the WHO FCTC requires a comprehensive ban on tobacco advertisement, promotion and sponsorship and it also requires that Parties:
 - “prohibit all forms of tobacco advertising, promotion and sponsorship that promote a tobacco product by any means that are false, misleading or deceptive or likely to create an erroneous impression about its characteristics, health effects, hazards or emissions”.
- The FDA authorizations only apply to the United States of America, which is not a Party to the WHO FCTC.
- Reduced exposure to toxicants does not equate to reduced risk.³
- The aerosol produced by a heated tobacco product has some substances that are not present in cigarette smoke, as well as other chemicals that are present in higher levels than in cigarette smoke.⁴
- Research indicates that people perceive the “lower exposure” claims as “lower risk claims”.⁵

The Convention Secretariat urges Parties to remain vigilant in protecting their tobacco control policies and legislation from any interference from the tobacco industry or those who work to further the industry’s interests and to continue striving to fully meet their obligations under the WHO FCTC and the decisions adopted by the Conference of the Parties, as stated above.

The Convention Secretariat avails itself of this opportunity to renew to the Permanent Missions to the United Nations Office and other international organizations in Geneva and to the Parties to the WHO FCTC the assurances of its highest consideration.



Geneva, 31 July 2020

² Decision FCTC/COP8(22) on novel and emerging tobacco products:
[https://www.who.int/fctc/cop/sessions/cop8/FCTC__COP8\(22\).pdf?ua=1](https://www.who.int/fctc/cop/sessions/cop8/FCTC__COP8(22).pdf?ua=1)

³WHO 2020 Heated Tobacco Products- Fact Sheet <https://www.who.int/publications/i/item/WHO-HEP-HPR-2020.2>.

⁴ ibid 2

⁵ Linda L. Pederson, Ph.D., David E. Nelson, M.D., M.P.H, Literature Review and Summary of Perceptions, Attitudes, Beliefs, and Marketing of Potentially Reduced Exposure Products: Communication Implications, Nicotine & Tobacco Research, Volume 9, Issue 5, May 2007, Pages 525–534, <https://doi.org/10.1080/14622200701239548>