Progress report on technical matters related to Articles 9 and 10 (Regulation of contents and disclosure of tobacco products, including waterpipe, smokeless tobacco and heated tobacco products).

Report by WHO

Purpose of the document

This report responds to requests made by the Seventh session of the Conference of the Parties (COP) to the World Health Organization (WHO) related to decision FCTC/COP7(14) on the further development of the partial guidelines for implementation of Article 9 (Regulation of the contents of tobacco products) and Article 10 (Regulation of tobacco product disclosures) of the WHO Framework Convention on Tobacco Control (WHO FCTC). It discusses tobacco addictiveness reduction measures, market monitoring of novel tobacco products, building country testing capacity, and development of chemical methods for analysing cigarettes, waterpipe tobacco and smokeless tobacco.

Action by the Conference of the Parties

The COP is invited to note this report.

Contribute to the Sustainable Development Goals (SDGs), if applicable: Target(s) 3.a and SDG 3.
Link to the workplan and budget item: No.
Additional financial implications if not included in the workplan and budget: None.
Author team(s): WHO/NMH.
Related document(s):
BACKGROUND

1. This document was prepared by WHO in response to the requests made through the Convention Secretariat by the Conference of the Parties (COP) at its Seventh session (7–12 November 2016 in New Delhi, India) in decision FCTC/COP7(14). This report incorporates the deliberations and scientific recommendations of the WHO Study Group on Tobacco Product Regulation (TobReg) and the WHO Tobacco Laboratory Network (TobLabNet).

CURRENT AND EMERGING KNOWLEDGE BASE ON ADDICTIVENESS REDUCTION MEASURES

2. The Convention Secretariat and WHO convened a face-to-face meeting on addictiveness reduction measures (Berlin, 15–16 May 2018), hosted by Germany with support from Canada. Experts considered background papers on addictiveness reduction and discussed the potential positive and negative individual and societal consequences, the conditions to support successful implementation, and the barriers to implementation. The meeting report is available at www.who.int/tobacco.

MARKET DEVELOPMENTS AND USAGE AND MARKET MONITORING OF NOVEL AND TOBACCO PRODUCTS

3. Shifts in the tobacco market due to awareness of tobacco risks, implementation of the WHO FCTC provisions and tightening of regulations have resulted in declining sales of cigarettes in high-income economies. The tobacco industry has responded by promoting “cleaner” alternative smoking options, as well as novel and emerging tobacco products, especially heated tobacco products, which have seen rapid market adoption in recent years. Global sales for heated tobacco products are projected to reach US$ 17.9 billion by 2021. Currently, products available in about 40 countries include IQOS, Glo, iFuse, Ploom, Ploom TECH and Lil. Further information is available at www.who.int/tobacco.

4. Recommendations: Countries desiring to monitor these trends should develop metrics, such as product use by different customer segments, as well as resources dedicated to and sales generated from different marketing and distribution channels, to gain a better understanding of the market. They should establish the infrastructure for collecting and cataloging data on these metrics, possibly via collaboration with external agencies with expertise in data capture and analytics or through in-house capacity.

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1 See decision FCTC/COP7(14).
2 Ninth WHO TobReg meeting held in Minnesota, United States on 5–7 December 2017.
3 Working group meetings on waterpipe tobacco held in Sigmaringen, Netherlands on 4–5 May 2017, and on smokeless tobacco held in New Delhi, India on 10–11 and 14 August 2017.
4 http://www.who.int/tobacco/publications/prod_regulation/en/
5 http://www.who.int/tobacco/publications/prod_regulation/heated-tobacco-products/en/
CHEMICALS IN CONTENTS AND EMISSIONS IN SMOKELESS TOBACCO PRODUCTS THAT CONTRIBUTE TO ATTRACTIVENESS, ADDICTIVENESS AND TOXICITY

5. Hundreds of isoprenoids in smokeless tobacco products contribute to attractiveness of these products due to their characteristic aromas. Flavouring agents, such as anethole (anise camphor), menthol, benzaldehyde, and tetramethylpyrazine, also increase the appeal of the products. Additives such as molasses, liquorice and fruit extracts improve the product’s taste, flavour and aroma, and prolong shelf life. Nicotine is the primary addictive substance in these products but other substances, such as alkaloids can contribute to addictiveness. Manufacturing processes can make nicotine more readily available for absorption into the body (for example, through the manipulation of pH, aerosol particle size, the addition of chemicals and changes in paper porosity and size of the cut tobacco material).

6. Smokeless tobacco products contain a number of toxic, mutagenic or carcinogenic chemicals that can contribute to the onset of noncommunicable diseases, including diabetes, heart disease, oral cancer and other oral pathologies. While there are methods to determine the range of levels of toxic constituents in smokeless tobacco products, some of these need validation in order to establish the analytical reproducibility that is consistent with data-reporting requirements. The levels of toxicants in tobacco products are so high that regulatory strategies should not be based on either safe levels or product safety, as standards for upper limits for ingredients or emissions will not necessarily result in decreased health risks. High-priority toxicants need to be identified to carry out the necessary analysis.

STANDARD OPERATING PROCEDURES (SOPS) FOR MEASURING NICOTINE AND TOBACCO-SPECIFIC NITROSAMINES (TSNAS) IN SMOKELESS TOBACCO

7. WHO TobLabNet Standard Operating Procedures (SOPs) for measuring nicotine and TSNAs in smokeless tobacco products are being developed and will be published at www.who.int/tobacco.

APPLICABILITY OF WHO TOBLABNET SOPS TO MEASURE HUMECTANTS AND AMMONIA IN SMOKELESS TOBACCO PRODUCTS

8. Following laboratory assessment, it is considered that with some modifications, WHO TobLabNet SOPs 06 and 07 are applicable to smokeless tobacco products. A similar method to SOP 06 (humectants) has been used successfully to test humectants in moist snuff. In this study, triethylene glycol was not detected in the test samples, implying that modification of the extraction procedure is not necessary for moist snuff. Precautions should be taken in gas chromatography (GC) measurements to avoid coelution of glycerol with triethylene glycol. The calibration range of glycerol and propane 1,2 diol (propylene glycol) should be adjusted for the higher levels of these compounds in smokeless tobacco products. Given the diversity of these products leading to highly variable humectant levels, the calibration range can be extended and sample extracts can be diluted, as necessary, to accurately measure ammonia.

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8 Sumitra Arora. (2018). Scientific information and analytical methods to measure chemicals in smokeless tobacco contents and emissions contributing to toxicity, addictiveness and attractiveness.
9. To use SOP 07 (ammonia), tobacco of some smokeless tobacco products must be reduced to a standard or unified particle size to ensure reproducibility. Some additives coelute with ammonia, so excellent chromatographic separation is needed to avoid false positives. Additionally, diluting or cleaning and pre-concentrating the samples to decrease the background signal can prevent negative effects in ion chromatographic (IC) analysis. Ammonia values for moisture must be corrected.

**REducing toxicants in smokeless tobacco products**

10. WHO TobReg recommends reducing the use of *Nicotiana rustica*, limiting bacterial contamination, requiring flue- or sun-curing rather than fire- or air-curing, pasteurization, improving storage conditions, eliminating carcinogenic ingredients such as areca nut and tonka bean, setting an upper limit of 2μg/g (dry weight) for N-nitrosonornicotine (NNN) plus 4-(methylnitrosamino)-1-(3-pyridyl)-1-butanone (NNK), an upper limit of 5ng/g (dry weight) for B[a]P and monitoring the levels of arsenic, cadmium and lead in tobacco.

11. TSNA levels can be decreased by reducing microbial populations, including disinfecting tobacco at harvest and heat treatment (pasteurization). Hygiene practices can decrease the concentrations of harmful agents in tobacco. Decreasing the levels of nicotine, free nicotine, arsenic, cadmium, lead, B[a]P, and NNN plus NNK can lower the levels of known addictive and toxic agents. Portable instrumentation is available to measure pH, ammonia, nitrate or nitrite, and it can detect and quantify nicotine, minor alkaloids, arecoline (areca nut), flavours or non-tobacco plant constituents, such as coumarin, diphenyl ether or camphor. Bacteria and fungi-specific culture plates may be used in identifying colony-forming units of products.

**Validation of the analytical chemical methods for aldehydes and volatile organic compounds (VOCS) in cigarette emissions**

12. Six laboratories in five countries (China, Japan, the Netherlands, Singapore and the United States of America) have participated in validating SOPs 08 and 09. Finalized methods will be published at www.who.int/tobacco.

**Applicability of WHO TobLabNet SOPs to the testing of nicotine and humectants in waterpipe tobacco products**

13. Due to differences between cigarettes and waterpipe tobacco, modification of existing WHO TobLabNet SOPs is necessary. Specifically, toxicant emissions depend on the combination of tobacco, the heat source, design, preparation method, puff topography and their interactions. For contents, the different matrices need to be taken into account. Pilot results for a simultaneous extraction and GC quantitation of nicotine and humectants in waterpipe tobacco are promising, but require further refinement. Human waterpipe smoking topography is characterized by a much larger puff volume, flow rate and puff number than cigarette smoking, resulting in much longer smoking sessions. Shortening of smoking sessions would greatly enhance laboratory testing efficiency.

14. **Recommendations:** The primary focus should be on regulating the characteristics and contents of waterpipe tobacco products and charcoal to protect public health. Setting of upper limits is recommended for contents, such as nicotine and humectants. Policy-makers should acknowledge differences in individual human waterpipe smoking topography when deciding

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a smoking regime, and consider using two extreme protocols, varying from low to high intensity. Policy-makers should be aware of new technologies and products, for example e-hookah, steam stones and flavoured e-liquids.

AVAILABILITY OF VALIDATED ANALYTICAL METHODS ON THE EXPANDED LIST OF TOXICANTS IN CONTENTS AND EMISSIONS OF TOBACCO PRODUCTS

15. Availability of validated analytical methods on identified priority toxicants in contents and emissions of tobacco products is necessary to advance tobacco product regulation. WHO TobLabNet has validated four methods for a group of priority toxicants, namely volatile organic chemicals, aldehydes, poly aromatic hydrocarbons and tobacco-specific nitrosamines, as identified by the WHO TobReg in the list of 39 priority toxicants (FCTC/COP/6/14, TRS 989) and deem that these methods can be expanded with minimal analytical effort to include other priority toxicants in the list. The WHO TobLabNet method for aldehydes, which is currently validated for acetaldehyde, formaldehyde and acrolein, can be extended to include acetone, butyraldehyde, crotonaldehyde and propionaldehyde. The WHO TobLabNet method for VOCs, currently validated for benzene and 1, 3 butadiene, can be extended to isoprene, toluene and acrylonitrile. Likewise, the WHO TobLabNet method for TSNAs (SOP 03), currently validated for NNN and NNK, can be extended to cover N-nitrosoanatabine (NAT) and N-nitrosoanabasine (NAB). In addition to the 11 priority toxicants of the identified 39 priority toxicants, the extension of WHO TobLabNet methods will provide Parties with a wider range of methods to analyse/monitor toxic chemicals in tobacco products. Certain available validated analytical methods commonly used in the analyses of other (that is to say, non-tobacco) consumer products, such as food, can be assessed and applied to tobacco products. The applicability of these methods to tobacco products and the development of SOPs for metals would mean that 24 (9+11+ 4) out of the 39 priority toxicants are covered by WHO TobLabNet methods.

16. Recommendations: WHO TobLabNet has recommended the expansion of its methods for cigarettes to cover more priority toxicants in the identified list of 39 priority toxicants. It recommends: (1) extending the existing SOPs to include the remaining aldehydes and VOCs; and (2) developing a SOP to determine metal content (Cd, As, Pb, Cr, Ni, Al, Hg) in cigarette tobacco filler. WHO TobLabNet also recommends and has begun work on: (1) developing an SOP for the determination of nicotine and humectants contents in waterpipe tobacco, and investigating the applicability of a combined method for both toxicants per dry matter; and (2) developing a SOP for the determination of metal content (Cd, As, Pb, Cr, Ni, Al, Hg) in waterpipe tobacco and charcoal.

STRENGTHENING CAPACITY IN TESTING OF TOBACCO PRODUCTS

17. WHO has published two practical guides entitled Tobacco product regulation: A basic handbook\(^{15}\) and Tobacco product regulation: Building tobacco laboratory capacity.\(^{16}\) WHO and its collaborating centres are developing online training modules on the use of WHO TobLabNet SOPs. The first four modules will address methods to test nicotine and ammonia in cigarette tobacco fillers and B[a]P and humectants in mainstream cigarette smoke. WHO is working through its collaborating centres to strengthen regional testing capacity.

Background papers and references to this report can be found at www.who.int/tobacco.

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\(^{16}\) [http://apps.who.int/iris/bitstream/handle/10665/260418/9789241550246-eng.pdf;jsessionid=52792574A603F041AC3E2A24F0999724?sequence=1](http://apps.who.int/iris/bitstream/handle/10665/260418/9789241550246-eng.pdf;jsessionid=52792574A603F041AC3E2A24F0999724?sequence=1)