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Title

Information sheet: measuring priority emissions in heated tobacco products, importance for regulators and significance for public health.

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INFORMATION SHEET

MEASURING PRIORITY EMISSIONS IN HEATED TOBACCO PRODUCTS, IMPORTANCE FOR REGULATORS AND SIGNIFICANCE FOR PUBLIC HEALTH

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Key messages

- Regulators in jurisdictions where heated tobacco products (HTPs) are not banned are urged to consider monitoring harmful compounds in the emissions of HTPs, such as nicotine, aldehydes and carbon monoxide, and to reduce their levels, as appropriate, according to WHO recommendations and the national context.
- The WHO Tobacco Laboratory Network is developing methods independently of the tobacco industry to measure priority toxicants in HTPs for eventual use in setting regulations.

What are heated tobacco products?

HTPs are tobacco products that contain tobacco, nicotine and non-tobacco additives such as humectants and flavourings (1). Tobacco in HTPs is heated by a device, producing aerosols containing nicotine, toxic chemicals and carcinogens that are also present in cigarette smoke and are harmful to health. Nicotine, which is highly addictive, is present in HTP emissions at levels similar to those in conventional cigarettes. While the levels of toxicants in HTP emissions are generally lower than in conventional cigarettes, reduced toxicant levels do not necessarily correspond to an equal reduction in health risk. In addition, the levels of some toxicants in HTP emissions are higher than in cigarette smoke, and some are exclusive to HTPs. Most HTP users also smoke cigarettes, with little intention of quitting cigarette smoking, thus exposing themselves to the toxicants in both products. More details on HTPs can be found in the WHO information sheet on Heated tobacco products (1).

Why measure and regulate tobacco products?

Regulation of tobacco products can help to reduce deaths and diseases resulting from tobacco use. Regulations to reduce the attractiveness, addictiveness, toxicity and use of tobacco products should therefore be part of a comprehensive tobacco control programme. Tobacco product regulations should include measurement of their contents and emissions, disclosure of the results to regulatory authorities, meaningful disclosure of relevant information to the public and regulation intended to reduce the exposure of the public to harmful chemicals (2). More detailed information on this topic is given in the information sheet on WHO TobLabNet methods for measuring priority contents and emissions in tobacco and related products (3), which stresses that the tobacco industry should not be involved in developing testing methods for product regulation. The WHO Tobacco Laboratory Network (TobLabNet), a global network of experienced, independent laboratories, is an effective alternative for method development and validation, which was previously



dominated by the tobacco industry, such as the International Standards Organization technical committee for tobacco. TobLabNet validates methods for regulatory purposes, such as product compliance, fulfilling national and international testing obligations and monitoring the market. Charging the costs of testing products by independent laboratories and product regulation, including product information disclosures, to tobacco manufacturers reduces the burden on regulators (4).

Why measure and regulate HTP emissions?

A new generation of HTPs were introduced in some markets in 2014, and since then the availability of these products has grown in many countries and regions. The WHO Study Group on Tobacco Product Regulation (WHO TobReg) recommends (5) application of "the most restrictive tobacco control regulations to heated tobacco products (including the device), as appropriate within national laws, taking into account a high level of protection for human health". Restrictive tobacco control regulations include a range of effective measures, including prohibition of tobacco products to reduce tobacco use and the resulting harmful effects such as disease, disability and death. An important measure is regulation of priority emissions, with the aim of reducing them. Significantly lower exposure to all toxicants reduces tobacco's harmful health effects.

Which HTP emissions should be measured as priorities for regulation?

The priority emissions identified by WHO TobReg (6) are important targets for product regulation. Although there are thousands of compounds in tobacco products and their emissions, including hundreds of toxicants, some of which cause cancer, the 39 most toxic compounds have been prioritized by WHO TobReg. The priority list of toxicants can be used for all smoked or inhaled tobacco products. Nine have been recommended by TobReg for mandated reduction in cigarette smoke. At a 2020 WHO Expert Meeting on HTPs (7), the experts determined that nicotine, carbon monoxide and aldehydes should be prioritized for testing for the following reasons.

- **Nicotine** is the main driver of addiction to tobacco products. Nicotine levels in cigarette emissions are measured and regulated in many countries and can also be measured in HTP emissions, in which nicotine is present at levels similar to those in conventional cigarettes.
- **Carbon monoxide** is formed when tobacco is partially burnt and is therefore a general marker of incomplete combustion (7). Combustion results in the formation of many toxicants. Carbon monoxide levels are already measured and regulated in cigarette emissions in many countries and could be measured at the same time as nicotine in HTP emissions.
- Aldehydes are toxic and can contribute to addiction. Aldehyde concentrations are higher than those of other toxicants in HTP emissions. The following aldehydes are proposed for regulation in HTP emissions on the basis of their toxicological and addictive properties.
 - Acetaldehyde irritates the airways and has been classified as a "possible carcinogen" by the International Agency for Research on Cancer (IARC) (7). Acetaldehyde may increase users' dependence on nicotine, which may cause them to smoke more in terms of both quantity and frequency, exposing them to higher levels of all toxicants.
 - *Formaldehyde* has been classified as a human carcinogen by IARC (7). Exposure can cause nasal or tracheal cancer and possibly blood cancer (leukaemia). Inhalation of formaldehyde can also irritate the airways and eyes and damage airway cells. Formaldehyde can increase dependence on nicotine, leading to increased smoking.
 - Acrolein is a highly reactive substance which can cause irritation even at low concentrations after short exposure (7). Because of its strong reactivity, acrolein acts at the place of initial contact. Exposure to acrolein during smoking (and passive smoking) can irritate the airways.

What TobLabNet methods are available for measuring priority chemicals in HTP emissions?

Development and validation of testing methods independently of the tobacco industry is crucial for the regulation of nicotine and tobacco products. Currently, no validated methods are available for measuring priority chemicals in HTPs. As HTPs are sold on about 50 markets globally, development of analytical methods is a priority. Such methods could be used to verify industry data, monitor the levels of priority toxicants in products and check compliance. WHO TobLabNet is developing and validating methods for determining the contents and emissions of nicotine and tobacco products, including methods for measuring nicotine, carbon monoxide and aldehydes in HTP emissions. The finalized methods will be published by WHO and made available to all countries.

What can regulators do to support method development by TobLabNet?

Regulators in countries that have laboratories that are members of TobLabNet (see https://apps. who.int/iris/bitstream/handle/10665/2604 <u>18/9789241550246-eng.pdf</u> for a full list) can support the laboratories in activities for effective regulation of nicotine and tobacco products. These include facilitation of product testing and participation in collaborative studies for the development of standard operating procedures for nicotine and tobacco products, such as by providing financial support. Countries with government laboratories or other industryindependent laboratories for analysis of tobacco and related products that are not currently part of TobLabNet can contact WHO to explore possible means of support.

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