INFORMATION SHEET ON

WHO TobLabNet methods for measuring priority contents and emissions in tobacco and related products

MARCH 2020 WHO/HEP/HPR/2020.1

Reducing tobacco product appeal and use through product regulation:

- Tobacco product regulation is a powerful tool that can help to decrease the appeal and subsequent use of tobacco products.
- Tobacco product regulation should be part of a comprehensive tobacco control programme.
- Tobacco product regulation includes measurement of contents and emissions of tobacco products, their regulation and disclosure to regulatory authorities and the public.
- Examples include bans or the restriction of flavours, bans on product categories e.g. smokeless tobacco or electronic nicotine delivery systems (ENDS), or disclosure of the contents of tobacco and related products, such as nicotine and sugars.
- Testing methods for product regulation should have zero industry involvement (industry-independent).
- The development and validation of testing methods is crucial to regulate tobacco products, including data verification.
- Tobacco product regulation need not be expensive as regulators can charge tobacco manufacturers for costs involved in testing products by independent labs.

Why is tobacco product regulation important?

Despite their devastating health effects, tobacco and related products are designed to appeal to young people, are addictive, openly marketed and either under-regulated or not regulated.¹ Given the number of people that die every year from tobacco-related illness, these products should be regulated. Tobaccoproduct regulation, which forms part of a comprehensive tobacco control programme, should thus be actively pursued. To achieve this, countries can require tobacco manufacturers to make their products less attractive, toxic and addictive, especially to young people, by amending existing tobacco-control laws to include tobacco product-regulation provisions. Regulatory measures, such as setting product standards or banning product features or categories, aim to reduce tobacco use prevalence and tobacco-related harm. Examples include restriction and/or banning of flavours and sugars in tobacco products, restriction on filter features, such as filter ventilation² and setting limits on the levels of emissions generated.^{2,3}

It must be noted that no machine smoking regimen can represent all human smoking behaviour; machine smoking testing is useful for characterizing cigarette emissions for design and regulatory purposes, but communication of machine measurements to smokers can result in misunderstanding about differences in exposure and risk between brands; data on smoke emissions from machine measurements may be used as inputs for product hazard assessment but they are not intended to be nor are they valid as measures of human exposure or risks and representing differences in machine measurements as differences in exposure or risk is a misuse of testing with WHO TobLabNet standards.



What is the significance of these methods for tobacco product regulation?

The importance of tobacco product regulation is reflected in Articles 9 and 10 of the WHO Framework Convention on Tobacco Control (WHO FCTC).4 Article 9 sets out the obligation of Parties in regulating the contents and emissions of tobacco products. Article 10, on the other hand, involves the disclosure of such information by tobacco manufacturers to responsible national authorities for tobacco-product regulation, for regulators to extract relevant information in a meaningful way to inform the public about the toxic constituents of tobacco products and the emissions that they may produce. The associated guidelines for both Articles recommend that Parties prohibit or restrict ingredients that increase palatability of tobacco products (e.g. flavourings) and also set out the requirements for independent testing and measurement of the contents and emissions of tobacco products.5

How can measuring tobacco product contents and emissions advance tobacco product regulation?

Regulators can measure and monitor levels of compounds in tobacco products or their emissions to understand the type and amount of chemical substances to which consumers are exposed. This may help formulate policies to reduce the toxicity, attractiveness and addictiveness of tobacco and have the potential to contribute to reduced tobacco use. Following implementation of regulatory policies, these compounds can be measured for compliance purposes and remedial action taken as necessary. Validated laboratory testing methods are needed to measure the contents (e.g. humectants and nicotine) and emissions (e.g. nicotine and carbon monoxide) of tobacco products for regulatory purposes and the cost of routine compliance testing, as well as verification of industry data can be charged to tobacco manufacturers.⁶ As a first step, countries can monitor and build intelligence on the products on their markets.

Why is it important for these methods to be developed independently of the tobacco industry?

As tobacco products are manufactured and intricately designed by the tobacco industry, their involvement in developing methods to test these products would be a clear conflict of interest. This is even more crucial given that the tobacco industry has a long history of misleading the public and working against well-intentioned tobacco-control policies.7 Examples include the use of ventilation holes in cigarettes to manipulate the emissions of tobacco products and promote so-called light and mild tobacco products as an alternative to quitting, while being fully aware that testing of these products, using International Organization for Standardisation (ISO) methods, will result in misleadingly low levels of the measured compounds. Therefore, tobacco industry activities, no matter how they are "dressed up", should always be monitored with caution and scepticism and regulatory test methods should be developed and validated independently of the tobacco industry.

Are ISO tobacco testing methods independent?

The industry exerts considerable influence on the adopted ISO testing methods for tobacco and tobacco products, as they make up by far the largest percentage of national and international technical committees. This led to WHO establishing an alternative global network of independent laboratories, the WHO Tobacco Laboratory Network (TobLabNet), to develop the methods for testing these products rather than adopting those developed under industry control and manipulation. Consequently, this will ensure the generation of independent and reliable information on tobacco products for regulatory purposes, thus building capacity for tobacco product regulation and strengthening implementation of relevant provisions.

More information on TobLabNet and its activities?

TobLabNet is a WHO technical advisory body, comprised of independent scientists with expertise in the fields of product regulation and laboratory analysis of tobacco contents, emissions and design features. It was established in 2005 and has members from the six regions of WHO. TobLabNet develops and validates methods to test the contents and emissions of tobacco products, supports WHO in building testing capacity in WHO Member States, and runs training workshops in countries under the leadership of WHO. TobLabNet works in unison with WHO TobReg, which provides scientifically sound and evidence-based recommendations to Member States through the WHO Director-General on tobacco product regulation.

Find more detailed information on the role of TobLabNet, how to become a member, how to request method development and/or assistance, etc. <u>here</u>. Find more on how to build laboratory testing capacities <u>here</u>.

What are WHO TobLabNet methods and how are they developed?

WHO TobLabNet methods⁸ are laboratory testing methods for tobacco and related products developed by part of WHO's global technical network on tobacco-product regulation. This group is made up of members from government, academic and other independent laboratories. TobLabNet methods are developed and validated independently of the tobacco industry, with no tobacco industry representative present at any of the meetings, nor involved in the development and validation of the methods (unlike ISO committees for example). These independent methods are recommended for use by regulators to test the contents and emissions of tobacco products. For example, TobLabNet validated an intense smoking protocol for generating emissions from cigarettes. The WHO Study Group on Tobacco Product Regulation (TobReg), another technical advisory group of WHO on tobacco product regulation, recommends the use of an intense smoking regime, rather than the US Federal Trade Commission (FTC)/ International Organization for Standardisation (ISO) testing regime.2

What is the difference between the ISO and the intense regime?

The ISO regime is less intense than human smoking behaviour, especially in the case of cigarettes with a high degree of filter ventilation. As the main addictive component in cigarette smoke is nicotine, and smokers need a certain amount of nicotine to maintain their addiction, they adapt their smoking behaviour to the nicotine levels present in smoke. One of the main factors determining nicotine levels are ventilation holes in the cigarette filter that dilute smoke. In response, smokers (partly) close the ventilation holes with their fingers and lips, and smoke more intensely. The ventilation holes remain open in the ISO regime, but are closed in the intense regime. Additionally, the intense regime uses larger, longer and deeper puffs.

What are priority contents and emissions of tobacco products and which methods are available?

The priority contents and emissions identified by WHO9 are important targets for product regulation. There are thousands of compounds in tobacco products and their emissions, of which the 39 most toxic compounds have been prioritised for testing by WHO-selected independent scientists. The WHO FCTC Conference of the Parties (COP) requested TobLabNet to develop testing methods for 12 of these compounds, which were further prioritised and considered the most important for monitoring.¹⁰ Nine of these are the toxicants in cigarette smoke recommended for mandated lowering by TobReg (Acetaldehyde, Acrolein, Formaldehyde, Benzene, 1,3-Butadiene, Carbon monoxide, Benzo[a]pyrene, NNK, NNN),² and the other three are priority contents in tobacco, namely nicotine, humectants and ammonia.^{3,9} These methods are available to regulators and other interested parties. 11 As many countries still use the ISO method for regulatory purposes and the principles of some of these methods guided the development and validation of TobLabNet methods, ISO methods are referenced in some of the TobLabNet methods. This does NOT mean that the industry had any involvement in developing the methods or interfered with the methods in any way. The reason is that TobLabNet methods are also validated for the very low emission levels from open filter holes, as with those achieved by the ISO method.

What is next for TobLabNet?

TobLabNet continues its work on developing and validating methods for measuring other compounds on the priority list to make a wider range of methods available to countries. It also continues validating methods for analysis of contents and emissions of other tobacco and related products, such as electronic nicotine delivery systems (ENDS) including e-cigarettes, heated tobacco products, smokeless tobacco, waterpipe tobacco products and other tobacco products. TobLabNet's continuing initiatives include efforts on building country capacity to implement validated methods. E-learning tools are being developed for training purposes on the various methods. Further, WHO continues to work with Member States and leverages the diverse expertise in TobLabNet and TobReg to build tobacco-product regulation capacity around the world.

Information included in this publication was gathered with the support of funding from the Government of the Netherlands and collaboration with the Netherlands National Institute for Public Health and the Environment (RIVM).

WHO/HEP/HPR/2020.1
© World Health Organization 2020.
Some rights reserved. This work is available under the CC BY-NC-SA 3.0 IGO licence.

References

- 1 Tobacco product regulation: basic handbook. Geneva: World Health Organization. 2018. (https://www.who.int/tobacco/publications/prod_regulation/basic-handbook/en/, accessed 30 October 2019).
- $\label{eq:control_of_control} 2 \quad Burns\,DM,\,Dybing\,E,\,Gray\,N,\,Hecht\,S,\,Anderson\,C,\,O'Connor\,R,\\ Djordevic\,et\,al.\,Mandated\,lowering\,of\,toxicants\,in\,cigarette\,smoke:\,a\,description\,of\,the\,World\,Health\,Organization\,TobReg\,proposal.\,Tob\,Control\,17(2):\,132-141\,(http://dx.doi.org/10.1136/tc.2007.024158).$
- 3 FCTC/COP/6/14 Work in progress in relation to Articles 9 and 10 of the WHO FCTC. 2014; Geneva: WHO FCTC (https://apps.who.int/gb/fctc/PDF/cop6/FCTC_COP6_14-en.pdf, accessed 30 October 2019).
- 4 WHO Framework Convention On Tobacco Control. Geneva: World Health Organization; 2003 (https://apps.who.int/iris/bitstream/handle/10665/42811/9241591013.pdf;jsessionid=73C81D-644617F8A663FAB839F46DB5B9?sequence=1, accessed 30 October 2019).
- 5 Partial guidelines for implementation of Articles 9 and 10. Geneva: WHO FCTC. 2012 (https://www.who.int/fctc/guidelines/adopted/article_9and10/en/, accessed 30 October 2019).
- 6 Tobacco product regulation: building laboratory testing capacity. Geneva: World Health Organization; 2018 (https://www.who.int/tobacco/publications/prod_regulation/building-laboratory-testing-capacity/en/, accessed 30 October 2019).
- 7 Tobacco industry strategies to undermine tobacco control activities at the World Health Organization. Geneva: World Health Organization. 2000 (https://www.who.int/tobacco/publications/industry/who_inquiry/en/, accessed 30 October 2019).
- 8 WHO TobLabNet methods. In: WHO/TFI [website] (https://www.who.int/tobacco/publications/en/, accessed 30 October 2019).
- 9 WHO Technical Report Series 951 The scientific basis of tobacco product regulation: second report of a WHO study group. Geneva: World Health Organization. Geneva: World Health Organization; 2008 (https://www.who.int/tobacco/global_interaction/tobreg/publications/9789241209519.pdf, accessed 30 October 2019).
- 10 Decision FCTC/COP3(9). Elaboration of guidelines for implementation of Articles 9 and 10 (Regulation of the contents of tobacco products and Regulation of tobacco product disclosures). Available at: http://apps.who.int/gb/fctc/PDF/cop3/FCTC_COP3_DIV3-en.pdf, accessed 30 October 2019).
- 11 Latest publications of the WHO TobLabNet. World Health Organization/TFI [website] (https://www.who.int/tobacco/industry/product_regulation/toblabnet/en/, accessed 30 October 2019).