

Report of the meeting to review the latest scientific evidence on the impact of cigarette ventilation on cigarette use

18–19 November 2019

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Executive summary

This report is of a meeting held on 18–19 November 2019 in Bilthoven, Netherlands, to review the latest scientific evidence on the impact of cigarette ventilation on cigarette use, in accordance with decision FCTC/COP8(21) of the Conference of the Parties (COP) to the World Health Organization Framework Convention on Tobacco Control (WHO FCTC). The objectives of the meeting, circulated to participants before the meeting, were to:

- review the latest scientific evidence on cigarette ventilation, presented in a series of background papers;
- collect relevant information on the potential and actual impact of cigarette ventilation on cigarette use;
- extract information to give regulators a better understanding of the use of ventilation in cigarettes; and
- obtain information that could be used by Parties to strengthen implementation of Articles 9 and 10.

The meeting, organized by the Secretariat of the WHO FCTC (Convention Secretariat) and WHO, was supported by The Netherlands. Participants were identified from a wide range of expertise, as specified in decision FCTC/COP8(21). The chairs of the WHO Study Group on Tobacco Product Regulation (TobReg) and the WHO Tobacco Laboratory Network (TobLabNet) also participated.

Seven background papers were commissioned by WHO from experts in cigarette ventilation to inform the debate on translating findings and evidence into policy and recommendations. They were drafted according to terms of reference drawn up by WHO. The titles of the papers were:

- Paper 1: Introduction to cigarette ventilation and possible implications for public health
- Paper 2: Cigarette ventilation mechanisms, market availability and prevalence of use
- Paper 3: Potential effects of cigarette ventilation on human smoking topography and behaviour
- Paper 4: Effects of cigarette filter ventilation on machine-measured yields
- Paper 5: Influence of cigarette ventilation on product appeal and consumer perception and use
- Paper 6: Potential effects of filter ventilation on smokers' health
- Paper 7: Regulatory considerations of policy measures for ventilated cigarettes and policy implications

Paper 3 was delivered only as a presentation. The other papers were also summarized in presentations.

The Partial Guidelines for Implementation of Articles 9 and 10 of the WHO FCTC, in appendix 2, provide a list of design features of cigarettes that might have policy implications for Parties, one of which is ventilation. The meeting therefore provided a platform for discussing policy implications of cigarette ventilation, with a view to further strengthening implementation and developing the Partial Guidelines on Articles 9 and 10. The Partial Guidelines recommend that Parties collect

data from manufacturers and importers on product characteristics, including design features, to understand the impact of those characteristics on levels of smoke emissions, interpret the measurements and be aware of the latest changes in cigarette design. The Partial Guidelines also recognize that the tobacco industry makes tobacco products more attractive to different segments of society by modifying or introducing new design features, which should be regulated by Parties.

The background papers describe the harm associated with cigarette ventilation,¹ including reducing the perception of risks and increasing appeal, potential exacerbation of risk for diseases such as certain type of lung cancer and non-cancer outcomes such as emphysema and chronic bronchitis, and how the tobacco industry targets specific segments of the society. The experts noted that the tobacco industry has a long-standing history of engineering and manipulating its products, including changing their characteristics to modify the delivery of toxicants and nicotine. One example is cigarette ventilation, which can make cigarettes attractive to different target groups. This includes increasing the porosity of cigarette paper or putting holes in filters to dilute the smoke yields measured by smoking machines and purportedly delivered to users, most of whom are oblivious to this deceptive technology. The technology is deceptive because, even though the tar and nicotine yields as measured by machines are reduced, smokers compensate for the reduced nicotine by smoking more intensely or covering the ventilation holes to achieve satisfying levels of nicotine. The greater intensity of smoking results in the same levels of tar and nicotine as in higher-tar-yield cigarettes. Those targeted by ventilated cigarettes include health-conscious smokers, women and potential new users, such as adolescents. Filter ventilation may facilitate uptake and maintenance of cigarette use and also deter cessation attempts.

Several gaps in evidence were identified, including global data on the use of ventilated and un-ventilated cigarettes, further information on smoking topography, tools to measure the overall public health benefit of banning or limiting filter ventilation and uptake of cigarettes with filter ventilation by young people in different countries. Further it was considered that post-implementation research on the impact of a ventilation ban, if implemented by countries that have the necessary regulatory environment, should address its effects on initiation, maintenance, degree of dependence and population prevalence, as well as its impact on health outcomes, such as lung cancer and other end-points.

In the background papers, some authors recommend banning (filter) ventilation, others describe problems with the existing limits set for tar, nicotine and carbon monoxide (TNCO), while others consider that, although the evidence indicates that a ban on cigarette ventilation would be logical, more data should be obtained to determine the effects of a ban and the regulatory measures necessary to minimize any unintended consequences.

On the basis of the background papers and the expertise presented at the meeting, the strength of the evidence for the key considerations was classified as follows.

¹ Filter ventilation, referred to in some of the papers as “cigarette ventilation”, is a form of cigarette engineering that creates a false impression of a “weaker” cigarette because of the dilution of smoke; it should be noted, however, that filter ventilation is not the only means available to manufacturers to make their cigarettes more attractive and palatable (another is paper porosity, for example).

Strong evidence

- In evaluating the evidence on the effects of cigarette ventilation on cigarette use, the experts categorized the following as substantiated by strong evidence.
 - Machine yields do not reflect human exposures.
 - Filter ventilation does not reduce disease risk.
 - Filter ventilation promotes appeal and product preference.
 - Removal of pack descriptors is insufficient to eliminate misperceptions of the risks of using ventilated products.
 - Filter ventilation misinforms consumers about the health risks of smoking and reduces consumers' perceptions of the health risks of smoking.
 - Most consumers are either unaware of the presence of vents or their function and unknowingly block them or increase their smoking intensity.
 - Filter ventilation changes combustion and dilutes cigarettes smoke, which changes physical and chemical profiles and biological properties, as assessed in *in vitro* and *in vivo* toxicology tests of smoke (based on machine tests).
 - Filter ventilation enables product elasticity, which leads to compensation and lack of reduction in exposures relative to nicotine and tar yields.
 - The market share of ventilated cigarettes increases as countries move towards high-income status.
 - Other mechanisms, such as menthol and physical parameters can be used to promote smoothness, for example, in addition to filter ventilation.

Highly suggestive evidence

- In evaluating the evidence on the effects of cigarette ventilation on cigarette use, the experts categorized the following as substantiated by highly suggestive evidence.
 - Filter ventilation increases the risk of lung adenocarcinoma.

Regulatory considerations

Although the evidence supports adoption of bans on filter ventilation, several regulatory mechanisms would have to be considered in order to limit unintended consequences. Further, countries are at different stages of tobacco control, and several do not apply even basic, proven interventions. Effective communication would prevent the tobacco industry from using any measure introduced to regulate cigarette ventilation to its advantage.

- From the point of view of regulation and enforcement, banning of filter ventilation would be the most practical measure and is better supported scientifically than the more complex approach of setting an allowable degree of ventilation.
- As the attractiveness of products is a feature used by the tobacco industry to deceive the public, this must be included in any regulation in order to decrease the adverse effect on population health by, eventually, reducing the prevalence of smoking.
- Current national laws in some countries that limit TNCO yields should be taken into consideration if policy measures are to be introduced to limit or ban cigarette ventilation.
- Coordination of a regulation banning cigarette ventilation with other regulations to reduce the appeal of tobacco products, such as plain packaging and regulated product descriptors, would increase its effectiveness.

- Communication to the public and decision-makers is a critical component and must be carefully planned before introducing a regulation on cigarette ventilation, to prevent or minimize unintended consequences. Communication should therefore provide the rationale for a policy, send clear messages to appropriate groups to explain the proposed changes and provide the necessary support to ensure effective application.
- All countries could already collect data on cigarette ventilation and the prevalence of use and marketing of such products. The availability of such data could be included in disclosure requirements, especially in countries with such regulations.

Countries must be prepared to respond to any legal challenges by the tobacco industry before taking any regulatory action.

Next steps

- The outcomes of this meeting will be reported to the Ninth Session of the COP (COP9) to the WHO FCTC in a joint report by the Convention Secretariat and WHO and used in the response to request 8 of decision FCTC/COP8(21).

1. Introduction

A meeting on cigarette ventilation was held in Bilthoven, Netherlands, on 18–19 November 2019, hosted by the Government of The Netherlands and the National Institute of Public Health and the Environment (RIVM) and convened by the Secretariat of the WHO Framework Convention on Tobacco Control (WHO FCTC) and WHO. The meeting was held pursuant to decision FCTC/COP8(21)¹ of the Eighth Session of the Conference of the Parties (COP8) to the WHO FCTC on implementation of Articles 9 and 10 of the Convention, in which the COP requested the Convention Secretariat to hold a meeting on cigarette ventilation with WHO:

REQUESTS the Convention Secretariat in cooperation with the WHO to hold a face-to-face meeting on cigarette ventilation, with a wide range of relevant experts, Party representatives and observers accredited to the COP independent from the tobacco industry, to gain an overview of the latest scientific evidence on the impact of cigarette ventilation on cigarette use and report back their findings to the Ninth Session of the COP.

In accordance with the request, meeting participants included staff from the Convention Secretariat and WHO, the chairs of the WHO Study Group on Tobacco Product Regulation (TobReg) and the WHO Tobacco Laboratory Network (TobLabNet), representatives of the host country, other Party representatives and observers to the COP who are independent of the tobacco industry. There were approximately 50 participants.

The aim of the meeting was to review the latest available scientific evidence on the impact of cigarette ventilation on cigarette use and review background papers on cigarette ventilation and its potential and actual impact on cigarette use to provide regulators with better understanding of the use of ventilation in cigarettes. It was also intended to provide evidence that could be used in further strengthening implementation of Articles 9 and 10 by the Parties to the Convention and the relevant Partial Guidelines.²

Before the meeting, WHO commissioned seven background papers on relevant aspects of cigarette ventilation to address the request and prepared terms of reference for each of the papers (see Annex 1) after an initial search of the scientific literature. The titles were:

- Introduction to cigarette ventilation and possible implications for public health
- Exploration of cigarette ventilation mechanisms, market availability and prevalence of use
- Potential effects of cigarette ventilation on human smoking topography and behaviour
- Effects of cigarette filter ventilation on machine-measured yields
- Effects of cigarette ventilation on product appeal and consumer perception/use
- Exploration of potential health effects of filter ventilation on consumers
- Regulatory considerations of policy measures for ventilated cigarettes and policy implications

A wide range of international experts active in the field of cigarette ventilation research was identified and assigned to write background papers, which set the scene for discussions during the meeting

¹ [https://www.who.int/fctc/cop/sessions/cop8/FCTC__COP8\(21\).pdf](https://www.who.int/fctc/cop/sessions/cop8/FCTC__COP8(21).pdf)

² https://www.who.int/fctc/treaty_instruments/guidelines_articles_9_10_2017_english.pdf

on the report to the Ninth Session of the COP. Six papers were circulated to participants before the meeting, with the agenda (Annex 2), an information circular and the list of participants (Annex 3).

Opening remarks were made by Mr Paul Blokhuis, State Secretary of Health, Welfare and Sport, Netherlands; Mr Hans Brug, Director-General, National Institute of Public Health, Netherlands; Dr Tibor Szilagyi, Convention Secretariat; and Dr Vinayak Prasad, acting Director, Department of Prevention of Noncommunicable Diseases, WHO. The meeting was chaired by Mr Denis Choinière, Health Canada, who also delivered opening remarks. Participants introduced themselves, with their institutional affiliations, and briefly noted their expectations of the meeting.

Each background paper was presented by the authors, followed by a session in which participants posed questions, sought clarifications and made comments. Summaries of the background papers are provided in Annex 1. In addition, two presentations were made on “The history and dynamics of cigarette ventilation” and “Setting context and expected outcomes”. Participants were reminded of the remit of the group, the history of cigarette ventilation and previous work relevant to the meeting, especially by TobReg, which presented scientific evidence on cigarette ventilation in the WHO Technical Report Series No. 1001 in 2017. The report was prepared in response to a request by the COP at its Sixth Session and includes a chapter on scientific evidence for the influence on smoking of cigarette characteristics such as slim and “super-slim” designs, filter ventilation and other innovative filter design features, including flavour-delivering capsules. The report illustrates how cigarette characteristics affect the public health objectives of the WHO FCTC and was considered by the Working Group on Articles 9 and 10 of the WHO FCTC at its meeting in February 2016.

The TobReg report noted that the main purpose of cigarette design is to increase the appeal of products by making them more palatable or attractive or portraying them as “less harmful”. The report also noted that filter ventilation reduces machine-generated emissions per cigarette and increases smokers’ perceptions of lighter taste and safety. TobReg proposed continuation of research on the design characteristics of tobacco products and innovations and made recommendations for policy, including:

- requiring manufacturers to disclose information on all the design features, parameters, specifications and levels of contents and emissions of current products, including cigarette paper, capsules in cigarettes filters and cigarette dimensions; and
- prohibiting filter ventilation and any other design characteristic that allows cigarette elasticity (increased puff volume by smokers, especially of lower tar varieties) and prohibiting filter capsules, slim cigarettes and any other attribute that increases attractiveness, smoke emissions or addictiveness.

TobReg noted that cigarettes are designed to reduce the negative aspects of the product, to ensure that smokers experience satisfaction during their use and to attract young people and novice users. The evidence shows that the physical characteristics of cigarettes, such as filter ventilation, have complex effects. Filter ventilation is a design feature that can easily be manipulated by smokers to obtain higher levels of nicotine and smoke emissions from a cigarette. Higher filter ventilation can change smoking behaviour, resulting in similar or greater exposure to toxic and carcinogenic emissions than would result from smoking less ventilated cigarettes.

2. Summaries of findings, research gaps and recommendations in the background papers

2.1 Introduction to cigarette ventilation and possible implications for public health

Design features are covered in the Partial Guidelines for Implementation of Articles 9 and 10 of the WHO FCTC to assist Parties in understanding the impact of these characteristics on smoke emissions, properly interpret data and keep up to date with changes to cigarettes design. Ventilation holes around cigarette filters are one of the main characteristics of cigarettes that contribute to dilution of mainstream cigarette smoke, resulting in lower concentrations of tar and nicotine in emissions, as measured in smoking machines. The request by COP at its Eighth Session to the Convention Secretariat and WHO to convene a meeting on the latest scientific evidence on the impact of cigarette ventilation on cigarette use is crucial, as it indicates that a global public health authority has decided to further understand the effects of design features of a cigarette, in particular, filter ventilation, on smoking behaviour. Cigarette ventilation has been promoted by the tobacco industry to maintain tobacco use. This paper describes the possible public health implications of this design feature and associated packaging and marketing, which have misled the population into believing that these cigarettes are less harmful than less ventilated or unventilated cigarettes. Regulatory perspectives and approaches and research gaps are also discussed.

Research gaps

- Investigate the impact on biomarkers of exposure of differences in cigarette ventilation.
- Study consumer perceptions of ventilated versus unventilated cigarettes.
- Find the best approaches to educating the public about the harm of ventilated cigarettes.
- Investigate the impact of banning filter ventilation on public health outcomes.

Recommendations

- Inform governments and consumers about the harm associated with filter ventilation and that the low yields typical with the ISO regime do not mean less exposure or harm.
 - Require cigarette manufacturers to disclose the characteristics of cigarettes that lead to low yields, and survey testing features, for example, by requiring that the ISO and WHO intense method include the yields of constituents.
 - Monitor the prevalence and perceptions of ventilated and lower-yield cigarettes in each country.
 - Eliminate all packaging, advertising and descriptions that mislead consumers into believing that ventilated or lower-yield cigarettes reduce their risk.
 - Consider banning or limiting cigarette design features that are associated with cigarette “elasticity”.
- **Major recommendations:**
 - Ban filter ventilation (and similar design features) after consideration of the public health outcomes of such a ban.
 - Eliminate descriptions, packaging, advertising and other means that indicate that ventilated cigarettes are safer, and recommend plain or standardized packaging.

- Extend reporting of cigarette emissions to cover cigarettes with 100% ventilation and with 100% blocking.
- Educate the public about the deceptive nature of ventilated cigarettes.
- **Additional recommendation:**
- Policy-makers and others should apply the lessons learnt from the deceptive claim of “harm reduction” for ventilated cigarettes by assessing and regulating electronic nicotine delivery systems, heated tobacco products and *snus*, especially in the way in which these products are marketed and used. Emerging “harm reduction products” must undergo rigorous testing to determine their impact on public health.

2.2 Exploration of cigarette ventilation mechanisms, market availability and prevalence of use

Filter ventilation is a common design feature of contemporary cigarettes, which have been used since the early 1970s in an attempt to undermine the intent of “tar” yield testing. It remains an important technology, even in countries that ceased yield testing and labelling over a decade ago. The tobacco industry rarely publicly acknowledges the existence of filter ventilation, and few tobacco control professionals currently pay it much attention. This lack of interest in the tobacco control community is unfortunate, given that filter ventilation has a profound influence on smokers’ beliefs and behaviour. Ventilated brands, as assessed by marketing proxies such as ISO “tar” numbers, “light/mild” or “smooth/fine” descriptors or direct observation, form the vast majority of those available in high-income countries (such as Australia, Canada, the United Kingdom of Great Britain and Northern Ireland and the United States of America) and represent a growing fraction of the market in middle-income countries (such as China). Such products were vigorously marketed by cigarette manufacturers to specific population groups, which led to appeal and acceptance. Ventilated brands appear to appeal primarily to smokers concerned about their health, women and younger smokers. Few smokers are aware of the existence or the function of filter ventilation. Given the ubiquity of filter ventilation and its negative public health consequences, regulators should prevent the tobacco industry from using this technology to influence smokers’ beliefs and behaviour.

Key points

- Ventilation is a key driver of lower emissions in ISO smoking machine tests and of misperceptions by consumers.
- Ventilation contributes to the harm of cigarette smoking, yet many smokers are unaware of ventilation and its function, even in their own brands.
- There is clear evidence of deception by the industry, which makes a strong case for reducing perceptions of harmfulness and a plausible case for filter ventilation having increased harm.
- As filter ventilation is an inherently deceptive technology, misleading many smokers into believing that they are reducing their smoking-related risks when they are not, its use should be prohibited.
- No research has been reported on whether education campaigns or plain packaging will overcome the deception of consumers.

Research gaps

- Information is lacking on the prevalence and extent of filter ventilation in cigarettes in countries, as both the number of brands on the market and the overall market share.
- A functional, enforceable definition of “no filter vents” that also anticipates substitute designs introduced by the industry could be effective.
- Consumer responses to a market-wide change in cigarette design should be studied and monitored.

Recommendations

- **Major recommendation**
 - Regulators should consider banning filter ventilated cigarettes, as the technology is inherently deceptive and misleads users into thinking they are reducing their harm.
- **Other recommendations**
 - Regulators should consider monitoring ventilation and other cigarette design features that affect emissions.
 - Regulators should consider introducing a requirement for justification of future design changes.

2.3 Potential effects of cigarette ventilation on human smoking topography and behaviour

A literature search was undertaken to evaluate the effect of filter ventilation on human smoking behaviour. In order to determine whether human smoking topography is correlated to filter ventilation, data were collected on filter ventilation, pressure drop and emissions (at least TNCO) and human topography (puff volume, puff duration, puff interval, number of puffs and number of cigarettes per day). Few publications were found on filter ventilation or pressure drop or on human smoking topography. Data on nicotine emissions and on human smoking topography (23 studies) were used to correlate human smoking topography with cigarette filter ventilation, with nicotine emissions used as a proxy for the degree of filter ventilation.

The review showed a tendency for decreasing puff volume, puff duration and number of puffs with increasing nicotine levels, as determined by the ISO regime; however, no significant change was found in puff interval or number of cigarettes smoked per day. In one study of human topography in which a research cigarette (Virginia tobacco) was smoked by seven smokers, wide variation was found among the smokers, which raises the question of whether the results of studies of nicotine level and filter ventilation can be used to determine the influence of these parameters on smoking behaviour.

The question of the best study design for determining the influence of filter ventilation on the smoking behaviour of smokers in general and individual smokers cannot be answered with the available evidence. Therefore, further research is essential to better understand the influence of filter ventilation on human smoking topography.

Key points

- Studies have shown a tendency for decreasing puff volume, puff duration and number of puffs with increasing ISO nicotine level.
- Wide variation in smoking topography was found among smokers using the same brand.
- In general, smokers tend to adapt smoking parameters to the nicotine level remaining after filter ventilation.
- If there is wide variation in topography among smokers using the same type of cigarette, can the results of studies of nicotine levels after filter ventilation be used to determine the influence of these parameters on smoking behaviour? Individual differences in how people smoke cigarettes with different degrees of ventilation should be recognized.

Research gaps

- Investigations should be conducted on the most robust study design for determining the influence of filter ventilation on the smoking behaviour of individual smokers and at population level.
- Exploration of the daily trends of smokers might indicate differences in behaviour (volume, number of puffs, frequency of smoking).
- The influence of butt length should be included in behavioural studies, as it is a topographical item important for determining exposure.

2.4 Effects of cigarette filter ventilation on machine-measured yields

Summary

Cigarette ventilation affects cigarette burning, the chemical composition of cigarette smoke and machine-measured emissions. Cigarette ventilation, due primarily to filter ventilation, has a strong effect on tobacco burning and smoke formation. Filter ventilation differs among countries and cigarette brands. While ventilation reduces the levels of many machine-measured smoke emissions, increased smoking intensity and blocking of filter vents increase emissions, especially from ventilated cigarettes, including the amount of nicotine. Research priorities include better understanding of the impact of ventilation on particle size distribution and deposition in the lung and more robust data on constituents other than nicotine and tobacco-specific nitrosamines and on effects other than cancer.

Key points

- Cigarette ventilation, primarily with filters, has a strong effect on tobacco burning.
- Ventilation results in reduced yields per cigarette yield of many constituents of gas and particulate phases measured in machine-generated smoke under standard smoking regimens, specifically the ISO regime.
- Increased smoking intensity and blocking of filter vents increase machine-generated constituent yields, greater increases being observed for ventilated cigarettes.
- One consequence of cigarette ventilation is elasticity, in which more intense smoking, particularly of highly ventilated cigarettes, increases the yields of harmful smoke constituents.
- Filter efficiency increases with higher filter ventilation and lower intensity of smoking.

Research gaps

- Investigate filter ventilation by brand and sub-brand worldwide to assess associations with market share and the potential impact of bans on filter ventilation.
- Further research should be conducted into the effect of filter ventilation on smoke particle size distribution and the chemical profile of particles.
- Filter design features (for example, physical dimensions, density, filter material, presence of other components), their interaction with filter ventilation and the effect on emissions should be characterized.
- Studies should be conducted of filter ventilation and the effects of pressure drop on filter efficiency and the implications for machine emissions and exposure of smokers.
- Data on overall cigarette ventilation and its relation to filter ventilation by brand and sub-brand should be collected systematically.

Recommendations

- **Major recommendation:**
 - Regulators should consider banning or limiting filter ventilation to 20%, after an impact assessment.
- **Other recommendations:**
 - Consideration should be given to setting an international standard for measuring filter efficiency.
 - Real-time surveillance of filter and cigarette design innovations should be conducted.
 - Regulators should consider using the WHO/Canadian Intense smoking regime in regulating products.
 - Consideration should be given to further regulating cigarette elasticity, after research on the yields of constituents.
 - Regulators should strongly consider requiring manufacturers to disclose extensive details on all cigarette characteristics relevant to cigarette ventilation.
 - Constituent yields per cigarette and per mg nicotine should be reported by manufacturers, with disclosure of the methods used in sufficient detail to allow reproducibility.

2.5 Influence of cigarette filter ventilation on product appeal and consumer use

Filter ventilation may influence product appeal, leading to a greater prevalence of use. A systematic search of the literature on cigarette filter ventilation, product appeal and use behaviour provided strong evidence that filter ventilation increases cigarette appeal by making the smoke appear milder, smoother and easier to inhale. Additionally, strong evidence was found that filter ventilation misleads smokers about the potential risks of smoking. Taken together, the evidence suggests that filter ventilation could facilitate uptake and maintenance of cigarette use and may dissuade cessation attempts; however, direct evidence for the influence of filter ventilation on smoking uptake, maintenance and dissuasion of cessation is not available.

The available evidence is sufficient to warrant a strong policy intervention. The authors concluded that policy-makers should consider banning or regulating filter ventilation. In addition, any communication on ventilation via product packaging and other marketing materials should be banned, preferably by the introduction of plain (standardized) product packaging.

Key points and findings

- Filter ventilation can result in higher nicotine delivery, which could lead to dependence on nicotine.
- Filter ventilation could facilitate uptake and maintenance of cigarette use and may dissuade cessation attempts.
- Filter ventilation increases cigarette appeal by making the smoke appear milder, smoother and easier to inhale.
- Filter ventilation misleads smokers about the potential risks of smoking.
- The evidence supports the adoption of bans on filter ventilation and communication of ventilation on product packaging.

Research gaps

- Evaluate the effect of ventilation, independently of other design aspects, such as additives.
- Assess the contribution of ventilation to consumer appeal, independently of other modifications, such as package design.
- Investigate whether ventilation increases perceptions of smoothness and decreases perceptions of risk in a dose–response manner.
- Investigate how manufacturers might subvert regulations on ventilation by manipulating other design features.
- Conduct research on the effect of filter ventilation on the perceptions and behaviour of adolescent consumers.
- Evaluate the influence of varying filter ventilation in targeting new sub-groups of consumers.
- Investigate the effect of ventilation on the development of symptoms of dependence, especially in sub-groups.
- Explore the influence of filter ventilation on maintenance of smoking behaviour, including changes in dependence and cessation attempts and outcomes.
- Conduct further population-level analyses to understand the influence of filter ventilation on the prevalence of cigarette use.
- Conduct research on internal tobacco industry documents to determine whether cigarette manufacturers use the design of and messages about ventilation to enhance the appeal of cigarette products.

Recommendations

- **Major recommendations**
- Regulators should consider banning filter ventilation after conducting research on how smokers adjust to unventilated, low-yield cigarettes.
- Consider accompanying a ban with regulation of cigarette nicotine levels to below a hypothetical threshold for dependence to prevent compensatory actions by the industry and consumers.

- **Alternative recommendation**
- Standards should be applied to filter ventilation to prevent smokers from misperceiving ventilated cigarettes as less risky alternatives to unventilated cigarettes.
- Require plain packaging and other restrictions on communication about differences between brands.
- Consider addition of statements on cigarette packs about the health risks associated with ventilated cigarettes.

2.6 Exploration of potential health effects of cigarette filter ventilation on smokers

Summary

Paradoxically, the risks for some lung cancers associated with smoking cigarettes have progressively increased, while, overall, smoking-related disease has decreased in parallel with reductions in smoking rates. Thus, the histopathological types of lung cancer have shifted during the past 60 years, such that lung adenocarcinomas are now the most common type of lung cancer associated with smoking. Several lines of evidence have identified two changes in cigarette design over time that might have contributed to the increase in lung adenocarcinoma, namely, the introduction of ventilation holes to cigarette filters, which has increased the extent of ventilation and the popularity of these cigarettes in the marketplace; and an increase in the content of tobacco-specific nitrosamines in tobacco and subsequently in cigarette smoke emissions.

Filter ventilation changes how a cigarette burns, allowing delivery of a greater volume of smoke and subsequently more tobacco toxicants. It also allows for elasticity in smoking, such that smokers smoke more intensely (compensate) to obtain satisfying nicotine blood levels, irrespective of smoking machine yields. The greater intensity of smoking may result in uptake of larger amount of smoke and toxicants, including tobacco-specific nitrosamines, and volatile organic compounds that reach deeper portions of the lungs to damage the types of cells that develop into adenocarcinomas.

Studies of smokers who switched from lower- to higher-ventilated cigarettes do not show any reduction in dose with increasing ventilation. This and studies of smoker perceptions indicate that cigarette filter ventilation has no benefit for public health. This report and others conclude that there is highly suggestive evidence that the worsening lung cancer risk and the increase in lung adenocarcinomas are due, at least partly, to increased cigarette filter ventilation, which is a modifiable cigarette design feature of no public health benefit.

A regulatory agenda for reducing smoking-related disease by banning cigarette ventilation is a reasonable approach. An alternative would be to mandate filter ventilation that exceeds, for example, 80%, to preclude complete compensation. A research agenda is discussed to assess unintended consequences of banning cigarette filter ventilation.

Key points and findings

- The report of the US Surgeon General in 2014 indicated that increases in the risks and rates of lung adenocarcinoma are due to cigarette filter ventilation, increased levels of 4-(methylnitrosamino)-1-(3-pyridyl)-1-butanone) in tobacco or both.
- Cigarette filter ventilation results in elasticity of use, whereby smokers alter their puffing behaviour to obtain more nicotine, so that more smoke enters the deeper part of the lungs.
- Increased filter ventilation increases the yields of smoke toxicants and their mutagenicity and tumorigenicity on a per mg nicotine basis.
- Banning filter ventilation will prevent elasticity, make cigarettes harsher and allow laboratory studies (such as smoke chemistry analysis) to compare tobacco products.
- A limitation to the weight of evidence is the results of studies that show no difference in biomarkers of exposure associated with filter ventilation; however, biomarkers are measured in surrogate tissues (such as blood and urine) and not in the lung. Biomarker studies clearly show that there is no reduction in exposure with increasing cigarette filter ventilation.

Research gaps

- Assessments should be conducted of switching to cigarettes with 0% ventilation and attendant changes in smoking behaviour, exposure, abuse liability, perceptions and impact on quitting.
- Epidemiological studies and surveillance should be conducted after implementation of any ban or regulation in order to assess the effect of such bans.

Recommendations

- **Major recommendation**
 - Filter ventilation should be banned.
- **Alternative recommendations**
 - Specific filter ventilation should be required (the actual level will have to be tested) that ensures that all cigarettes have the same level of ventilation.
 - Alternatively, consideration could be given to permitting two classes of marketed cigarette products – with filters that provide > 50% and 0% ventilation.

2.7 Regulatory considerations of policy measures for ventilated cigarettes and policy implications

Ventilation of commercial cigarettes not only inaccurately suggests to consumers that some brands are less harmful than others but can increase their appeal and lead to regular smoking by reducing the averseness (and enhancing the pleasurable elements) of smoking experimentation. To date, no countries have regulations to restrict the use of ventilation, although several have successfully reduced the attractiveness of products to children, primarily by addressing flavours. Regulations to reduce the toxicity of products have been less effective. Several countries can regulate emissions, and setting a narrow range of allowed emissions may be an indirect way of restricting ventilation.

Regulatory action should focus on youth appeal, ease of initiation and consumer deception. The action must ensure that tobacco companies cannot introduce other product changes that could counter the effect of the regulation. As testing methods and reporting systems are already widely accepted, regulation of cigarette ventilation would not pose an undue burden on government agencies or cigarette manufacturers. Systems for monitoring the market for illegal activity, assessing compliance and evaluating the impact of such measures should be in place before regulations are implemented. As evaluation can be conducted in several phases, short-term responses could be used to predict long-term outcomes. As it is fully expected that the tobacco industry will actively contest any regulatory action, government agencies must have adequate evidence and be prepared for a long legal contest. It would be helpful if countries that already have advanced regulatory systems (such as Brazil, Canada, Chile, countries in the European Union and the USA) set a standard for ventilation and carefully evaluate the outcome. This would provide evidence on which other countries could base similar actions. In order to create and maintain public support, clear communication should precede and accompany regulation. Countries are encouraged to engage experts to guide them through all stages of enactment and enforcement of regulations before undertaking actions to limit cigarette tip ventilation.

Key points and findings

- Although several countries have the authority to regulate tip ventilation, this has not yet been done.
- Countries that do not have explicit regulatory authority over product design might use their regulatory authority over emissions to indirectly limit ventilation and set a narrow range of allowable TNCO yields from an appropriate smoking regimen.
- To date, attempts to address the design (ingredients, additives, contents, design features) of tobacco products have been to reduce the appeal to young people and not to reduce toxicity.
- Before countries take action to limit or prohibit cigarette ventilation, they should:
 - have the authority to regulate product design or emissions;
 - regulate according to appeal or attractiveness;
 - assess manufacturers' compliance;
 - require testing; and
 - define the testing protocol and evaluate both anticipated and unanticipated outcomes.
- Countries should be prepared for a prolonged legal battle with tobacco companies, as they are well aware that maintenance of cigarette sales is contingent on attracting new users to replace those who die early from using the products they sell.
- Countries should require manufacturers to report product tip ventilation, so that data can be collected on the distribution of products marketed in each jurisdiction.
- Regulations to limit or eliminate tip ventilation should be based on studies that show an association between tip ventilation and transition from experimentation to regular use.
- Countries with advanced regulatory systems (such as Brazil, Canada, Chile, countries in the European Union and the USA) should set a ventilation standard and carefully evaluate the outcome to provide evidence on which other countries could base similar actions.

Research gaps

- Studies of an association between filter ventilation and transition from experimentation to regular use



- Research on use of various ventilation products by young people as compared with adults
- Research on the use of vent-blocked cigarettes as compared with other tobacco and nicotine products and on potential switching.

Recommendations

- **Major recommendations**

- Regulatory action should focus on appeal to young people and ease of initiation.
- Regulators should assess product changes by manufacturers that could counter the effect of a ventilation ban or regulation before introducing regulations.

- **Other recommendations**

- Regulation of product design and emissions and according to appeal or attractiveness
- Systems to assess manufacturers' compliance, including testing and defined testing protocols
- Evaluation of both anticipated and unanticipated outcomes, including industry interference and opposition.

- **'Additional recommendation**

- Regulators should consider requiring manufacturers to report filter ventilation, so that data can be collected on the distribution of products marketed in each jurisdiction.

3. Discussion of the strength of the evidence for findings and regulatory considerations

On the basis of the discussions during the two days, evidence on cigarette ventilation from the background papers and the expertise represented at the meeting, the experts classified the strength of the evidence for key considerations and made recommendations for regulation.

Findings agreed by experts

- **Strong evidence**

In evaluating the evidence on the effects of cigarette ventilation on cigarette use, the experts categorized the following as substantiated by strong evidence:

- Machine yields do not reflect human exposure.
- Filter ventilation does not reduce the risk of disease.
- Filter ventilation increases appeal and product preferences.
- Filter ventilation misinforms consumers about the health risks of smoking and reduces consumers' perception of the health risk of smoking.
- Removal of pack descriptors is insufficient to eliminate misperceptions of the risk associated with using ventilated products.
- Most consumers are either unaware of vents or their function and unknowingly block filter vents or otherwise increase their smoking intensity.
- Filter ventilation changes the combustion of tobacco, which changes the physical, chemical and biological properties of smoke, as assessed *in vitro* and *in vivo* (in machine tests).
- Filter ventilation enables product elasticity, which leads to compensation and no reduction in exposure to nicotine and tar.
- The market share of ventilated cigarettes increases as countries move towards high income.
- Mechanisms other than filter ventilation, such as menthol and physical parameters, can be used to promote smoothness.

Highly suggestive evidence

In evaluating the evidence on the effects of cigarette ventilation on cigarette use, the experts categorized the following as substantiated by highly suggestive evidence.

- Filter ventilation increases the risk for lung adenocarcinoma.

Regulatory considerations

Although the evidence supports the adoption of bans on filter ventilation, several mechanisms should be in place before such a measure can be recommended, to limit unintended consequences. Further, several countries do not yet use basic, proven measures for tobacco control. Communication would be key to preventing the tobacco industry from using any measure on cigarette ventilation to its advantage.

- From the point of view of regulation and enforcement, banning filter ventilation³ is a practical measure, and, because there is no evidence for setting different allowable levels of ventilation, a ban is also more scientific than a more complex approach of limited filter ventilation.

³ Most, but not all, of the experts who participated in the meeting supported a ban on filter ventilation.

- As attractiveness is a characteristic that the tobacco industry may use, through product design features, to deceive the public, it is important that it be included in regulation. The purpose of such regulation would be to decrease the adverse health effects of cigarette use on the population and, eventually, to reduce tobacco use.
- Current regulations that limit TNCO yields must be addressed, as they are engrained in national laws and will have to be taken into consideration before policy is introduced to limit or ban cigarette ventilation.
- Coordination with other regulations and provisions that address the appeal of products, such as plain packaging and banning product descriptions, would enhance a ban on ventilation.
- Communication to the public and decision-makers is critical and must be carefully designed before any regulation on cigarette ventilation is introduced to prevent or minimize unintended consequences. This can be ensured by e.g. providing the rationale for any policy intervention, sending appropriate, clear messages explaining changes and what they mean and providing support to groups, as necessary.
- All countries could already collect data on cigarette ventilation and prevalence, which could be included in disclosure requirements, especially for countries that already have such regulations.
- Countries must be prepared to respond to legal challenges from the tobacco industry before taking any regulatory action.

Other important considerations discussed by the experts and other participants, which were taken into account with the findings of the background papers to formulate the recommendations above, are listed below.

Consideration	Discussion
Increase in appeal	Filter ventilation increases the appeal of cigarettes by making the smoke milder, smoother and easier to inhale.
Industry deception and misleading of consumers and regulators	<p>The tobacco industry has engaged in deception for years by creating a perception that some of its products reduce harm.</p> <p>Filter ventilation misleads smokers about the potential risks of smoking. Consumer misperceptions about harm reduction should be corrected by effective communication and clear messages that lower machine yields do not indicate less harm.</p> <p>Filter ventilation could facilitate uptake and maintenance of cigarette use and may deter cessation attempts.</p>
Human exposure to toxicants	<p>As a lower machine-determined yield, typical of the ISO regime, does not signify less human exposure to the toxicants, the risk of diseases associated with smoking remains. Exposure is at least the same with reduced machine-measured emissions and could even be higher.</p> <p>As promoted in tobacco industry advertisements, higher regular smoking rates have been observed, especially among young people who initiate smoking by experimenting with low-yield cigarettes, which could then be linked to use of ventilated cigarettes.</p>

Definitions and standard terminology	<p>The terminology used for cigarette filter ventilation should be consistent. For example, “tar” is often inappropriately used to approximate toxicity. Therefore, a better definition of “tar” should be found.</p> <p>A functional, enforceable definition of “no filter vents”, which covers other substitute designs that the industry could use to achieve a comparable effect, would be useful.</p>
Health effects	<p>Filter ventilation may be linked to an increased incidence of lung adenocarcinoma, although several components of cigarette emissions may contribute to this effect, and it is difficult to establish the proportion of adenocarcinomas that are attributable to filter ventilation.</p> <p>Volatile compounds can have health effects other than lung cancer, further supporting arguments for or against limiting or banning filter ventilation. The incidence of non-cancer outcomes in smokers, such as chronic bronchitis and emphysema, should be explored, with the increase in risk for chronic obstructive pulmonary disease over the years.</p> <p>More scientific evidence is needed that the overall lung cancer rate will decrease or that the number of disability-adjusted life years will increase as a result of limiting or banning cigarette ventilation. This will extend knowledge of the biological effects of changes in smoke chemistry and will further support the argument for regulatory action on cigarette ventilation.</p>
User preference	<p>The tobacco industry targets specific user groups. Female smokers were found to prefer ventilated cigarettes. The uptake of cigarettes with filter ventilation by young people in different countries should be investigated to inform regulation.</p> <p>Although advertisements suggest that experimentation with low-yield cigarettes results in greater uptake, the experts were unaware of any studies of the correlation between experimentation and regular use.</p>
Smoking topography	<p>Filter ventilation leads readily to modification of the intensity of puffing to regulate nicotine delivery. This depends on the profile of each user and the product brand.</p> <p>Compensatory smoking is a key effect of filter ventilation. Consumer behaviour includes the intensity and number of cigarettes smoked per day.</p> <p>Ventilation has other effects on smoking topography, such as the relation between the extent of cigarette ventilation and cigarette use and between the extent to which smokers compensate according to the degree of ventilation, but further research is necessary.</p> <p>Consumer choices may be intentional, and some may prefer higher or lower nicotine levels.</p>



Smoking regimes	<p>Although TobReg recommended the Canadian intense method for measuring TNCO, there were divergent views on the smoking regime that should be used.</p> <p>Flow rates affect results, and different flow rates are used in methods for measuring emissions.</p> <p>All the experts noted that the ISO regime, which is used in many countries, is flawed for several reasons, including generating very low yields of TNCO, and the tobacco industry has capitalized on this flaw to mislead the public and regulators for several years.</p> <p>Different methods of machine testing should be explored, especially in some countries, to better reflect TNCO yields. Further, in some countries, limits on TNCO based on the ISO regime are engrained in their regulations, which may be a challenge for regulatory action on cigarette ventilation.</p>
Banning of filter ventilation	<p>Although a ban on ventilation would be beneficial, it is currently not feasible in all countries because it is not supported by their regulatory framework. Many other interventions could be considered (e.g. media advertisements, educational campaigns) to increase the chances of success and the desired regulatory outcome. A multifaceted approach should be taken to any intervention on cigarette ventilation. Interactions between filter ventilation and other additives may also play a role.</p> <p>As a ban may not be feasible in all countries, Parties might opt to establish limits on toxicants from ventilated cigarettes and later provide guidance on operationalization.</p> <p>In considering a policy measure on filter ventilation, countries should be aware of the regulatory implications in the context of wider tobacco control. Several factors will have to be considered before a decision can be made to limit or ban cigarette ventilation.</p>
Educating the public	<p>The harmful effects of “lighter” cigarettes should be emphasized; however, if regulations are to be established for cigarette filter ventilation (such as limiting or banning it), effective communication should be given so that consumers can adjust to, for example, cigarettes with “no vent filters”.</p> <p>Sustained education is required to inform the public that most cigarettes are ventilated (as appropriate, depending on the market shares of ventilated cigarettes in the country) and that ventilated cigarettes also have harmful effects.</p> <p>Clear messages should be given that most cigarettes on the market are ventilated as a deliberate industry manipulation to increase the exposure of users to toxic substances above the machine-determined nicotine and tar yields.</p>

Regulatory authority	<p>Regulatory authority differs from country to country and according to the interpretation of national law. In considering a regulatory measure for cigarette ventilation, an important factor for a country is whether it has the authority to adopt and monitor such a measure. If this is not specified in the law, there will be no legal basis to act. Therefore, consideration should be given to introducing this measure into national law to allow the country to regulate or ban cigarette ventilation.</p>
Existing regulations	<p>As some countries have the authority to regulate product standards, the industry cannot argue that policy measures on cigarette ventilation would be a huge burden. These countries may be able to use existing provisions to regulate design features. For example, some countries can prohibit “technical features that change the taste or smell” of cigarettes. The language of relevant legislation could be reviewed by each country for use in regulating ventilation.</p> <p>Alternative ways for countries to regulate ventilation should be explored when current regulations do not permit it, such as language specifically about emissions.</p> <p>The flexibility of regulatory language varies around the world but should keep one step ahead of the scientific evidence to ensure that the language is accessible to the layperson. This will be important for educational campaigns.</p>
Unintended consequences	<p>Caution must be exercised in regulating filter ventilation to ensure that unintended outcomes are anticipated and limited to the extent possible. For example, public interest in cigarettes should not be increased by any new regulation.</p> <p>It has been argued that banning filter ventilation could increase addiction to nicotine. Measures should be in place to prevent such an unintended consequence.</p> <p>Banning filter ventilation could increase exposure to toxicants if such cigarettes are smoked at the same intensity as ventilated cigarettes. While it is expected that smokers will reduce their smoking intensity if vents are removed, it is not known whether this will be the case.</p>
Country data	<p>Data on, for example, the prevalence of use, user profiles and regulation of these products in several countries should be analysed to determine differences in the use and regulation of ventilated and unventilated cigarettes globally.</p> <p>Data on lung cancer in countries in which there is greater use of unventilated cigarettes should be analysed.</p> <p>Regulators should decide whether to ban or limit ventilation on the basis of data on use, regulations and regulatory frameworks.</p>

Access to data, including those held by the industry	<p>More data held by the tobacco industry on the history of cigarette ventilation and unpublished data should be made available to regulators to inform policy. Regulators who have the authority to request such data should require the industry to report on cigarette ventilation.</p> <p>Such documents could also be used to study the transition from initiation to regular use and could be considered to counter industry arguments.</p>
Justification for policy intervention	<p>Aspects for which there is strong evidence can be used to justify proposal of a policy measure to ban or limit filter ventilation.</p> <p>Filter ventilation results in higher levels of some toxicants, as evidenced by constituent yields after higher-intensity smoking and blocking of ventilation holes.</p> <p>Misperception of harm by consumers might justify policy intervention. More information is required on how higher smoking intensity reduces filter efficiency.</p> <p>As there will be resistance from the tobacco industry to new policies, consideration should be given to including cigarette ventilation in relevant regulation or legislation from the outset, to ensure that the drafts cover this fundamental aspect of cigarette design. Legislation could also include aspects that might be offered by tobacco companies to replace the potential “benefits” of cigarette ventilation, such as paper porosity.</p>
Tobacco industry response to regulation or opposition	<p>When formulating a policy on filter ventilation, regulators must preempt and prepare for industry opposition, which may include claims of health benefits of the use of filter ventilation and effects on the black market.</p> <p>The industry could counter a ban by modifying the harshness of cigarettes by manipulating other product characteristics of constituents. Therefore, industry activities and product changes must be monitored to determine their possible effects.</p> <p>Regulators should use the argument of more intensive smoking of ventilated cigarettes, as the industry is likely to argue that filter ventilation reduces harm to consumers.</p>
Harm vs appeal	<p>The design (ingredients, additives, contents and design features⁴) of tobacco products have been successfully regulated in some countries to reduce their appeal to the general population (including young people), but less action has been taken to reduce toxicity. An approach based on appeal and attractiveness, rather than toxicity reduction, might therefore be more successful.</p>

⁴ Including bans on menthol, flavours, slim cigarettes and 100-mm cigarettes

4. Research gaps

The main research gaps identified by the authors of the background papers and other experts and other participants at the meeting are presented below.

Impact of cigarette ventilation on public health

- New information is required to better understand the impact of banning filter ventilation on public health, including the impact of cigarettes with different degrees of ventilation on biomarkers of exposure.

Consumer perceptions and responses

- Assessment of the contribution of cigarette ventilation to consumer appeal requires independent consideration of other modifications, such as package design, by the scientific community and policy-makers.
- More research should be conducted to understand whether ventilation increases perceptions of smoothness and decreases perceptions of risk in a dose-response manner and consumer perceptions of ventilated and unventilated cigarettes, especially among adolescents.
- Consumers' responses towards major changes in cigarette design, such as market-wide introduction of cigarette ventilation, should be considered, monitored and carefully managed. Mechanisms for post-market surveillance should be explored.

Educating the public and preventing unintended consequences

- Studies should be conducted on effective communication strategies, approaches and pathways that can reach and educate the public about the harm of ventilated cigarettes, to prevent unintended consequences.

Collecting national data on brands and monitoring market trends

- The prevalence and extent of filter ventilation in cigarettes should be studied in all countries, as both the number of brands on the market and their overall market share, to build national intelligence on ventilated cigarettes for policy decisions.
- Data on filter ventilation in various brands and sub-brands available worldwide should be collected to assess the association between filtration and market share.

Evaluating and reporting the effects of filter ventilation

- The effect of filter ventilation on smoke particle size distribution, the chemical profile of particles, the effect of pressure drop on filter efficiency and filter ventilation and their implications for machine emissions and smoker exposure should be studied.
- Data on cigarette ventilation and its association with filter ventilation by brand and sub-brand and the mechanisms, including reporting templates, should be collected systematically.

Further investigation of the influence of cigarette ventilation on cigarette use

- Research is required to access internal tobacco industry documents, which will yield information on cigarette manufacturers' efforts to enhance cigarette product appeal by their

design and messages about use of ventilation.

- Studies that indicate an association between filter ventilation and transition from experimentation to regular use should be analysed urgently by regulators.
- Population-level analyses to understand the influence of filter ventilation on the prevalence of cigarette use should be conducted, with research on the relative use of vent-blocked cigarettes and other tobacco and nicotine products, with a focus on potential switching.
- Evidence should be collected on the use of different ventilated products by young people and by adults.

Exploring the possible effects of other design features

- Further research should be conducted on the effect of cigarette ventilation independently of other design changes, such as additives.
- Other features of filter design, such as physical dimensions, density, filter material, other components and their interaction with filter ventilation and effect on emissions, should be characterized.

Evaluation of the health effects of cigarette ventilation

- Studies should be conducted on the effect of ventilation on the development of symptoms of dependence, especially in population sub-groups. The influence of filter ventilation on maintaining smoking, including changes in dependence and cessation attempts and outcomes, should be addressed.
- Cancer and non-cancer outcomes associated with cigarette ventilation should be explored, as the results could support arguments for limiting or banning filter ventilation.

Further industry manipulation of products, possible evasion of regulations and unintended consequences

- A key research gap is how manufacturers might subvert ventilation regulations by manipulating other design features. This should be carefully assessed in a number of ways, including a review of evidence, monitoring of industry activity, product testing, engagement with consumers and post-market surveillance. It will also be important to investigate ways in which the tobacco industry could communicate with the public and to put measures in place to minimize such communication.

Understanding the influence of filter ventilation on targeted groups

- The influence of differences in filter ventilation on new sub-groups of consumers, especially children and women, should be studied, and epidemiological studies should be conducted after implementation of any ban or regulation to assess the effect on smokers.

5. Next steps

This report of the consideration of experts and the findings of each of the commissioned background papers pursuant to paragraph 8 of decision FCTC/COP8(21) will form the basis of the report to COP9. The background papers will be revised by the authors according to the comments of the participating experts and finalized. WHO will work further with the authors to adapt the papers for publication in peer-reviewed journals, as appropriate. Additional materials and publications will be made available, translated into the six official languages of the United Nations, to raise awareness of the meeting outcomes.

6. Report to the Ninth Session of the Conference of the Parties

The Convention Secretariat and WHO will prepare a report to COP9, giving the main findings of the background papers, in accordance with decision FCTC/COP8(21). The report will include the recommendations made after discussion by the group of experts and other information considered relevant to the COP, including the limitations of the current evidence, the regulatory context in different countries and anticipated consequences. The report will be available in the six official languages of the United Nations and will be published on the Convention Secretariat's website at least 60 days before the Ninth Session of the COP, with links to relevant resources.

Annex 1.

Summaries of the written background papers

Paper 1

Introduction to cigarette ventilation and possible implications for public health (Nuan Ping Cheah and Dorothy Hatsukami)

Design features are covered in the Partial Guidelines for Implementation of Articles 9 and 10 of the WHO Framework Convention on Tobacco Control (WHO FCTC). Ventilation holes in cigarette filters are one of the main features of cigarette products that contribute to dilution of mainstream cigarette smoke, resulting in lower emissions of tar and nicotine as measured by machine methods. Cigarette filter ventilation is, however, a defective design feature, which has been promoted by the tobacco industry to maintain tobacco use. This feature makes cigarettes “elastic”, allowing cigarette smokers to compensate for lower machine-determined nicotine and tar levels by smoking more intensely or covering the ventilation holes to achieve higher, more satisfying levels of nicotine, the addictive chemical in tobacco. Because of this smoking behaviour, smokers do not have lower exposure to cigarette toxicants and carcinogens or to disease risk to the extent indicated by reduced tar yields. Furthermore, filter ventilation changes the chemical and biological properties of tobacco smoke, which may, with more intense smoking, contribute to the increased incidence of lung adenocarcinoma.

Despite these findings, smokers continue to misperceive cigarettes with lower tar and nicotine yields as safer than those with higher tar and nicotine, primarily because of deceptive marketing practices and package descriptors and the milder, light taste of these cigarettes. This misperception contributes to the appeal and uptake of these cigarettes and to continued smoking. Unfortunately, as countries achieve higher income status, the market share of ventilated filter cigarettes also increases. These issues call for the following regulatory actions, particularly in relation to Articles 9 and 10 of the WHO FCTC:

- requiring manufacturers to disclose and conduct country-specific surveillance on cigarette design features that are associated with reduced machine-determined tar and nicotine yields;
- extending reporting to regulatory authorities of mainstream cigarette smoke emissions to include short-listed priority chemicals emitted when filter ventilation is unblocked (ISO) and 100% blocked (WHO Intense);
- educating the public on deceptions about ventilated cigarettes and the possibly increased harm associated with this cigarette design feature;
- introducing plain or standardized packaging to eliminate all descriptors, packaging, messaging and advertising that explicitly or implicitly suggest that these cigarettes are safer;
- prohibiting all advertising in which ventilated filter cigarettes are depicted explicitly or implicitly as healthier; and
- potentially prohibiting filter ventilation and other cigarette design features that allow cigarette “elasticity”.

National information on filter ventilation is limited. If filter ventilation is banned, the following research should be conducted:

- assessing the impact of the ban on initiation, maintenance, level of dependence and population prevalence; and
- monitoring the impact of the ban on health outcomes, such as lung cancer and non-cancer end-points.

Paper 2

Exploration of cigarette filter ventilation mechanisms, market availability and prevalence of use (Richard J. O'Connor and Ron Borland)

Filter ventilation, the addition of holes to the tipping paper, is an unobtrusive, apparently simple technology that has complex effects on both smoke chemistry and smoking behaviour. Ventilation of cigarettes arose in response to increasing public knowledge about the health risks of smoking and subsequent governmental and industry efforts to respond to increasing public concern about those risks. It remains an important technology, even in countries in which yield testing and labelling ceased over a decade ago. To increase filter ventilation of cigarettes, engineers can increase the number of vents, increase the size of individual vents, alter their shape and also move the ventilation zone closer to the mouth end of the cigarette. They can also make the tobacco rod denser so that it is more resistant to air flow through it, thus allowing more of each puff to enter through the vent holes at any flow rate. The tobacco industry rarely publicly acknowledges the existence of filter ventilation, and few tobacco control professionals currently pay much attention to it, which is unfortunate, given that filter ventilation has a profound influence on smokers' beliefs and behaviour.

It was not until the mid-1990s that consensus emerged among public health experts that the “low tar” programme had failed its public health goals and should be dismantled. Ventilated brands, as assessed by marketing proxies such as ISO “tar” numbers and “light/mild” or “smooth/fine” descriptors or by direct observation, form the vast majority of the brands available in high-income countries such as Australia, Canada, the United Kingdom and the USA, and a growing fraction of the market in low-to middle-income countries such as China. The products were accompanied by vigorous, targeted marketing by cigarette manufacturers to specific population groups that led to appeal and acceptance. In the context of overall declining cigarette sales over time in the USA, examination of unit sales by “tar” group market share shows that much of the lost sales volume is in the “high-tar” (> 15 mg) category. The market for the lowest “tar” groups has also collapsed since the 1990s, when (and again in 2009–2011) the sharp decline in the >15-mg category was almost entirely paralleled by a rise in the 10–15-mg group. Given the strong inverse correlation between “tar” and filter ventilation, a reasonable explanation is that the “tar” level of a high-selling product(s) shifted downwards, probably by increasing ventilation. Laboratory testing of cigarettes in several international markets supports the hypothesis of an association between levels of filter ventilation and country income.



Ventilated brands appear to appeal primarily to health-concerned smokers, women and younger smokers. Few smokers are aware of the existence and function of filter ventilation. The tobacco control community successfully campaigned to ban the terms “light” and “mild” and similar misleading descriptors, in line with Article 11 of the WHO FCTC; however, despite an initial decrease in misperceptions when these descriptors were removed, the belief that cigarettes with more filter ventilation are less harmful reasserted itself over time.

Although ventilation contributes to the harm associated with cigarette smoking, many smokers are unaware of its existence and its function, even when they smoke brands that are vented. There is clear evidence of deception on the industry’s part, a very strong case for reduced perceptions of harmfulness and a plausible case for filter ventilation having increased harm. Consumers do not understand the technology of ventilation and indeed are misled by it, as it does not reduce consumers’ health risks. Therefore, its use in commercial products should be banned. To lay the groundwork for such regulation, governments should begin to monitor ventilation and other design features of cigarettes (porosity, tobacco weight, rod density, filter efficiency) that affect emissions. The result of such surveillance could be used as a comparator for future product standards.

Paper 4

Effects of cigarette filter ventilation on machine-measured yields

(Irina Stepanov and Peter Joza)

Cigarette ventilation is the airflow that enters various parts of the cigarette rod from directions other than the main axis, that is, the lit end. It is expressed as the percentage contribution of the airflow to the total flow exiting a cigarette’s mouth-end. Cigarette ventilation dilutes the smoke leaving the mouth-end, and modification of cigarette design to increase ventilation has been used by cigarette manufacturers to achieve substantial reductions in nicotine and other harmful emissions generated by smoking machines.

The main cigarette characteristic that contributes to its ventilation and subsequent reductions in machine-measured is the presence and the number and size of holes in the filter tipping paper; however, cigarette paper porosity and permeability, the type and density of the tobacco filler and cigarette geometry (circumference, length) also play a role. Because of its major impact on overall cigarette ventilation, filter ventilation has been reported most frequently in both industry and academic research publications. Analysis of those publications shows that, since ventilated filters were first introduced in the 1970s, the market share of cigarettes with high filter ventilation has been increasing worldwide, particularly in higher-income countries.

In addition to diluting the smoke, filter ventilation modifies tobacco burning and smoke composition by:

- reducing the temperature of the coal;
- reducing the amount of tobacco burnt during each puff;
- increasing the number of puffs per cigarette;
- diffusing some gas-phase components from the tobacco rod;

- reducing the water content of smoke particles;
- increasing particle coagulation due to longer residence time of the smoke in the rod; and
- higher retention of smoke components by the filter.

Generally, the yields of smoke constituents measured under similar machine-smoking conditions are reduced somewhat proportionally to the filter ventilation level. There is, however, a complex relation between the degree of filter ventilation and the levels of harmful emissions measured in different smoking regimens. Overall, the emissions from more highly ventilated cigarettes are more dramatically increased in response to increased smoking intensity. Therefore, higher-intensity smoking protocols, such as that of the WHO TobLabNet, are more appropriate for adequate assessment of smoke emissions. Furthermore, emissions normalized to nicotine yield are less affected by ventilation than per-cigarette measures and should therefore provide better chemical assessment of a cigarette brand.

Identified research gaps include lack of systematic data on filter ventilation by brand and sub-brand worldwide; lack of clarity on the effect of filter ventilation on smoke particle size distribution and the chemical profile of particles; lack of data on how filter efficiency is affected by filter ventilation and the potential implications for exposure of smokers; and lack of understanding of how other filter design features (such as physical dimensions, density, type of filter material) and other cigarette characteristics that contribute to its ventilation interact with filter ventilation and affect smoke emissions.

The main proposed policy recommendation is to assess the impact of banning filter ventilation. It is also recommended that the WHO/Canadian Intense smoking regimen be used for regulatory purposes and that manufacturers report constituent yields per cigarette and per mg nicotine. Other recommendations address research, such as systematic collection of data on filter and cigarette ventilation and monitoring of relevant innovations.

Paper 5

Influence of cigarette filter ventilation on product appeal and consumer use (Vaughan W. Rees and Reinskje Talhout)

For decades, tobacco manufacturers have systematically manipulated the design and formulation of their products to enhance their appeal to consumers. Cigarettes are designed to both meet the preferences of current consumers and to increase interest in use among targeted groups of potential new consumers. Cigarette manufacturers have successfully enhanced the appeal of their products through systematic manipulation of both product characteristics and the way in which products are communicated and made available to consumers. These manipulations accomplish two related goals: enhancing the potential for the product to promote dependence (abuse liability) and enhancing positive perceptions of the product by consumers. Both methods of enhancing appeal can influence smoking behaviour: higher abuse liability is linked to more rapid initiation of dependence, greater dependence and greater difficulty in quitting, and certain positive attitudes or perceptions appear to increase the likelihood of related behaviours, including smoking.

Filter ventilation may influence product appeal, thus supporting initiation and sustained smoking, leading to a greater prevalence of use. A systematic literature search on cigarette filter ventilation and product appeal and use behaviour indicated an influence of filter ventilation on the various constructs that comprise cigarette product appeal and product use. Filter ventilation dilutes the smoke available to the smoker and is perceived as smoother, less harsh and less irritating than smoke delivered from unventilated cigarettes. Filter ventilation thus facilitates inhalation of smoke and results in the misconception that these cigarettes are less harmful. Evidence suggests that, by modifying the sensory experience of smoking, filter ventilation contributes to perceptions of smoking risk and increasing consumer preferences for ventilated brands. Ventilation may enhance abuse liability by encouraging intense puffing, thereby increasing nicotine delivery. Insufficient data are available to determine whether perceptions of smoothness increase with the degree of filter ventilation or whether ventilation influences smoking uptake among youth.

The influence of filter ventilation on product appeal suggests that filter ventilation can promote cigarette uptake, sustain use and lower cessation rates. Further research should be conducted to understand whether ventilation influences the prevalence of cigarette use by encouraging smoking initiation, sustained use and/or cessation outcomes. We recommend further research on cigarette ventilation, independently of other design features, such as the use of additives. Regulations to restrict both filter ventilation and communication of ventilation themes via product packaging and other marketing materials should be considered.

Paper 6

Exploration of potential health effects of cigarette filter ventilation on smokers (Peter. G. Shields and Ghazi Zaatari)

Paradoxically, the risk for lung cancer associated with smoking cigarettes has increased progressively, while the overall prevalence of smoking-related disease has decreased in parallel with reductions in smoking rates. Specifically, the histopathological types of lung cancer have shifted over the past 60 years, whereby lung adenocarcinomas are now the most common. This is linked to changes in cigarette design during the second half of the last century. The implication is that cigarette design, smoking behaviour and exposure to toxicants in smoke have changed to increase the risk of lung adenocarcinoma. Two changes in cigarette designs over time have been identified:

- the introduction of ventilation holes to cigarette filters, which has been increasing in degree of ventilation and popularity in the marketplace; and
- an increase in the content of tobacco-specific nitrosamines in tobacco and subsequently in cigarette smoke emissions.

In view of identified dose–response relations, the public health community advocated for methods to reduce smoking-machine tar yields (total particulate matter not including volatile compounds), and cigarette manufacturers widely adopted cigarette filter ventilation; however, there have been several unintended adverse consequences of filter ventilation, with either worse or no beneficial effects. Filter ventilation changes how a cigarette burns, allowing delivery of a greater volume of smoke and subsequently higher amount of tobacco toxicants. Filter ventilation also

allows elasticity of smoking, such that smokers smoke more (compensate) to obtain satisfying nicotine blood levels, irrespective of the stated smoking machine yields. The higher amounts of smoke and toxicants, including tobacco-specific nitrosamines, and volatile organic compounds will ultimately reach deeper, more peripheral areas of the lungs and damage the types of cells that develop into adenocarcinomas. Studies of switching from lesser to more ventilated cigarettes do not show any reduction in toxicants with increased ventilation. These findings and studies of smokers' perceptions indicate that cigarette filter ventilation has no public health benefit. This report and others conclude that there is highly suggestive evidence that the increase in lung cancer risk and of lung adenocarcinomas are due, at least partly, to increased cigarette filter ventilation. This is therefore a modifiable design feature with a public health benefit.

A regulatory agenda for reducing smoking-related disease by banning cigarette ventilation is a reasonable approach. Alternatively, filter ventilation could be mandated to exceed, for example, 50% to preclude complete compensation. A research agenda is discussed in this paper to assess unintended consequences of banning cigarette filter ventilation.

Paper 7

Regulatory considerations of policy measures for ventilated cigarettes and policy implications (David Ashley and Micah Berman)

The transition from experimentation to regular use of tobacco is strongly influenced by whether the initial experiences are pleasurable. Ventilation can shift the balance between the aversive irritation and the hedonic aspects of tobacco use. Thus, ventilation increases the prevalence of tobacco use, directly increasing the harm caused by tobacco.

To date, no countries have attempted to regulate cigarette ventilation. Uruguay allows only a single representation of each brand, limiting the number of different ventilation levels within a brand family, but this does not limit the range of ventilation levels available on the market, as a whole. Several countries have put regulations in place, but tip ventilation has not yet been regulated. Countries that have no explicit regulatory authority over product design could regulate emissions as an indirect means to limit ventilation and could set a narrow range of allowable delivery of tar, nicotine and carbon monoxide with an appropriate smoking regimen.

Attempts to address the design (ingredients, additives, contents, design features) of tobacco products have been directed to reduce the appeal to young people and not to reduce toxicity. While the attempts have mainly targeted flavours, this approach could be applied to other properties, such as ventilation, which increases product appeal to naive users and especially young people. An additional approach could be to prevent manufacturers from deceiving consumers about their products.

Before countries take action to limit or prohibit cigarette ventilation, they must have the authority to regulate product design or emissions and to regulate according to appeal or attractiveness. They should have systems for assessing manufacturers' compliance, for requiring testing, for defining

the testing protocol and for evaluating both anticipated and unanticipated outcomes. Countries should be prepared to address the introduction of illicit products onto their market. They should be fully equipped and prepared to conduct such actions effectively to maximize the benefits and reduce unintended consequences.

Actions to limit cigarette ventilation will be strongly opposed by industry, because they are well aware that maintenance of cigarette sales is contingent on attracting new users to replace those who die early from using the products they sell. Efforts to thwart effective regulation include delaying tactics, development of contradictory scientific arguments, lobbying of decision-makers and lawsuits. Countries should be prepared for a prolonged battle with companies; success will require sufficient, continual effort.

Regulations should focus on appeal to young people and initiation and ensure that other product changes that could counter the effect of the regulation are not permitted. Countries are encouraged to engage experts to guide them through the stages of enacting and enforcing regulations before they take action to limit cigarette tip ventilation. Reports from countries that have regulatory measures to adopt a ventilation standard and have carefully evaluated the outcome would provide evidence upon which other countries could base similar actions.

Annex 2. Meeting agenda

Day 1: 18 November 2019

- 9:00–9:20 Welcome and opening remarks
- The Government of the Netherlands: Paul Blokhuis, State Secretary of Health, Welfare and Sport (5 min)
 - National Institute of Public Health and the Environment: Director-General, Hans Brug (5 min)
 - Secretariat of the WHO FCTC and the Protocol: Tibor Szilagyi (5 min)
 - WHO: Vinayak Prasad (5 min)
 - Chair: Denis Choinière (5 min)
- 9:25–10:05 Participants briefly state their institutional affiliations and meeting expectations (1 min each)
- Leticia Martinez
- 10:05–10:25 History and dynamics of cigarette ventilation
- Reinskje Talhout
- 10:25–10:45 Setting the context and expected outcomes
- Leticia Martinez
 - Ranti Fayokun
- 10:45–11:00 Coffee break
- 11:00–11:35 Paper 1: Introduction to cigarette ventilation and possible implications for public health
- Nuan Ping Cheah and Dorothy Hatsukami (20 min)
- Questions and answers
- Chair (15 min)
- 11:35–12:10 Paper 6: Exploration of potential health effects of filter ventilation on consumers
- Peter Shields and Ghazi Zaatari (20 min)
- Questions and answers
- Chair (15 min)
- 12:10–13:10 Lunch
- 13:10–14:30 Laboratory demonstration of the effect of filter ventilation on emissions
- RIVM
- 14:30–15:05 Paper 3: Potential effects of cigarette ventilation on human smoking topography and behaviour
- Walther Klerx (20 min)
- Questions and answers
- Chair (15 min)
- 15:05–15:40 Paper 4: Effects of cigarette filter ventilation on machine-measured yields
- Irina Stepanov and Peter Joza (20 min)
- Questions and answers
- Chair (15 min)
- 15:40–15:55 Coffee break

- 15:55–16:30 Paper 5: Effects of cigarette ventilation on product appeal and consumer perception and use
 – Reinskje Talhout and Vaughan W Rees (20 min)
 Questions and answers
 – Chair (15 min)
- 16:30–17:05 Paper 2: Exploration of cigarette ventilation mechanisms, market availability and prevalence of use
 – Richard O Connor and Ron Borland (20 min)
 Questions and answers
 – Chair (15 min)
- 17:05–17.25 Day 1 wrap up
 – Chair

Day 2: 19 November 2019

- 9:00–09:10 Short remarks
 – Chair
- 9:10–09:20 Day’s proceedings, including explanation of the objectives of the interactive session and of the breakout sessions
 – Ranti Fayokun
- 09:20–10:05 Paper 7: Regulatory considerations of policy measures for ventilated cigarettes and policy implications
 – David Ashley and Micah Berman (25 min)
 Questions and answers
 – Chair (20 min)
- 10:05–10:20 Coffee break
- 10:20–11:30 Group workshop and interactive session for discussion on each paper for preparation of the report to COP9
 – This will be similar to a poster session. Authors and reviewers of each paper will be situated in different parts of the meeting room near a summary of key points on the latest evidence in the papers. Participants are expected to walk around the room and engage with authors and reviewers to clarify points made or suggest additional comments for preparation of the report to COP9.
- 11:30–12:05 Report of key findings in each paper
 – Lead authors of the seven papers (5 min each)
- 12:05–13:15 Lunch
- 13:15–14:25 Breakout sessions
 – Group 1: Framing the key messages from papers 1–6 according to the latest evidence
 – Group 2: Outline of the COP9 report and guidance on main conclusions and recommendations
 – Group 3: Regulatory implications of findings in paper 7
 – Group 4: Policy recommendations from each paper, pros, cons, considerations and unintended consequences

- 14:25–15:05 Plenary
A member of each group will share key points for consideration for inclusion in the COP9 report with the input of other participants (10 min per group)
– Chair
- 15:05–15:20 Coffee break
- 15:20–16:05 Plenary to discuss the output of each group and to agree on items to be included in the COP9 report
– Group 1 (5 min)
– Group 2 (5 min)
– Group 3 (5 min)
– Group 4 (20 min)
Plenary discussion on the outline of the COP9 report (10 min)
- 16:05–16:20 Quick review of the outline of the COP9 report
– Ranti Fayokun
- 16:20–16:40 Summary, action points (responsibilities) and time frames
– Chair
- 16:40–17:00 Wrap up and closing remarks
– Chair – Denis Choinière (5 min)
– Secretariat of the WHO FCTC and the Protocol – Vera Da Costa e Silva (5 min)
– WHO – Vinayak Prasad (5 min)

Annex 3. List of participants

Experts

Dr David Ashley, Research Professor, Department of Population Health Sciences, School of Public Health, Georgia State University, Urban Life Building, Suite 857, 140 Decatur Street, PO Box 3995, Atlanta, GA 30303-3995, USA

Dr Micah Berman, Associate Professor, Health Services Management & Policy, College of Public Health & Moritz College of Law, Ohio State University, 210 Cunz Hall, 1841 Neil Avenue, Columbus, OH 43210-1351, USA

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Dr Nuan Ping Cheah, Director, Pharmaceutical, Cosmetics and Cigarette Testing Laboratory, Pharmaceutical Division, Applied Sciences Group, Health Sciences Authority, 11 Outram Road, 169078, Singapore (Chair, TobLabNet)

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Dr Ghazi Zaatari, Professor and Chairman, Department of Pathology and Laboratory Medicine, American University of Beirut, PO Box 11-0236, Riad El Solh 1107 2020, Beirut, Lebanon (Chair, WHO Study Group on Tobacco Product Regulation (TobReg))

Professor Efthimios Zervas, Environmental Impacts Technology, Director, Laboratory of Technology and Policy of Energy and Environment, Director, MSc Program Environmental Design, School of Science and Technology, Hellenic Open University, Parodos Aristotelous 18, 26335 Patra, Greece

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Representatives of Parties

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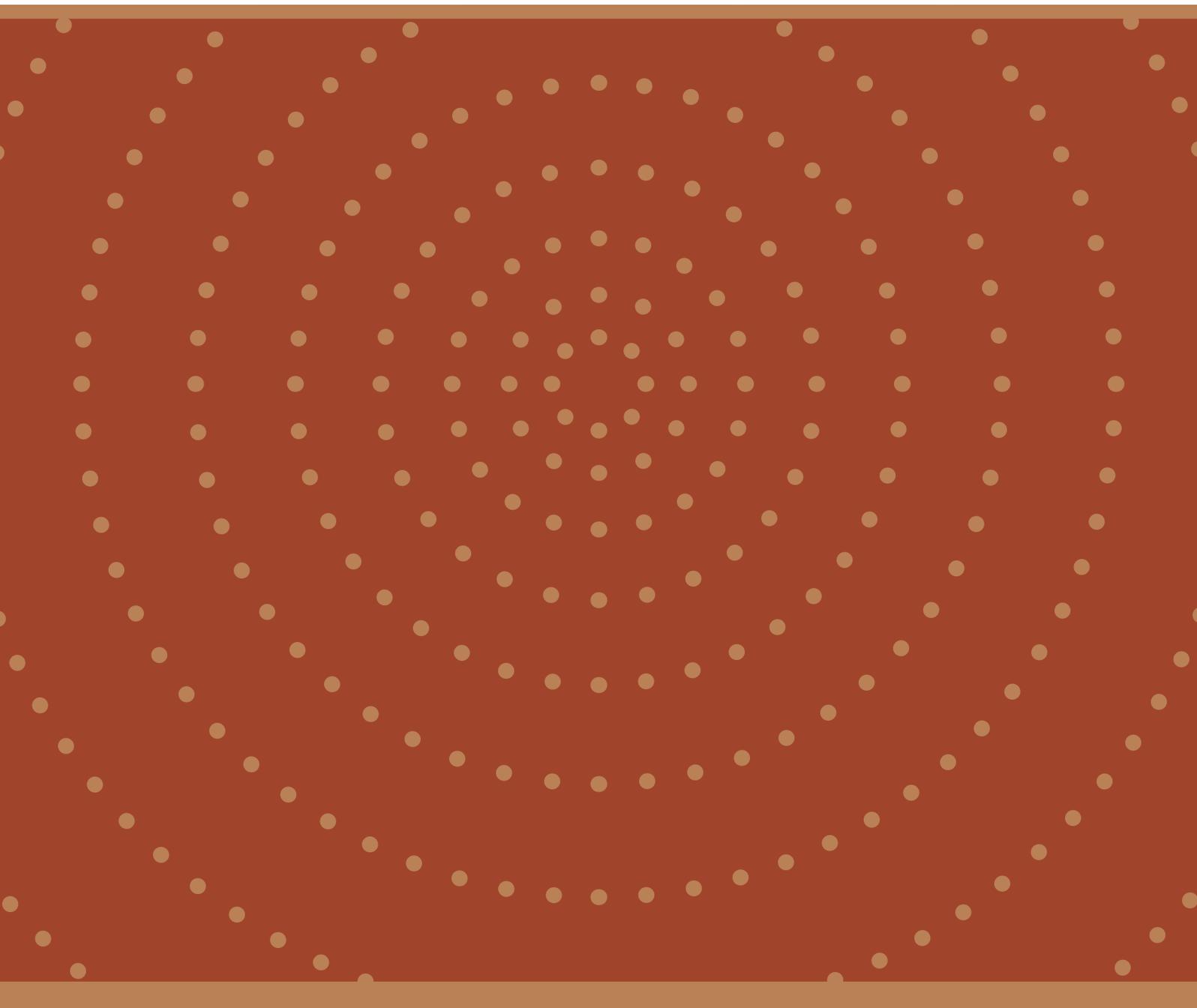
Secretariat of the WHO Framework Convention on Tobacco Control, Geneva, Switzerland

Dr Vera Luiza da Costa e Silva, Head

Dr Tibor Zoltan Szilagyi, Coordinator, Reporting and Knowledge Management

Ms Leticia Martinez Lopez, Technical Officer, Reporting and Knowledge Management





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