

Meeting report

[Final unedited]

Meeting to review the latest available scientific evidence on the impact of cigarette ventilation on cigarette use

18 - 19 November 2019

Executive summary

This report provides a record of the meeting on cigarette ventilation, to gain an overview of 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). To achieve this, a meeting was held from 18-19 November 2019 to:

- i.) review the latest scientific evidence on cigarette ventilation, as presented in a series of background papers;
- ii.) gather relevant information on the potential and actual impact of cigarette ventilation on cigarette use;
- iii.) extract information that might help regulators gain a better understanding of the use of ventilation in cigarettes; and
- iv.) obtain information that could be used by Parties to strengthen the implementation of Articles 9 and 10.

The meeting, which was jointly organised by the Secretariat of the WHO FCTC (Convention Secretariat) and WHO, was supported by the host country (Netherlands) and built on previous experience of WHO and the experts represented, the existing scientific evidence, as well as on decision FCTC/COP8(21) of the COP. Participants examined the latest scientific evidence on the impact of ventilation on cigarette use.

Participants were identified and drawn from the categories of experts specified in decision FCTC/COP8(21); as a result, a wide range of expertise was represented at the meeting. The Chairs of the WHO Study Group on Tobacco Product Regulation (TobReg) and the WHO Tobacco Laboratory Network (TobLabNet) also participated in the meeting, the scope and purpose of which was articulated in a document circulated to participants prior to the meeting.

Six background papers, commissioned by WHO, informed the deliberations. These were authored by diverse experts active in the field of cigarette ventilation research and addressed the requests of the COP outlined in decision FCTC/COP8(21). These were drafted based on the terms of reference for each of the papers, as developed by WHO. The titles of the papers are as follows:

- **Paper 1:** Introduction to cigarette ventilation and possible implications for public health
- **Paper 2:** Exploration of cigarette ventilation mechanisms, market availability and prevalence of use
- **Paper 4:** Effects of cigarette filter ventilation on machine-measured yields
- **Paper 5:** Effects of cigarette ventilation on product appeal and consumer perception/use
- **Paper 6:** Exploration of potential health effects of filter ventilation on consumers
- **Paper 7:** Regulatory considerations of policy measures for ventilated cigarettes and policy implications

Additionally, a presentation was delivered on commissioned *Paper 3* on the '*Potential effects of cigarette ventilation on human smoking topography and behaviour*', for which a background paper was not developed.

Discussions focussed on the science and the findings of each of the papers, as articulated by the authors, who delivered presentations based on their papers. This informed the debate about translation of these findings and evidence into policy and recommendations to the ninth session of the COP.

The Partial Guidelines for Implementation of Articles 9 And 10 of the WHO FCTC recognizes the importance and recommends to Parties the collection of data, from manufacturers and importers, on product characteristics, including design features, helping Parties understand the impact of such characteristics on smoke emission levels, proper interpretation of the measurements obtained and to be updated on the latest changes in cigarette design features. The Partial Guidelines set out the design features of cigarettes, many of which relate to cigarette ventilation, as well as recognize that the tobacco industry makes tobacco products more attractive to different segments of society by modifying existing or introducing new product design features, which should therefore be regulated by the Parties.

The commissioned background papers emphasized the harms associated with cigarette ventilation¹, including reduced risk perception and increased appeal, potential exacerbation of disease risks, such as

¹ Filter ventilation, referred to in some of the papers, to some extent interchangeably with cigarette ventilation, is a subset 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 aspect of cigarette ventilation available to manufacturers to make their cigarettes more attractive and palatable (another one is paper porosity, for example).

certain type of lung cancers and potentially non-cancer outcomes (for example, emphysema and chronic bronchitis), and how the tobacco industry targets specific segments of the society. Experts noted that the tobacco industry has a long-standing history of engineering and manipulating its products by various means, including changing product characteristics and modifying the delivery of toxicants and nicotine. A good example of this is cigarette ventilation, which is a deceptive technology that makes cigarettes attractive to different target groups. This is achieved by increasing cigarette paper porosity or putting holes in filters to dilute the smoke yields as measured by smoking machines and purportedly delivery to users, who are mostly oblivious of this deceptive technology. The technology is deceptive because even though the tar and nicotine yields are reduced when measured by machines, 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 receiving the same level of tar and nicotine as higher tar yield cigarettes. It was noted that among those targeted with different types of ventilated cigarettes are health concerned smokers, women and potential new users, such as adolescents. One of the key findings is that filter ventilation could facilitate uptake and maintenance of cigarette use, and also deter cessation attempts.

Several research gaps were identified, including the need to gather global data for the use of ventilated and non-ventilated cigarettes, the need for further knowledge on smoking topography to understand smokers' behaviour, the need to develop tools to measure the overall public health benefit of banning or limiting filter ventilation, and investigating youth uptake of cigarettes with filter ventilation in different countries. Further it was considered that post-implementation research on the impact of a ventilation ban, if implemented by the countries that have the regulatory environment to support such a ban, should evaluate effects on initiation, maintenance, level of dependence and population prevalence, as well as the impact of the ban on health outcomes, such as lung cancer and health and non-cancer endpoints.

Based on the findings of the background papers, some authors recommended banning of (filter) ventilation, some expressed challenges associated with limits set for Tar (T), Nicotine (N) and Carbon monoxide (CO) in existing legislation, while others expressed that although banning seems logical based on available evidence, consideration should be given to obtaining more data to study the effects of a ban on cigarette ventilation and supporting regulatory measures necessary to minimize unintended consequences, before a ban can be recommended.

Overall, based on available evidence to date as informed by the background papers, and the expertise represented at the meeting, the strength of evidence on the key considerations was classified as follows:

- **Strong evidence**

In evaluating the evidence on the effects of cigarette ventilation on cigarette use, the experts categorised 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 risk misperceptions of using ventilated products.
- Filter ventilation misinforms consumers about the health risks of smoking and reduces consumer health risk perception of smoking.
- Majority of consumers are either unaware of vents or their function, and unknowingly blocking filter vents or otherwise increasing 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.
- Proportion of market share of ventilated cigarettes increases as countries move towards high income.
- 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 categorised the following as substantiated by highly suggestive evidence

- Filter ventilation increases lung adenocarcinoma.

Regulatory considerations

Although the evidence supports the adoption of bans on filter ventilation, several regulatory mechanisms would need to be put in place and considered before such a measure could be recommended in order to limit unintended consequences. Further, countries are at different stages of tobacco control, which is an important factor when considering the adoption of a ban, given that several countries do not have basic and

proven tobacco control interventions. Communication would also be key to prevent the tobacco industry from using any measure introduced to regulate cigarette ventilation to its advantage.

- From a regulatory and enforcement point of view, banning filter ventilation is more practical and, because there is no evidence for setting a different specific allowable ventilation, this is also more scientifically supportable than a more complex approach, of setting a specific level of ventilation.
- Attractiveness is a feature that the tobacco industry may use to deceive the public, and, therefore, it is important that this is included in the regulation. The purpose of such regulation would be to decrease the adverse health impact on the population and, eventually, to result in less smoking.
- The current regulations that limit tar (T), nicotine (N) and carbon monoxide (CO) (collectively known as TNCO) yields must be addressed in countries that have these regulations, as these are engrained in national laws and this will need to be taken into consideration if policy measures are to be introduced to limit or ban cigarette ventilation.
- A coordinated response with other regulations and provisions targeted at addressing the appeal of tobacco products, such as plain packaging and banning product descriptors, would enhance a regulation banning cigarette ventilation.
- Communication to the public and decision-makers is a critical component and must be carefully crafted, prior to introducing any regulations on cigarette ventilation, to prevent or minimise unintended consequences. This will be achieved through a number of ways, including by providing the rationale for any policy intervention, targeting appropriate groups with clear messages explaining the proposed changes and what this means, and providing support to these groups, as needed, among others.
- A preliminary step that all countries could take now is to collect data on cigarette ventilation and prevalence of use and marketing. This can be part of disclosure requirements, especially for countries that have such regulations in place.

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

Next steps

- The meeting outcomes will be reported to the Ninth session of the Conference of the Parties to the WHO FCTC in a joint report by the Convention Secretariat and the WHO, and feed into deliberations in response to request 8 of decision FCTC/COP8(21).

1. Introduction/background

The cigarette ventilation meeting was held in Bilthoven, the Netherlands, from 18 - 19 November 2019. The meeting was hosted by the Government of the Netherlands and the National Institute of Public Health and the Environment (RIVM), and jointly convened by the Secretariat of the World Health Organization Framework Convention on Tobacco Control (WHO FCTC) and the World Health Organization (WHO). This is pursuant to decision FCTC/COP8(21) of the Eighth session of the Conference of the Parties (COP) to the WHO FCTC, on the implementation of Articles 9 and 10 of the WHO FCTC, in which the COP requested the Convention Secretariat to hold a face-to-face meeting on cigarette ventilation in cooperation with WHO. The relevant text is as follows:

“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 WHO, staff from the Convention Secretariat, the Chairs of the WHO Study Group on Tobacco Product Regulation (TobReg) and the WHO Tobacco Laboratory Network (TobLabNet), representatives of the host country, Party representatives and observers to the COP, who are independent of the tobacco industry. There were approximately 50 participants in attendance and the primary purpose of the meeting was to review the latest scientific evidence on the impact of cigarette ventilation on cigarette use. To achieve this, participants considered the following objectives:

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

Prior to the meeting, WHO had commissioned seven background papers covering the relevant aspects of cigarette ventilation to address the request and developed terms of reference (TOR) for each of these papers based on an initial search of scientific literature. The titles of these are outlined below:

- 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 were identified and assigned to develop the background papers, which set the scene for discussions during the meeting and will inform the development of the report to the Ninth session of the COP. In total, six papers were circulated to participants, prior to the meeting, as part of the background documents for the meeting. The Agenda, information circular and the list of participants were also circulated to participants ahead of the meeting.

Opening remarks were delivered by Mr Paul Blokhuis, the State Secretary of Health, Welfare, and Sport in the Netherlands, Mr Hans Brug, the Director-General, from The National Institute of Public Health and the Environment (RIVM), Dr Tibor Szilagyi of the Convention Secretariat, and Dr Vinayak Prasad, acting Director of the Department of Prevention of Noncommunicable Diseases. The meeting was chaired by Mr Denis Choiniere of Health Canada, who also delivered some opening remarks, which was followed by participants introducing themselves by stating their institutional affiliations and briefly noting their expectations from the meeting.

Day 1 focussed on the science and the findings of each of the papers as articulated by the authors in a presentation, which was followed by a Question and Answer session, in which participants had the opportunity to pose questions to authors, seek clarifications and provide comments based on their review of the papers. Summaries of these presentations are provided in the *Annex*. This informed the debate on Day 2 about how to translate evidence into policy and recommendations to the Ninth session of the COP.

In addition, two presentations were delivered on ‘*The history and dynamics of Cigarette Ventilation*’ and ‘*Setting Context and Expected Outcomes*’ to set the scene and maintain the focus of the meeting. Participants were reminded of the remit of the group and of the history of cigarette ventilation and previous work, of relevance to the meeting, especially by the TobReg, which published a report with a chapter on the scientific evidence on cigarette ventilation in its Technical Report Series (TRS 1001) in 2017. The report was prepared in response to a request by the COP at its Sixth session (13–18 October 2014) and includes a chapter on the scientific evidence on specific cigarette characteristics of interest, such as slim and “super-slim” designs, filter ventilation, and innovative filter design features, including flavour-delivering

mechanisms, such as 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 primary purpose of cigarette design is to increase the appeal of the product (that is, to make it more palatable, attractive, or to influence consumers perception by portraying cigarettes as “less harmful”). Further, it found that filter ventilation results in lower machine-generated emissions per cigarette, perceptions of lighter taste and safety by smokers, and proposed continuing research on the design characteristics of tobacco products and innovations. It also gave policy recommendations, which include:

1. Requiring manufacturers to disclose information on all the design features, parameters, specifications, and levels of contents and emissions of current products, such as cigarettes and emerging products. Examples include cigarette paper, capsules in cigarettes filters and cigarette dimensions; and
2. Prohibiting filter ventilation and any other design characteristic that allows cigarette elasticity (increased puff volume by smokers, especially of lower tar varieties); and preventing filter capsules, slim cigarettes, and any other product attribute that increases its attractiveness, smoke emissions or addictiveness.

The presenter noted that cigarettes are designed in a way to reduce the negative aspects of the product, to ensure that smokers experience satisfaction during product use, as well as to attract young people and novice users. Evidence also shows that physical characteristics of cigarettes, such as filter ventilation, have complex effects on multiple outcomes. Filter ventilation is a design feature that can be easily 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 higher exposure to toxic and carcinogenic emissions than would result from smoking less ventilated cigarettes.

2. Key findings, research gaps and recommendations, as articulated by authors

The authors put forward the following summaries, key points, recommendations and research gaps, based on the drafted background papers, which were discussed by participants during the meeting.

Paper 1 - Introduction to cigarette ventilation and possible implications for public health

Summary

Design features are one of the measures covered in the Partial Guidelines for implementation of Articles 9 and 10 of the WHO FCTC. In this regard, it is important for Parties to understand the impact of these characteristics on smoke emissions, properly interpret data obtained and keep up to date with any changes to cigarettes design features. Ventilation holes around cigarette filters are one of the main features of cigarette product characteristics which contributes to the dilution of mainstream cigarette smoke, resulting in lower emissions of tar and nicotine as measured by machine determined methods. At the Eighth session, the COP requested the Convention Secretariat and WHO to convene a meeting to gain an overview of the latest scientific evidence on the impact of cigarette ventilation on cigarette use and to report back to the Ninth session of the COP. This is a crucial milestone where global public health authority has taken a determined interest to furthering their understanding of the effects of design features of a cigarette, in particular, filter ventilation and how smokers' behaviours are affected by it. Cigarette ventilation is a defective design feature, which has been promulgated by the tobacco industry's interest in maintaining tobacco use. The paper looks at the possible public health implications of this design feature, and associated packaging and marketing that has misled the population into believing that these cigarettes are less harmful than lower or non-ventilated cigarettes. Regulatory perspectives and approaches, and research gaps are also discussed.

- ***Key points/findings***

- **Research gaps**
 - Investigate the impact of cigarettes that vary in ventilation on biomarkers of exposure.
 - Study consumer perceptions of ventilated versus unventilated cigarettes.
 - Explore best approaches to educate the public about the harms of ventilated cigarettes.
 - Investigate the impact of banning filter ventilation on public health outcomes.

- **Recommendations**
 - Educate the government and consumers about the harms associated with filter ventilation—that the low yields, typical of the ISO regime, does not mean lower exposure or harm.
 - Require cigarette manufacturers to disclose the cigarette characteristics that lead to low-yields and implement surveillance of testing features. For example, by requiring ISO and WHO intense method to determine constituent yields.

- Monitor the prevalence and perceptions of ventilated/lower yield cigarettes in each country.
- Eliminate all packaging/advertising/descriptors that mislead consumers into believing that ventilated/lower yield cigarettes are lower risk.
- Consider banning/limiting cigarette design features that are associated with cigarette "elasticity."
- **Major recommendations:**
 - Regulators should consider banning filter ventilation (and similar design features) after taking into consideration public health outcomes of this ban.
 - Regulators should eliminate descriptors/packaging/advertising, etc. that indicate ventilated cigarettes are safer, with a plain/standardised packaging recommended.
 - Regulators should expand the reporting of cigarette emissions to include reporting based on 100% ventilation and 100% blocking.
 - The public should be educated on the deceptions of ventilated cigarettes.
- **Additional recommendation**
 - Policymakers and others should apply the lessons learned from the deception of ventilated cigarette "harm reduction" in assessing and regulating electronic nicotine delivery systems (ENDS), heated tobacco products (HTPs) and Snus, with a focus on the way these products are marketed and used. The emerging "harm reduction products" require rigorous testing to determine their impact, positive or negative, on public health.

Paper 2 - Exploration of cigarette ventilation mechanisms, market availability and prevalence of use

Summary

Filter ventilation is a common design feature of contemporary cigarettes, which began to be used around 1970 as an attempt to undermine the intent behind "tar" yield testing. It remains a highly important technology, even in countries which 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 much attention to it. The lack of interest from the tobacco control community is unfortunate, given that filter ventilation has a profound influence on smokers' beliefs and behaviours.

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 available brands in high-income countries (for example, United States of America, Canada, United Kingdom of Great Britain and Northern Ireland, Australia) and a growing fraction of the market in low-middle income countries (such as the People’s Republic of China). Such products were accompanied by vigorous targeted marketing by cigarette manufacturers to specific population groups that led to appeal and acceptance. 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. Given the ubiquity of filter ventilation and its negative public health consequences, regulators should move to prevent the tobacco industry from using it to influence smokers’ beliefs and behaviours.

- ***Key points***

- Ventilation is a key driver of reduced smoking machine test emissions using the ISO regime, and of consumer misperceptions.
- Ventilation contributes to harms associated with cigarette smoking, yet many smokers are unaware of ventilation and its function, even when their own brands are ventilated.
- 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.
- Filter ventilation is an inherently deceptive technology, therefore its use should be prohibited as it is misleading many smokers to believe they are reducing their smoking-related risks, when they are not.
- There is no research on whether education campaigns or plain packaging will cause consumers to be less deceived.

- ***Research gaps***

- Information on prevalence and the extent of filter ventilation among cigarettes in all countries, both as a function of number of brands on the market and overall market share, is needed.
- Arriving at a functional, enforceable definition of ‘no filter vents’ that also anticipates and takes into account substitute designs of the industry could be used to achieve a comparable effect.
- The effects of consumer responses and behaviours of a major change to cigarette design being introduced on a market-wide basis should be studied and monitored.

- **Recommendations**

- *Major recommendation*

- Regulators should consider banning filter ventilated cigarette design, as the technology is inherently deceptive and misleads users to think they are reducing their harm.

- *Other recommendations*

- Regulators should consider monitoring ventilation and other cigarette design features that impact emissions.
- Regulators should consider introducing the requirement that future design changes be justified.

Presentation 3 - Potential effects of cigarette ventilation on human smoking topography and behaviour

As previously noted, there was no paper elaborated on this subject. A summary of the presentation delivered on the above-mentioned topic, as well as the key points are provided.

Summary

A search of literature was undertaken to evaluate the effect of filter ventilation on human smoking behaviour. To determine if human smoking topography is correlated to filter ventilation, data were gathered on filter ventilation, pressure drop and emission data (at least TNCO), and combined with human topography (puff volume, puff duration, puff interval, number of puffs and number of cigarettes per day). Only a few publications were found to contain data on filter ventilation/pressure drop data, as well as on human smoking topography. Nicotine emission data combined with human smoking topography data (23 studies) was also used to determine correlation of human smoking topography with cigarette filter ventilation, using nicotine as emissions levels as a proxy for the degree of filter ventilation.

The literature review showed a tendency for decreasing values for puff volume, puff duration and number of puffs related to increasing nicotine level, as determined by the ISO regime. However, no significant change was found in the results for puff interval and number of cigarettes per day. To test whether within brand/type variability shows correlation between filter ventilation and human topography, data from one study investigating a research cigarette (Virginia tobacco) smoked by 7 individual smokers, were evaluated. This study showed a large variability in topography between smokers using the same brand/type of cigarette, raising the question as to whether the results of nicotine level/filter ventilation studies can be used for the determination of the influence of these parameters on smoking behaviour.

The key question is “what is best study design to determine the influence of filter ventilation on the smoking behaviour of smokers in general and individual smokers?” As this question remains unanswered based on available evidence, further research is important and necessary to better understand the influence of filter ventilation on human smoking topography.

- **Key points**

- Data in publications show a tendency for decreasing values of puff volume, puff duration and number of puffs related to increasing nicotine ISO level.
- A within brand study showed high smoking topography variability between smokers using the same brand.
- In general, tendency smokers will adopt smoking parameters depending on nicotine level/filter ventilation.
- Topography variability between smokers using the same brand/type of cigarette is very high: can the results of nicotine level/filter ventilation studies be used for the determination of the influence of these parameters on smoking behaviour? However, it is important to recognize and acknowledge that there will be individual differences in how people smoke cigarettes with varying degrees of ventilation.

- **Research gaps**

- Investigation into the most robust study design for the determination of the influence of filter ventilation on the smoking behaviour in individual smokers and at the population level.
- Exploration of the daily trend of smokers may give an indication of changing behaviour within subjects (volume, puffs, shorter time between cigarettes).
- The influence of butt length should be considered and included in behavioral studies, given that it is a topographical item important for exposure.

Paper 4: Effects of cigarette filter ventilation on machine-measured yields

Summary

The speaker presented on the effects of cigarette ventilation on cigarette burning process and chemical composition of cigarette smoke, and its impact on the machine-measured emissions. The presentation showed that cigarette ventilation, driven primarily by filter ventilation, has a profound impact on the process

of tobacco burning and smoke formation. Variations in filter ventilation across countries and cigarette brands were presented. It was also emphasized that, while the ventilation results in per-cigarette reductions for many machine-measured smoke emissions, increases in smoking intensity and blocking filter vents leads to increases in such emissions, with greater increases being observed for ventilated cigarettes. The impact of filter ventilation on emissions expressed on per-mg nicotine basis, as well as the association between filter ventilation and filter efficiency, were also discussed.

The follow-up discussion highlighted additional gaps and research priorities, such as the need to better understand the impact of ventilation on particle size distribution and deposition in the lung, as well as the need for more robust data on constituents beyond nicotine and nitrosamines, and effects beyond cancer.

- **Key points**

- Cigarette ventilation, driven primarily by filter ventilation, has a profound impact on the process of tobacco burning.
- Ventilation results in per-cigarette yield reductions for many gas- and particulate-phase constituents measured in the machine-generated smoke under standard smoking regimens, specifically the ISO regime.
- Increases in smoking intensity and blocking filter vents leads to increases in machine-generated constituent yields, with greater increases being observed more for ventilated cigarettes.
- A key consequence of cigarette ventilation is elasticity, leading to increased yields of harmful smoke constituents with higher intensity of smoking, particularly for highly ventilated cigarettes.
- Filter efficiency increases with higher filter ventilation and lower intensity of smoking.

- **Research gaps**

- Investigate filter ventilation data by brand and sub-brand worldwide to assess association between filtration and market share, and to assess potential impact of bans on filter ventilation.
- Further research into the effect of filter ventilation on smoke particle size distribution and the chemical profile of particles.
- Characterisation of filter design features (for example, physical dimensions, density, filter material, presence of other components), their interaction with filter ventilation and effect on emissions.
- Exploration of filter ventilation and pressure drop effects on filter efficiency, as well as implications for machine emissions and smoker exposure.

- Systematically collect data on overall cigarette ventilation and its relationship with filter ventilation by brand and sub-brand.
- **Recommendations**
 - **Major recommendation:**
 - Regulators should consider banning or limiting filter ventilation at 20%, with regulation – this must however be preceded by an impact assessment.
 - **Other recommendations:**
 - Consideration should be given to developing an international standard for measuring filter efficiency.
 - Real time surveillance of filter and cigarette design innovations should be implemented.
 - Regulators should consider using the WHO/Canadian Intense smoking regime in regulating products.
 - Consideration should be given to further regulating cigarette elasticity, following future research into constituent yields.
 - Regulators should 'strongly consider' requiring manufacturers to disclose extensive details on all cigarette characteristics that are relevant to cigarette ventilation.
 - Constituent yields by manufacturers should be reported on a per cigarette and per mg nicotine basis. In doing this, regulators should ensure methods are disclosed by manufacturers in sufficient detail to allow for reproducibility.

Paper 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 literature search on cigarette filter ventilation, product appeal and use behaviour provided strong evidence that filter ventilation increases cigarette appeal by making the smoke 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 on 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 themes via product packaging and other marketing materials should be banned, preferably through the introduction of plain (standardized) product packaging.

- **Key points/findings**

- Filter ventilation can result in higher nicotine delivery, which could lead to dependency 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 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 via product packaging.

- **Research gaps**

- Evaluate the effect of ventilation independent of other accompanying design changes, such as the use of additives.
- Assess consumer appeal contribution of ventilation independently of other modifications, such as pack design.
- Investigate whether ventilation increases perceptions of smoothness and decreases risk perceptions in a dose-response manner.
- Investigate how manufacturers might subvert ventilation regulations by manipulating other design features.
- Research into the effect of filter ventilation on adolescent consumer perceptions and behaviours.
- Evaluate the influence of varying filter ventilation on targeting new sub-groups of consumers.
- Investigate the effect of ventilation on the development of dependence symptoms, especially among sub-groups.
- Explore the influence of filter ventilation on the 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.
- Research into internal tobacco industry documents to yield insights into cigarette manufacturers' efforts to enhance cigarette product appeal with design/messaging of ventilation.

- **Recommendations**
 - **Major recommendations**
 - Regulators should consider banning filter ventilation but precede regulation with research into how smokers adjust to unventilated, low yield cigarettes.
 - Consider pairing a ban with regulation that sets cigarette nicotine levels below a hypothetical threshold for dependence to prevent compensatory workarounds by the industry and behaviour from consumers.
 - **Alternative recommendation**
 - Standards should be applied to filter ventilation to prevent smokers from misperceiving ventilated cigarettes as less risky alternatives to non-ventilated cigarettes.
 - Plain packaging requirements and other restrictions on brand difference communication.
 - Regulators should consider using corrective statements on cigarette packs about the health risks associated with ventilated cigarettes.

Paper 6: Exploration of potential health effects of cigarette filter ventilation on smokers

Summary

Paradoxically, the risk of some lung cancers from smoking cigarettes has progressively increased while overall smoking-related disease has decreased in parallel with reduction in smoking rates. Specifically, the histopathological types of lung cancer have shifted over the last 60 years, where now lung adenocarcinomas are the most common. Several lines of evidence have identified two changes in cigarette designs over time, that might contribute to the increase in lung adenocarcinoma, namely, 1) the introduction of ventilation holes to cigarette filters, which has been increasing in degree of ventilation and popularity in the marketplace; and 2) an increase in the content of tobacco-specific nitrosamines (TSNA) in tobacco and subsequently in cigarette smoke emissions.

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

Human switching studies from lesser to higher ventilated cigarettes do not show any reduction in dose by increased ventilation. This, plus smoker perception studies, indicate that there is no public health benefit for cigarette filter ventilation. This report and others conclude that there is highly suggestive evidence that the worsening of lung cancer risk and increased lung adenocarcinomas are due to, at least in part, increased cigarette filter ventilation, which is a modifiable cigarette design feature of no public health benefit.

A regulatory agenda for a reduction in smoking-related disease by banning cigarette ventilation is a reasonable approach, or mandating filter ventilation to exceed, for example, 80% to preclude complete compensation. A research agenda is discussed herein to assess for unintended consequences of banning cigarette filter ventilation.

- **Key points/findings**

- The 2014 Surgeon General Report's found that lung adenocarcinoma risks and rates have increased due to cigarette filter ventilation, increased NNK (4-(methylnitrosamino)-1-(3-pyridyl)-1-butanone) tobacco levels, or both.
- Cigarette filter ventilation allows for elasticity of use, and smokers alter their puff profiles to smoke more intensely due to lower nicotine yields so that more smoke may go into the deeper part of the lungs.
- Increased filter ventilation increases smoke toxicant yields (including NNK), mutagenicity and tumorigenicity on a per mg nicotine basis.
- Banning filter ventilation will prevent elasticity, make cigarettes harsher, and will better allow for laboratory studies (such as smoke chemistry analysis) to compare tobacco products.
- Limitations in the weight of evidence reviews are biomarker studies showing no differences in exposure by filter ventilation, but the biomarkers are measured in surrogate tissues (for example, 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**

- Assessment of switching to cigarettes with 0% ventilation, and attendant changes smoking behaviour, exposure, abuse liability, perceptions and impact on quitting is necessary.
- There is a need for epidemiology studies and surveillance after the implementation of any bans or regulations to assess the effect of such bans.

- **Recommendations**
 - **Major recommendation**
 - A complete ban of filter ventilation preferred.
 - **Alternative recommendations**
 - A requirement for a specific filter ventilation (the actual level will need to be tested) that ensures all cigarettes have the same level of ventilation.
 - Alternatively, consideration can be given to exploring two classes of marketed products, which have filters with >50% and 0% cigarette ventilation.

Paper 7: Regulatory considerations of policy measures for ventilated cigarettes and policy implications

Summary

In addition to inaccurately suggesting to consumers that some brands are less harmful than others, ventilation of commercial cigarettes can increase their appeal and may lead to regular smoking by reducing the averseness (and enhancing the pleasurable elements) of smoking experimentation. To date, no countries have taken regulatory steps to restrict the use of ventilation, even though several have taken successful measures to reduce product attractiveness to children, primarily related to flavours. Efforts to regulate product characteristics based on changes to toxicity have not been equally effective. Several countries have the authority to 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 and ease of initiation or consumer deception. Efforts must ensure that other product changes that could counter the effect of the regulation are not permitted. Because testing methods and reporting systems are already widely accepted, regulating cigarette ventilation would not cause an undue burden on government agencies or cigarette manufacturers. Systems to monitor the market for illegal activity, assess compliance, and evaluate the impact of such measures should be put in place before any regulations are implemented. Evaluation can be multi-tiered so that short-term responses can be used to portend long-term outcomes. It is fully expected that the tobacco industry will actively contest any regulatory action, so government agencies must possess adequate evidence and be prepared for a long legal contest. It would be most helpful for countries who have advanced regulatory systems (such as Brazil, Canada, countries in the European Union, the United States, Chile) to advance a ventilation standard and carefully evaluate the outcome. This would provide evidence upon which other countries could base similar actions. In order to create and maintain public support, clear communication should proceed and

accompany regulation. Countries are encouraged to engage experts who can help guide them through all stages of enacting and enforcing regulations before undertaking actions to limit cigarette tip ventilation.

- **Key points/findings**

- Several countries have the authority to put regulations in place, but regulation of tip ventilation has not been enacted to date.
- 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 delivery of TNCO yields, using an appropriate smoking regimen.
- To date, successful attempts to address the design (ingredients, additives, contents, design features) of tobacco products have been aimed at reducing youth appeal and not reducing toxicity.
- Before countries take action to limit or prohibit cigarette ventilation, countries should:
 - have the authority to regulate product design or emissions;
 - regulate based on 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 battle with tobacco companies 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.
- Countries should require manufacturers to report product tip ventilation so that data can be gathered on the distribution of products marketed in each jurisdiction.
- Regulatory actions limiting or eliminating tip ventilation would be informed by studies that provide an association between tip ventilation and transition from experimentation to regular use.
- It would be most helpful for countries that have advanced regulatory systems (such as Brazil, Canada, the European Union, the United States, Chile) to advance a ventilation standard and carefully evaluate the outcome, in order to provide evidence upon which other countries could base similar actions.

- **Research gaps**

- Studies that provide an association between filter ventilation and transition from experimentation to regular use.
- Research on youth use of different ventilation products compared to adults should be explored.

- There is a need for research that evaluates the use of vent-blocked cigarettes in the context of other tobacco and nicotine products, with focus on potential for switching.
- **Recommendations**
 - ***Major recommendations***
 - Regulatory action should focus on youth appeal and ease of initiation.
 - Regulators should explore introducing regulation against product changes by manufacturers that could counter the effect of ventilation ban or regulation.
 - ***Other recommendations***
 - Regulating product design/emissions and regulating based on appeal/attractiveness.
 - Having systems in place to assess manufacturer's compliance, including testing and defined testing protocols.
 - Evaluating 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 gathered on the distribution of products marketed in each jurisdiction.

3. Discussions, key findings agreed by experts and regulatory considerations

Discussions ensued after each of the papers and clarifications were sought from authors. Experts also provided some useful insights on the papers and made suggestions to authors to refine the papers. All participants participated in a poster session which further presented the opportunity to discuss the key findings of each of the papers. The authors of each paper presented the key findings in the poster session and noted the comments and suggestions by experts, as well as clarified points raised by experts on the posters. The updated information presented by experts based on the review of literature was found to be consistent with the 2016 TobReg report, thereby leading to similar conclusions to TobReg. Additionally, there were two breakout sessions in which experts discussed the key findings of the commissioned papers and regulatory considerations with respect to cigarette ventilation. Following discussions over the two days and based on available evidence on cigarette ventilation, as informed by the background papers, and the

expertise represented at the meeting, the strength of evidence on the key considerations was classified by experts, as below, and some regulatory recommendations were put forward, as follows.

Key findings agreed by experts

- **Strong evidence**

In evaluating the evidence on the effects of cigarette ventilation on cigarette use, the experts categorised 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.
- Filter ventilation misinforms consumers about the health risks of smoking and reduces consumer health risk perception of smoking.
- Removal of pack descriptors is insufficient to eliminate risk misperceptions of using ventilated products.
- Majority of consumers are either unaware of vents or their function, and unknowingly block filter vents or otherwise increase smoking intensity.
- Filter ventilation changes combustion 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.
- Proportion of market share of ventilated cigarettes increases as countries move towards high income.
- Other mechanisms, such as menthol and physical parameters. can be used to promote smoothness in addition to filter ventilation.

Highly suggestive evidence

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

- Filter ventilation increases lung adenocarcinoma.

Regulatory considerations

Although the evidence supports the adoption of bans on filter ventilation, several mechanisms will need to be put in place and considered before such a measure can be recommended, to limit unintended consequences. Further, countries are at different stages of tobacco control, which is an important factor when considering a ban, given that several countries do not have basic and proven tobacco control interventions. Communication would also be key to prevent the tobacco industry from using any measure introduced on cigarette ventilation to its advantage.

- From a regulatory and enforcement view, banning filter ventilation² is more practical and, because there is no evidence for setting a different specific allowable ventilation, this is also more scientifically supportable than a more complex approach of specific limited filter ventilation.
- Attractiveness is a characteristic that the tobacco industry may use, through product design features, to deceive the public, and, therefore, it is important that this is included in regulation. The purpose of such regulation would be to decrease the adverse health impact of cigarette use on the population and, eventually, to result in less tobacco use.
- The current regulations that limit tar (T), nicotine (N) and carbon monoxide (CO) (collectively known as TNCO) yields must be addressed in countries that have these regulations, as these are engrained in national laws and this will need to be taken into consideration if policy measures are to be introduced to limit or ban cigarette ventilation.
- A coordinated response with other regulations and provisions targeted at addressing the appeal of products, such as plain packaging and banning product descriptors, would enhance a regulation banning ventilation.
- Communication to the public and decision-makers is a critical component and must be carefully crafted prior to introducing any regulations on cigarette ventilation to prevent or minimise unintended consequences. This will be achieved through a number of ways including by providing the rationale for any policy intervention, targeting appropriate groups with clear messages explaining changes and what this means, providing support to these groups, as needed, among others.
- A preliminary step that all countries could take now is to collect data on cigarette ventilation and prevalence. This can be part of disclosure requirements especially for countries that have such regulations already in place.

² Most, but not all, of the experts participating in the meeting supported a ban on filter ventilation.

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

Other important considerations discussed among experts and other participants, which were taken into account along with the key findings of each of the background papers, to formulate the recommendations above, are enumerated in the table below:

Considerations	Expanded discussions that informed recommendations
1 Increase in appeal	<ul style="list-style-type: none"> ○ Filter ventilation increases cigarette appeal by making the smoke milder, smoother, and easier to inhale.
2 Industry deception, and misleading consumers and regulators	<ul style="list-style-type: none"> ○ The tobacco industry has engaged in years of deception by creating a perception of reduced harm on its products. ○ Filter ventilation misleads smokers about the potential risks of smoking - it is important to correct consumer misperception about harm reduction through effective communication and to formulate clear messages explaining that lower machine yields do not indicate lower harm. ○ Filter ventilation could facilitate uptake and maintenance of cigarette use and may deter cessation attempts.
3 Human exposure to toxicants	<ul style="list-style-type: none"> ○ As a lower machine-determined yield, typical of the ISO regime, does not signify a lower human exposure to the toxicants, the risk of associated smoking diseases still exists. It is important to note that exposure is at least the same even with reduced machine-measured emissions and could even be higher. ○ As it has been promoted in tobacco industry advertisements, greater regular smoking rates have been observed, especially among the youth that initiate consumption with low yield cigarette experimentation, which could then be linked to the use of ventilated cigarettes.
4 Definitions and standardised terminology	<ul style="list-style-type: none"> ○ Consistent terminology in cigarette filter ventilation is necessary, for example, ‘tar’ is often inappropriately used in terms of its toxicity. Therefore, a better definition of ‘tar’ is needed.

		<ul style="list-style-type: none"> ○ A functional and enforceable definition of ‘no filter vents’, which also considers substitute designs that the industry could use to achieve a comparable effect, would be useful.
5	Health effects	<ul style="list-style-type: none"> ○ Filter ventilation may be linked with an increased incidence of lung adenocarcinoma, although there are various variables in the cigarette, which may contribute to this effect. However, it is difficult to establish the proportion of changes in adenocarcinomas that are attributable to filter ventilation. ○ Volatile compounds can have other health effects apart from lung cancer, which can further support arguments for or against limiting or banning filter ventilation – these non-cancer outcomes should be explored, for example, the incidence of chronic bronchitis and emphysema among smokers, as well as an increase in the risk of Chronic Obstructive Pulmonary Disease (COPD) over the years. ○ More scientific evidence is needed to prove that the overall lung cancer rate will decrease or that Disability-Adjusted Life Years (DALY) will improve as a result of limiting or banning cigarette ventilation. This will expand our knowledge of biological effects of changes in smoke chemistry and will further support the argument for regulatory action on cigarette ventilation.
6	User preference	<ul style="list-style-type: none"> ○ The tobacco industry targets different user groups – females were found to prefer ventilated cigarettes, but it would be important to investigate youth uptake of cigarettes with filter ventilation in different countries to inform regulatory pathways. ○ Although it has been suggested from advertisements that there may be greater uptake after low yield cigarette experimentation, experts are not aware of any studies correlating experimentation with regular use.
7	Smoking topography	<ul style="list-style-type: none"> ○ Filter ventilation makes it easy to modify the intensity of puffing behaviour and to regulate nicotine delivery – this is dependent on the user profile of each person and the product brand used. ○ A key effect of filter ventilation on consumer behaviour include compensatory smoking behaviour, which depends on the intensity and number of cigarettes per day.

	<ul style="list-style-type: none"> ○ There are other effects, such as those relating the degree of cigarette ventilation to cigarette use and to what extent smokers compensate based on the degree of ventilation, but further research is needed on smoking topography. ○ It is important to note that consumer choices could be intentional, and some may prefer higher/lower nicotine levels.
<p>8 Smoking regimes</p>	<ul style="list-style-type: none"> ○ Although TobReg recommended the Canadian intense method for measuring TNCO, there were divergent views on the smoking regime that should be used. ○ Different flow rates will change results, as different methods of measuring emissions use different flow rates. ○ All experts noted that the ISO regime, which is used in many countries, is flawed, for several reasons, including generating very low yields for TNCO, which the tobacco industry has capitalised on to mislead the public and regulators for several years. ○ Different methods of machine testing may need to be explored, especially for some countries, to better reflect TNCO yields. Further, some countries have limits for TNCO based on the ISO regime engrained in their national regulations, which may present a challenge for regulatory action on cigarette ventilation.
<p>9 Banning of filter ventilation</p>	<ul style="list-style-type: none"> ○ Although a ban on ventilation would be beneficial, it is currently not feasible in all countries. This is because it may not be supported by existing regulatory frameworks and there are many other interventions to consider (TV/radio ads, educational campaigns, etc.) in considering a ban to increase the chances of it being successful and achieving the desired regulatory outcomes. This highlights the importance of a multifaceted approach to any intervention on cigarette ventilation. There are also interactions between filter ventilation and other additives which may play a role. ○ Since a ban may not be feasible in all countries, Parties may opt to establish limits on toxicants from ventilated cigarettes, and later provide guidance on how to operationalise

		<ul style="list-style-type: none"> ○ In considering a policy measure on filter ventilation, a country will need to decide based on its regulatory context and this will need to be considered in the context of wider tobacco control. ○ Several factors will need to be considered before a decision can be made on whether to limit or ban cigarette ventilation.
10	Educating the public	<ul style="list-style-type: none"> ○ It is necessary to emphasize the harmful effects of “lighter” cigarettes but, at the same time, if regulations are to be put in place for filter or cigarette ventilation (for example, limiting or banning filter ventilation), consumers should be educated through effective communication to allow them to adjust to, for example, cigarettes with ‘no vent filters’. ○ Sustained public educational initiatives are required to inform the public that most cigarettes are ventilated (as appropriate, depending on the market shares of ventilated cigarettes in the respective Parties) and that ventilated cigarettes also have harmful effects. ○ It would also be important to provide clear messages to the public that the cigarettes available on the market are mostly ventilated, through deliberate industry manipulation, which increases exposure of users to toxic substances relative to the machine determined nicotine and tar yields.
11	Regulatory authority	<ul style="list-style-type: none"> ○ Regulatory authority differs from country to country and according to the interpretation of a country’s law. ○ In considering a regulatory measure for cigarette ventilation, one of the important factors for a country is whether it has the regulatory authority for adopting and monitoring such a measure. This is because, in case this is not specified in the law, there will be no legal basis to act. Therefore, consideration should be given to introducing such a measure in national laws or other regulatory mechanisms that will allow the country to regulate or ban cigarette ventilation.
12	Existing regulations	<ul style="list-style-type: none"> ○ Some countries have the authority to regulate product standards, therefore, the industry cannot argue that policy measures on cigarette ventilation would be a huge burden.

	<ul style="list-style-type: none"> ○ In these countries, there may be a possibility to use existing provisions to regulate the design features. For example, some countries can prohibit “technical features changing taste or smell” of cigarettes. ○ The language already in place in the legislation of each country can be reviewed as this could be used to regulate ventilation based on existing policies. ○ Alternative ways will need to be explored for countries to regulate ventilation where the regulatory language may not allow for it – for example, when the language is specifically about emissions. ○ Country flexibility for regulatory language is variable around the world, but there is a need to move one step ahead of the scientific evidence and create a language that is accessible to the layperson. This will be important in educational campaigns.
<p>13 Unintended consequences</p>	<ul style="list-style-type: none"> ○ Caution must be exercised when regulating filter ventilation, as unintended outcomes should be anticipated and limited to the extent possible. For example, it would be important not to consequently increase public interest in cigarettes. ○ It has also been argued that banning filter ventilation could also create increased addiction to nicotine, so measures should be put in place to prevent such a consequence, even though unintended. ○ Banning filter ventilation may increase exposure to toxicants if such cigarettes are smoked with the same intensity as ventilated cigarettes. While the expectation is that smokers will reduce smoking intensity in response to the removal of vents, it is not known if this will actually happen.
<p>14 Country data</p>	<ul style="list-style-type: none"> ○ Data, for example, on prevalence of use, user profiles, and regulation of these products from several countries should be analysed, as there are differences in the use/regulation of ventilated and non-ventilated cigarettes globally. ○ Lung cancer data from some countries where there is greater use of non-ventilated cigarettes should be explored. ○ Based on country data on use, regulation and regulatory framework, regulators can decide whether to ban or limit ventilation.

<p>15</p> <p>Access to data, including those held by the Industry</p>	<ul style="list-style-type: none"> ○ Further discussion about gaining more historical data held by the tobacco industry on cigarette ventilation is necessary, as the industry has a lot of data to which regulators do not currently have access. There are also unpublished data. ○ Gaining access to such data and industry reports would be important to inform policy. Regulators who have the regulatory authority to request these data can exercise this authority by requiring the industry to report on cigarette ventilation. ○ The documents can also be used to research the transition from initiation to regular use and could be considered to counter industry arguments.
<p>16</p> <p>Justification for policy intervention</p>	<ul style="list-style-type: none"> ○ Areas for which strong evidence currently exists can be used as justification to propose a policy measure to ban or limit filter ventilation. ○ Filters ventilation cause a higher level of some toxicants than evident from constituent yields from a mix of higher intensity smoking or blocking ventilation holes. ○ Also, misperception of harm in consumers might justify policy intervention. ○ It would be necessary to expand our knowledge of how higher smoking intensity reduces filter efficiency. ○ Knowing that there will be resistance from the tobacco industry with respect to new policies, consideration should be given to including cigarette ventilation in any relevant regulation or legislation from the outset, in order to make such drafts broad enough to cover this fundamental aspect of cigarette design. The legislation could also include other aspects that may be offered by tobacco companies to replace the potential “benefits” of cigarette ventilation, such as paper porosity.
<p>17</p> <p>Tobacco industry response to regulation or opposition</p>	<ul style="list-style-type: none"> ○ When formulating a policy on filter ventilation, regulators need to preempt and prepare for industry opposition. This may include claims of health benefits from the use of filter ventilation and the black-market effects. ○ It should be noted that the industry could modify the harshness of cigarettes to counter any ban, by manipulating other product

		<p>characteristics of constituents. Therefore, industry activities and product changes must be monitored to determine the possible effects.</p> <ul style="list-style-type: none"> ○ Regulators should counter with arguments on greater intensity of smoking, as the industry is likely to argue that filter ventilation reduces harm to consumers.
18	Harm vs appeal	<ul style="list-style-type: none"> ○ There have been successful attempts to address the design (ingredients, additives, contents, design features³) of tobacco products to reduce appeal in the general population (also among the youth), but less so on reducing toxicity. ○ Therefore, an approach based on appeal and attractiveness, rather than toxicity reduction, may be more successful.

4. Key research gaps

The key research gaps identified by authors of the background papers, as well as those raised by experts and collectively considered by participants during the 2-day meeting, are presented below under 10 themes, namely **1.)** Understanding the impact of cigarette ventilation on public health; **2.)** Studying consumer perception and responses; **3.)** Educating the public and preventing unintended consequences; **4.)** Gathering country data on brands and monitoring market trends; **5.)** Evaluating the effects of filter ventilation on smoke particle size distribution and the chemical profile of particles and reporting; **6.)** Further investigating the influence of cigarette ventilation on cigarette use; **7.)** Exploring the possible effects of other design features; **8.)** Evaluation of the health effects of cigarette ventilation; **9.)** Further industry manipulation of products, possible evasion of regulations and unintended consequences; and **10.)** Understanding the influence of filter ventilation on targeted groups.

Understanding the impact of cigarette ventilation on public health

- New knowledge must be gained to better understand the impact of banning filter ventilation on public health. This includes investigation of the impact of cigarettes that vary in ventilation on biomarkers of exposure at country level.

³ Including ban on menthol, flavours, slim cigarettes and 100mm length cigarettes (100s).

Studying consumer perception and responses

- Assessment of the contribution of cigarette ventilation on consumer appeal requires consideration independently of other modifications, such as pack design, from the scientific community and policymakers.
- More research evidence is necessary to better understand whether ventilation increases perceptions of smoothness and decreases risk perceptions in a dose-response manner, and to investigate and study consumer perceptions of ventilated and unventilated cigarettes, especially of adolescents.
- Consumers' responses and behaviours toward major changes in cigarette design, such as cigarette ventilation being introduced on a market-wide basis, should be considered, monitored and carefully managed. Therefore, mechanisms for post-market surveillance should be explored.

Educating the public and preventing unintended consequences

- There is a need to explore effective communication strategies, approaches and pathways that have the potential for wider outreach and to educate the public about the harms of ventilated cigarettes, to prevent unintended consequences.

Gathering country data on brands and monitoring market trends

- Gathering evidence on the prevalence and extent of filter ventilation among cigarettes in all countries, both as a function of the number of brands on the market and overall market share, is necessary to build country intelligence on ventilated cigarettes to guide policy action.
- In considering this, collection of data on filter ventilation based on the various brands and sub-brands available worldwide to assess the association between filtration and market share would be key.

Evaluating the effects of filter ventilation and reporting

- The effect of filter ventilation on smoke particle size distribution and the chemical profile of particles, as well as the effect of pressure drop on filter efficiency and filter ventilation, and their implications for machine emissions and smoker exposure, should be considered.
- Systematic collection of data on overall cigarette ventilation and its association with filter ventilation by brand and sub-brand, and the mechanisms for this, including reporting templates, is needed.

Further investigating the influence of cigarette ventilation on cigarette use

- Research is required in order to gather internal tobacco industry documents, which will help yield insights into cigarette manufacturers' efforts to enhance cigarette product appeal with design and the messaging of ventilation use.
- Studies that provide an association between filter ventilation, and transition from experimentation into regular use, should be explored and require urgent attention by regulators.
- Population-level analyses to understand the influence of filter ventilation on the prevalence of cigarette use are needed, and research that evaluates the use of vent-blocked cigarettes in the context of other tobacco and nicotine products, with a focus on the potential for switching, should be explored.
- There is a need to gather evidence on youth use of different ventilated products compared to adults.

Exploring the possible effects of other design features

- The effect of cigarette ventilation independent of other accompanying design changes, such as the use of additives, requires further research.
- The characterization of other filter design features such as physical dimensions, density, filter material, presence of other components, and their interaction with filter ventilation and effect on emissions must be studied.

Evaluation of the health effects of cigarette ventilation

- It is essential to consider the effect of ventilation on the development of dependence symptoms, especially among population sub-groups. The influence of filter ventilation on maintaining smoking behaviour, 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 these have the potential to support arguments against limiting or banning filter ventilation and, thus, further action on cigarette 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 will need to be carefully assessed through a number of ways, including review of available evidence, monitoring of industry activities, 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 put measures in place to minimise such communication.

Understanding the influence of filter ventilation on targeted groups

- The influence of varying filter ventilation on targeting new sub-groups of consumers, especially children and women, is needed, and epidemiological studies following the implementation of any bans or regulations would be essential to assess the effect on smokers.

5. Next steps

This report, which takes into consideration experts' deliberations, as well as the key findings of each of the commissioned papers, in pursuance of paragraph 8 of decision *FCTC/COP8(21)*, in which the Convention Secretariat was requested, "*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.*" will form the basis of the report to COP9.

The background papers will be revised by authors based on participating experts' comments and will go through a few rounds of reviews, following which they will be finalised and published as supplementary documentation for COP9, under the Convention Secretariat's website, and on the WHO website. It is expected that the papers will be published by November 2020, and there will be a reference to these papers in the COP9 report for readers interested in obtaining further details on each of the papers. Additionally, WHO will work with authors to further develop the papers, with a view to publishing them in peer-reviewed journals, in the 2nd Quarter of 2021. It is also expected that additional materials and/or publications, will be made available in comprehensible language and translated to the six official languages of the United Nations to raise awareness about the meeting outcomes and the key findings of the papers.

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

The Convention Secretariat and WHO will jointly prepare a high-level report of no more than four pages to COP9, which will highlight the key findings of the background papers in accordance with decision FCTC/COP8(21). This report will include the recommendations identified through the discussions of the group of experts, as well as other information considered relevant to the COP, based on the limitations of the current evidence, regulatory context in different countries, and anticipated and unanticipated consequences.

It is anticipated that the report will be ready by November 2020 and will feed into deliberations of the COP in response to paragraph 8 of decision FCTC/COP8(21) about the scientific findings on cigarette ventilation on cigarette use. This 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 sixty days before the Ninth session of the COP, with links to the background papers and relevant resources. Further, experts will be notified once the report is published.

Annex

Summaries of background papers

Paper 1: Introduction to cigarette ventilation and possible implications for public health (Nuan Ping Cheah and Dorothy Hatsukami)

Design features are one of the measures covered in the Partial Guidelines for implementation of Articles 9 and 10 of the World Health Organization Framework Convention on Tobacco Control (WHO FCTC). Ventilation holes around cigarette filters are one of the main features of cigarette product characteristics which contributes to the dilution of mainstream cigarette smoke, resulting in lower emissions of tar and nicotine as measured by machine determined methods. However, cigarette filter ventilation is a defective design feature, which has been promulgated by the tobacco industry's interest in maintaining tobacco use. This design feature makes the cigarettes "elastic", allowing cigarette smokers to compensate for the lower machine-determined nicotine and tar levels by smoking more intensely, or covering the ventilation holes as a means of achieving higher and more satisfying levels of nicotine, the addictive chemical in tobacco. Because of this alteration in smoking behaviour, smokers do not experience reductions in exposure to cigarette toxicants and carcinogens or in disease risk to the extent reflected by the reduction in tar yields. Furthermore, filter ventilation changes the chemical profiles and biological properties of tobacco smoke, which may in part, along with the greater intensity of smoking, contribute to the increased incidence of lung adenocarcinoma.

Despite these findings, smokers continue to misperceive the lower tar and nicotine yield cigarettes as safer than higher tar and nicotine cigarettes, primarily as a result of the deceptive marketing practices and package descriptors, and the milder and light taste of these cigarettes. This misperception contributes to cigarette appeal and uptake, and to continued smoking. Unfortunately, as countries achieve high income status, the market share of ventilated filter cigarettes also increases. These issues call for the following regulatory actions, particularly related to Articles 9 and 11 of the WHO FCTC:

- Requiring manufacturers to disclose and conducting country-specific surveillance on cigarette design features that are associated with reducing tar and nicotine yields based on machine determined yields.
- Expanding the reporting of mainstream cigarette smoke emissions to include shortlisted priority chemicals to regulatory authority based on smoking conditions where filter ventilation is unblocked (ISO) and 100% blocked (WHO Intense).

- Educating the public about the deceptions related to ventilated cigarettes and the possible increase in harm associated with this cigarette design feature.
- Introduce plain or standardized packaging. This measure will eliminate all descriptors, packaging, messaging and advertising that explicitly or implicitly indicate that these cigarettes are safer.
- Prohibiting all advertising that explicitly or implicitly depict ventilated filter cigarettes as healthier.
- Potentially prohibiting filter ventilation and other cigarette design features that allows cigarette elasticity.

Country level information on filter ventilation is limited. If a ban on filter ventilation were to be implemented, the following research would be important to conduct post-implementation:

- Assessing the impact of ventilation ban on initiation, maintenance, level of dependence and population prevalence.
- Monitoring the impact of filter ventilation ban on health outcomes, such as lung cancer and non-cancer endpoints.

Paper 2: Exploration of cigarette filter ventilation mechanisms, market availability, and prevalence of use (Richard J. O'Connor, PhD and Ron Borland, PhD)

Filter ventilation, the addition of holes to the tipping paper, is an unobtrusive and apparently simple technology that has complex effects on both smoke chemistry and smoking behaviour. Ventilation of cigarettes arose in response to the development of knowledge among the public of the health risks of smoking, and the subsequent governmental and industry efforts to respond to increasing public concern about those risks. It remains a highly important technology, even in countries which ceased yield testing and labelling over a decade ago. To increase the level of filter ventilation of cigarettes, engineers can increase the number of vents, increase the size of individual vents, alter their shape, and they can 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 come in through the vent holes at any particular flow rate. The tobacco industry rarely publicly acknowledges its existence and few tobacco control professionals currently pay much attention to it. The lack of interest from the tobacco control community is unfortunate, given that filter ventilation has a profound influence on smokers' beliefs and behaviours.

It was not until the mid-1990s that a consensus emerged among public health experts that the "low tar" program had failed its public health goals and needed to 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 available brands in high-income countries (for example, United States of America, Canada, United Kingdom of Great Britain and Northern Ireland, Australia) and a growing fraction of the market in low-middle income countries (such as the People's Republic of China). Such 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 United States, examining unit sales by 'tar'-group market share shows that much of the lost sales volume has come from the 'high-tar' (>15mg) category. The market for the lowest 'tar' groups has also collapsed since the 1990s. The late 1990s (and again between 2009-2011) showed a sharp decline in the >15 group, almost entirely paralleled by a rise in the 10-15 mg group. Given the strong inverse correlation between 'tar' and filter ventilation, a reasonable hypothesis to explain this is that a high-selling product(s) shifted downward in 'tar' level, likely by increasing ventilation. Laboratory testing of cigarettes across international markets is consistent with the hypothesis of an association between levels of filter ventilation and country income level.

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, evidence suggests that, despite initial declines in misperceptions when light/ mild descriptors were removed, beliefs that cigarettes with higher levels of filter ventilation were less harmful reasserted themselves over time.

Ventilation contributes to harms associated with cigarette smoking, yet many smokers are unaware of ventilation and its function, even when their own brands 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. Ventilation, as a technology, is not understood by consumers – indeed they are misled by it – and does not positively impact consumers’ health risks. Therefore, its use in commercial products should be banned. To lay the groundwork for such a regulation, governments should begin to monitor ventilation and other design features of cigarettes (porosity, tobacco weight, rod density, filter efficiency) that impact emissions. Such surveillance would provide a comparator for future product standards.

Paper 4: Effects of cigarette filter ventilation on machine-measured yields (Irina Stepanov and Peter Josa)

Cigarette ventilation is the airflow that enters various parts of the cigarette rod from directions other than the main axis, that is, the lighting end. It is expressed as the percent contribution of such airflow to the total flow exiting a cigarette's mouth-end. Cigarette ventilation dilutes the smoke exiting the mouth-end of the cigarette, and modifications to cigarette design features to increase its ventilation have been used by cigarette manufacturers to achieve substantial reductions in nicotine and other harmful emissions generated by smoking machines.

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

In addition to diluting the smoke, filter ventilation modifies the process of tobacco burning and smoke composition through:

- (i) reduction of the temperature of the coal;
- (ii) reduction in the amount of tobacco burned during each puff;
- (iii) increase in the number of puffs per cigarette;
- (iv) diffusion of some gas-phase components out of the tobacco rod;
- (v) reduction in the water content of the smoke particles;
- (vi) increased particle coagulation due to longer residence time of the smoke in the rod; and
- (vii) higher retention of smoke components by the filter.

Generally, the yields of smoke constituents measured at similar machine-smoking conditions are reduced somewhat proportionally to the filter ventilation level. However, there is a complex relationship between the degree of filter ventilation and the levels of harmful emissions measured by using different smoking regimens. Overall, higher ventilated cigarettes show more dramatic emission increases in response to increased smoking intensity. Therefore, using higher intensity smoking protocols, such as the WHO

TobLabNet, is more appropriate for the adequate assessment of smoke emissions. Furthermore, emissions normalized to nicotine yield are less affected by ventilation than per-cigarette measures and, therefore, should provide a more adequate chemical assessment of a cigarette brand.

Identified research gaps include the lack of systematic data on filter ventilation by brand and sub-brand worldwide; the 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 exposures in smokers; and lack of understanding of how other filter design features (physical dimensions, density, type of filter material, etc.) and other cigarette characteristics contributing to its ventilation interact with filter ventilation and affect smoke emissions.

The main proposed policy recommendation is to perform an impact assessment of banning filter ventilation. It is also recommended that the WHO/Canadian Intense smoking regimen is used for regulatory purposes, and that constituent yields are reported by manufacturers on per cigarette and per mg nicotine basis. Other recommendations are aimed to address the identified research gaps, such as systematic collection of data on filter and cigarette ventilation, and monitor 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 consumer appeal. Cigarettes are designed both to 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-level characteristics, and the way in which products are communicated and made available to consumers. These manipulations accomplish two related goals: i) enhancing the potential for the product to promote dependence (abuse liability); and ii) enhancing consumer's positive perceptions of the product. Both methods of enhancing appeal have the potential to influence smoking behaviour: higher abuse liability is linked with more rapid initiation of dependence, greater severity of dependence and greater difficulty quitting, while certain positive attitudes or perceptions are held by several well-supported theories to increase the likelihood of the occurrence of related behaviours, including smoking.

Filter ventilation may influence product appeal, 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 provided evidence on the influence of filter ventilation on multiple constructs that comprise cigarette product appeal and product use.

Data showed that filter ventilation dilutes the smoke available to the smoker, and is perceived as smoother, less harsh and less irritating than smoke delivered from non-ventilated cigarettes. As such, filter ventilation facilitates inhalation of smoke, and results in the misconception that such cigarettes are less harmful. The evidence suggests that by modifying the sensory experience of smoking, filter ventilation plays a role in shaping perceptions of smoking risk and increasing consumer preferences for ventilated brands. Ventilation may enhance abuse liability by encouraging intensive puffing, thereby increasing nicotine delivery. There were insufficient data 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 has the potential to promote cigarette uptake, sustain use, and lower cessation rates. Further research is needed to understand whether ventilation influences the prevalence of cigarette use through 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 the use of 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, MD and Ghazi Zaatari, MD)

Paradoxically, the lung cancer risk of smoking cigarettes has progressively increased while overall smoking-related disease has decreased in parallel with reduction in smoking rates. Specifically, the histopathological types of lung cancer have shifted over the last 60 years, where now lung adenocarcinomas are the most common, and this is linked to changes in cigarette design that have occurred during the last half of the century. The implication is that cigarette design, smoking behaviour, and smoke toxicant exposure have changed historically to increase lung adenocarcinoma risk. Several lines of evidence have identified two changes in cigarette designs over time, namely:

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

The public health community, considering dose-response relationships, advocated for methods to reduce smoking machine tar yields (total particulate matter not including volatile compounds), and cigarette filter ventilation was widely adopted by the cigarette manufacturers. However, there have been several adverse unintended consequences of filter ventilation consistently demonstrating either worse or no beneficial impacts. For worsening effects, filter ventilation changes how a cigarette burns, allowing for delivery of a greater volume of smoke and subsequently higher amount of tobacco toxicants. Filter ventilation also allows for elasticity of smoking, so that smokers smoke more (compensation) to obtain satisfying nicotine blood levels, irrespective of the stated smoking machine yields. The uptake of higher amount of smoke and toxicants, including tobacco specific nitrosamines, and smoke volatile organic compounds will ultimately reach deeper and more peripheral portions of the lungs to damage the types of cells that develop into adenocarcinomas.

Human switching studies from lesser to higher ventilated cigarettes do not show, at least, any reduction in toxicants by increased ventilation. This, plus smoker perception studies, indicate that there is no public health benefit for cigarette filter ventilation. This report and others conclude that there is highly suggestive evidence that the worsening of lung cancer risk and increased lung adenocarcinomas are due to, at least in part, increased cigarette filter ventilation. Thus, this is modifiable cigarette design feature of public health benefit.

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

Paper 7: Regulatory considerations of policy measures for ventilated cigarettes and policy implications (Dr David Ashley and Micah Berman)

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

To date, no countries have attempted to enact regulation of cigarette ventilation. Uruguay has taken regulatory action to allow only a single representation of each brand, limiting different ventilation levels within brand families, but this does not limit the range of ventilation levels across the market, as a whole. Several countries have authority to put regulations in place, but regulation of tip ventilation has not been enacted to date. Other 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 delivery of TNCO using an appropriate smoking regimen.

To date, successful attempts to address the design (ingredients, additives, contents, design features) of tobacco products have been aimed at reducing youth appeal and not reducing toxicity. While this has been primarily aimed at flavours, this approach could be applied to other properties, such as ventilation, which increases product appeal to naive users, especially youth. An additional approach may be preventing manufacturers from deceiving consumers about their products.

Before countries take action to limit or prohibit cigarette ventilation, countries should have the authority to regulate product design or emissions and regulate based on appeal or attractiveness. They should have systems in place to assess manufacturer's compliance, require testing, define the testing protocol and evaluate both anticipated and unanticipated outcomes. Countries need to be prepared to address the introduction of illicit products into their market. Countries should be fully equipped and prepared to carry out these actions effectively in order to maximize benefits and reduce unintended consequences.

Actions taken 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 will include delaying tactics, development of contradictory science, lobbying of decision-makers, and lawsuits. Countries should be prepared for a prolonged battle with companies; success will require sufficient continual effort.

Regulatory action should focus on youth appeal and ease of initiation and ensure that other product changes that could counter the effect of the regulation are not permitted. Countries are encouraged to engage experts who can help guide them through all stages of enacting and enforcing regulations before undertaking actions to limit cigarette tip ventilation. It would be most helpful for countries who have advanced regulatory measures to adopt a ventilation standard and carefully evaluate the outcome. This would provide evidence upon which other countries could base similar actions.