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David Hammond, Friedrich Wiebel, Lynn T Kozlowski, Ron Borland, K Michael Cummings, Richard J O'Connor, Ann McNeill, Greg N Connolly, Deborah Arnott and Geoffrey T Fong

*Tob. Control* 2007;16:8-14  
doi:10.1136/tc.2005.015297

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## REVIEW

# Revising the machine smoking regime for cigarette emissions: implications for tobacco control policy

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*Tobacco Control* 2007;16:8–14. doi: 10.1136/tc.2005.015297

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Received 1 December 2005  
Accepted 17 August 2006

**Background:** The WHO Framework Convention on Tobacco Control includes provisions for testing and regulating cigarette emissions. However, the current international standard for generating cigarette emissions—the ISO machine smoking regime—is widely acknowledged to be inappropriate for purposes of setting regulatory restrictions.

**Objective:** To review alternatives to the ISO machine smoking regime and the extent to which they: 1) Represent human smoking behaviour, 2) Reduce the potential for industry exploitation, particularly in the area of risk communication, and 3) Serve as suitable measures for product regulation.

**Methods:** Emissions data from 238 Canadian cigarette brands tested under the ISO and “Canadian Intense” machine smoking regimes.

**Results:** None of the alternative smoking regimes, including the Canadian Intense method, are more “representative” of human smoking behaviour and none provide better predictors of human exposure.

**Conclusions:** Given that alternatives such as the Canadian Intense regime are subject to the same fundamental limitations as the ISO regime, key questions need to be addressed before any smoking regime should be used to set regulatory limits on smoke emissions. In the meantime, regulators should remove quantitative emission values from cigarette packages and more work should be done on alternative machine smoking methods.

The issue of how to test and regulate conventional cigarettes represents a critical challenge for tobacco control. To date, the primary means of testing cigarette toxicity has been to machine smoke the cigarettes according to a standard puffing regime and to measure the chemical emissions in the mainstream smoke. In many jurisdictions, these cigarette “yields” are printed on packages and represent the only source of information on constituents or toxicity available to consumers. Cigarette emissions also serve as a regulatory standard in several of jurisdictions, including the European Union, where brands that generate emissions >10 mg of tar, 1 mg of nicotine or 10 ppm of carbon monoxide are prohibited.

The puffing regime used to machine smoke the cigarettes—the International Organization for Standardization (ISO) regime<sup>1</sup>—is widely recognised to be inadequate for the purposes of product regulation or consumer information. The ISO regime constitutes a set of puffing parameters that systematically underestimate smoking behaviour in humans.<sup>2–4</sup> Tobacco manufacturers have also designed cigarette brands to perform one way under the machine smoking conditions, but to deliver much greater smoke constituents to humans.<sup>5–6</sup> As a result, the emissions generated under the ISO smoking regime have little relationship with actual measures of human exposure, and exaggerate the differences between brands in a manner that has proved deceptive to both consumers and regulators.<sup>7–9</sup> Overall, the emissions from the ISO regime have served as more of an industry marketing tool to falsely reassure health-concerned smokers, rather than as a valid measure of cigarette toxicity.<sup>2 10–12</sup>

There is a growing movement to develop a more meaningful machine testing method. The World Health Organization's Framework Convention on Tobacco Control (FCTC)—the world's first international public health treaty—includes provisions for testing and regulating cigarette emissions under

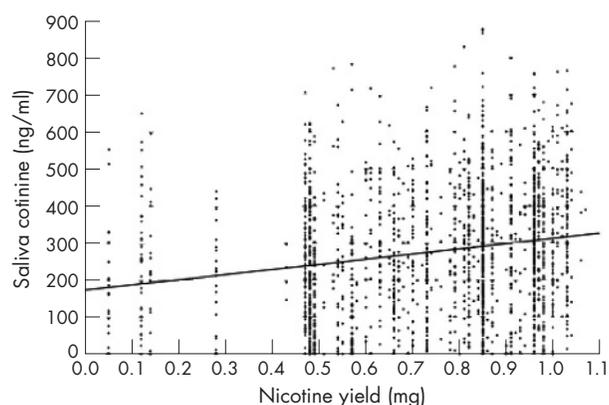
Article 9.<sup>13</sup> These provisions will need to be specified now that the FCTC has come into force. After discussions with the WHO, the ISO convened a working group (ISO TC 126 WG9) to develop recommendations for “...a robust and practical smoking regime that as far as possible is representative of smokers' behaviour”. Meanwhile, the World Health Organization's Study Group on Tobacco Product Regulations (WHO TobReg) has developed its own set of recommendations, which were under consideration by the ISO Working Group.<sup>14</sup> There are also concerns that the ISO committee structure responsible for setting tobacco standards is dominated by the tobacco industry.<sup>12</sup>

Before any new testing regime is implemented, it is critical to ensure that the new standards will serve the interests of public health rather than the tobacco industry. The purpose of this paper is to review the smoking regimes that are under consideration by the ISO Working Group, and to examine the implications for tobacco control policy and product regulation. In particular, we examine the extent to which the proposed regimes will: (1) succeed in “representing” smoking behaviour in humans and generate better predictors of human exposure; (2) reduce the potential for industry exploitation, particularly in the field of risk communication; and (3) help to establish more effective regulatory limits on cigarette toxicity.

## SMOKING BEHAVIOUR IN HUMANS

The ISO Working Group seeks to make the machine smoking regimen more representative of smoking behaviour in humans. This will undoubtedly involve a more intensive set of puffing

**Abbreviations:** FCTC, Framework Convention on Tobacco Control; ISO, International Organization for Standardization; NNK, 4(methylnitrosamino)-1-(3-pyridyl)-1-butanone; WHO TobReg, World Health Organization's Study Group on Tobacco Product Regulations



**Figure 1** Population-based estimates of nicotine uptake versus International Organization for Standardization (ISO) nicotine yield.<sup>7</sup>

parameters than the current ISO regime. However, to adequately represent smoking behaviour in humans, the new regime must not simply be more intense; it must also reflect compensatory smoking, a fundamental aspect of smoking behaviour in humans.<sup>10</sup>

Smoking behaviour in humans is primarily driven by nicotine. People smoke to achieve a particular nicotine dose and will adjust their smoking behaviour to maintain this dose across products.<sup>15 16</sup> Therefore, smokers increase the number and intensity of their puffs when switching to a brand that generates a lower nicotine emission under the ISO machine smoking conditions.<sup>17–19</sup>

Figure 1 shows the considerable individual variation in nicotine intake among smokers, as published by Jarvis *et al.*<sup>7</sup> Some people are simply lighter smokers and pursue lower levels of nicotine, whereas others who smoke the same brand have higher nicotine needs and either smoke a greater number of cigarettes or smoke each cigarette more intensely.

No single standard smoking machine test can reflect the individual variation in nicotine uptake among smokers. Most brands recruit a heterogeneous group of smokers with different nicotine uptakes to the extent that the average nicotine uptake is similar across brands. Indeed, there are no marked differences in nicotine uptake across brands at the population level: individuals who smoke a lower ISO emission product have similar nicotine uptake as those who smoke higher-emission products.<sup>7 8</sup>

To achieve similar nicotine uptake across brands, some brands need to be smoked more intensely than others. This is true for an individual smoker when switching brands, as well as at the population level when comparing smokers of different brands.

A recent review of smoking topography among people smoking their usual brands found that brands with lower ISO tar emissions were smoked more intensely than brands with higher ISO tar emissions.<sup>4</sup> In other words, there are systematic differences in how certain brand designs are smoked by consumers.

Overall, there are few differences in human uptake either between smokers using different brands or within a smoker when switching products. Ultimately, it is the smoker who determines the delivery of a product and the product that determines the puffing behaviour necessary to achieve that delivery.

For cigarette emissions to have any association with population levels of human exposure, machine smoking regimes must reflect the systematic differences in puffing behaviour across products. Unlike humans, the ISO regime

**Table 1** International Organization for Standardization smoking regime and potential alternatives

Smoking regime <sup>a</sup>	Puff volume (ml)	Puff frequency (s)	Filter blockage (%)	Flow rate (ml/s)
ISO	35	60	0	17.5
Option A	55	30	50	27.5
Option B	60	30	50	30
Option C	45	30	100	22.5
Option D	55	30	100	27.5

<sup>a</sup>All options include International Organization for Standardization (ISO) puff durations (2 s) and butt length (filter+8 mm).

smokes all brands using the same puffing profile regardless of their product design. As a result, highly ventilated brands—which are smoked more intensely by humans—generate much lower emissions under machine testing. This creates a misleading ranking of brands that is an artefact of the smoking machine and is not a reflection of the actual smoking behaviour of humans. Indeed, the ISO regime operates on principles that are opposite to those of smoking behaviour in humans: whereas human puffing varies across brands and nicotine uptake is kept relatively constant, the ISO smoking regime holds puffing constant across brands and produces variable nicotine emissions.

## PROPOSED ALTERNATIVES TO THE ISO SMOKING REGIME

The ISO Working Group considered four alternative smoking regimes, all of which can be characterised as more intensive variants of the current ISO standard (table 1).

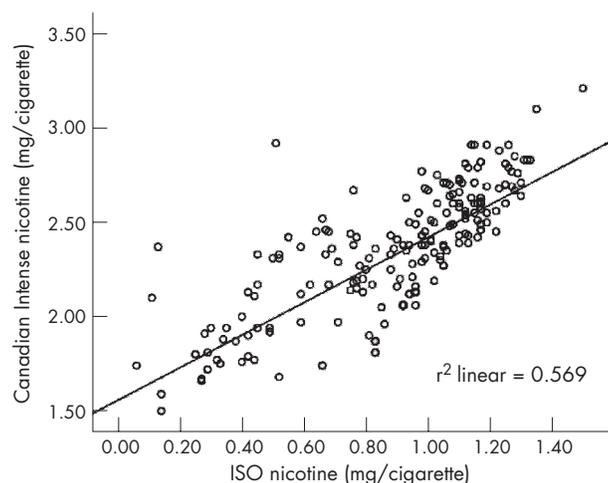
The WHO TobReg committee has endorsed Option D, on the grounds that it comes closest to representing the “maximum exposure level to which an ordinary smoker could reasonably be expected to be subject when smoking...”.<sup>14</sup> Option D has already been implemented in Canada<sup>20</sup> and is typically referred to as the “Canadian regime”.<sup>1</sup>

Figure 2 shows the nicotine yields for 238 Canadian brands tested under the Canadian Intense regime, compared with ISO nicotine yields for the same brands.<sup>22</sup> On average, the nicotine emissions more than double under the Canadian regime (ISO mean 0.9 v Canadian mean 2.3 mg,  $p < 0.001$ ), whereas tar emissions (not shown) almost triple (ISO mean 10.7 v Canadian mean 30.5 mg,  $p < 0.001$ ).

Figure 2 illustrates the high correlation between the nicotine emissions generated by the Canadian brands and the nicotine emissions generated by the ISO regime ( $r = 0.75$ ,  $p < 0.001$ ). However, the range of nicotine emissions under the Canadian Intense regime is proportionally less than the range produced under the ISO regime: there is a twofold difference between the highest and lowest nicotine emissions under the Canadian regime, compared with a 15-fold difference in the ISO nicotine emissions.

A recent study examined the extent to which nicotine emissions from the ISO regime and the Canadian regime were associated with nicotine uptake among a sample of Canadian smokers. Neither set of nicotine emissions was markedly related to salivary cotinine, a reliable measure of nicotine uptake; in fact, the correlation coefficient between nicotine

<sup>1</sup>Although the Canadian regime has been called a “maximum” smoking regime, it is not. Rather, the puffing parameters for the Canadian regime (55 ml puffs drawn every 30 s) are closer to mean human puffing parameters, even for low-ventilated brands. For example, a recent study of Canadian smokers recorded an average of 52 ml puffs for the three most popular brands, all of which were low-ventilated brands (mean ventilation = 5%,  $n = 17$ ).<sup>21</sup>



**Figure 2** Canadian versus International Organization for Standardization (ISO) nicotine emissions from 238 Canadian brands.

uptake and the Canadian nicotine emissions (part  $r=0.16$ ,  $p>0.05$ ) was even lower than the correlation for the ISO nicotine emissions (part  $r=0.24$ ,  $p>0.05$ ). In short, the emissions from the Canadian regime are no more related to human uptake than are the ISO emissions.<sup>22</sup>

The other three smoking regimes proposed in table 1 have yet to be evaluated by scientists independently of the tobacco industry. Although we currently lack the data to examine these regimes in detail, data from the Canadian and Massachusetts regimes (45-ml puff volumes, 30-s puff frequencies and 50% vent blocking)<sup>23</sup> suggest that each of the three alternative methods will have a similar, though more modest effect on emissions than the Canadian Intense regime, owing to less intensive puffing parameters or the reduced filter ventilation blocking. Although each of the testing regimes will help to “characterise” how a product performs under a given set of smoking conditions, none of the smoking regimes “represent” human behaviour in terms of compensatory smoking and none is likely to produce emissions that will be markedly associated with human exposure or risk, either for individual smokers or for population-level differences between brands.

### CIGARETTE EMISSIONS AS REGULATORY LIMITS

The Canadian smoking regime was not developed to represent smoking behaviour in humans. Rather, it was designed to generate emissions under a more intensive set of smoking parameters that would provide a “maximum” exposure limit that could be exceeded by very few smokers. Consistent with this rationale, the WHO TobReg has proposed using the emissions from the Canadian method as a standard metric from which “upper limits” on emissions could be set. To ensure that the emission reductions are technically feasible, the WHO TobReg recommends using the range of emissions from brands already on the market to set limits (eg, brands with 4(methylnitrosamino)-1-(3-pyridyl)-1-butanone (NNK):nicotine levels above the mean for a particular market would be prohibited).

The concept of an intensive testing regime is intuitively appealing because it minimises the likelihood that the machine emissions will underestimate human exposure. This approach also avoids the impossible task of trying to predict individual levels of exposure using machine testing methods. Nevertheless, as shown above, “intensive” regimes produce differences in emissions that are an artefact of the testing regime and are not associated with smoking in humans.

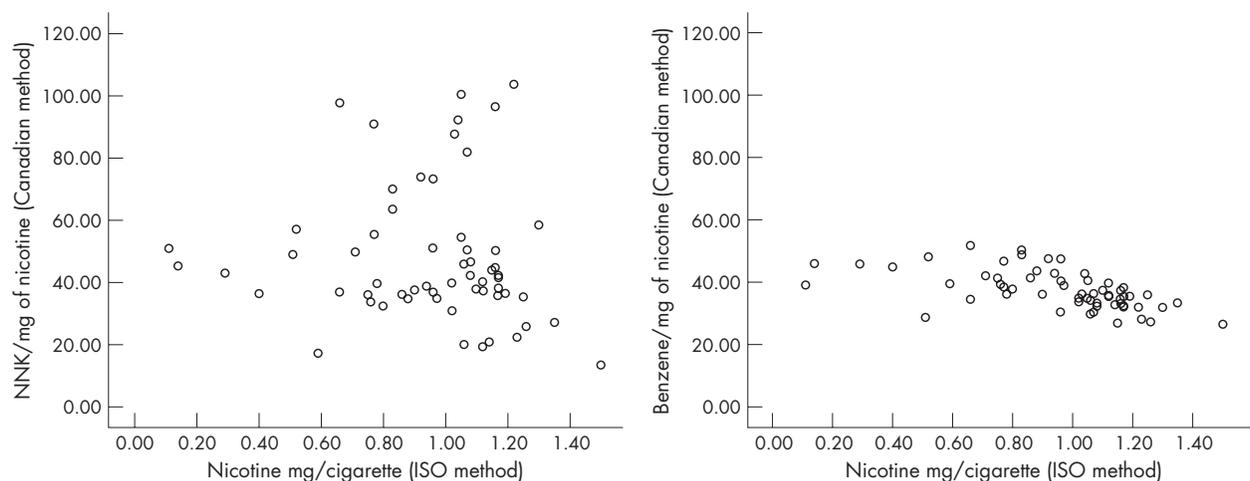
Therefore, the different “maximum” values generated under the Canadian method do not represent differences in the “maximum” values of human use.

One strategy for addressing compensatory smoking and, presumably, for making cigarette emissions more relevant to human behaviour is to classify cigarettes on the basis of their smoke toxin:nicotine ratios.<sup>24, 25</sup> For example, rather than setting a limit on the absolute emission of potent lung carcinogens such as NNK, limits would instead be set on the NNK level/mg of nicotine. If smokers “titrate” for nicotine, then brands with lower toxin:nicotine ratios may deliver fewer toxic constituents to smokers as they seek to reach their nicotine dose.

The use of toxin:nicotine ratios appears to be gaining momentum as a potential regulatory strategy.<sup>14</sup> This would represent an improvement on the use of cigarette emissions as a measure of exposure, but only if the toxin:nicotine ratios remained constant across the range of nicotine emissions. However, as Kozlowski and O’Connor<sup>10</sup> have previously noted, toxin:nicotine ratios are not fixed, but change in response to smoking conditions.<sup>26</sup> Toxin:nicotine ratios can also obscure important differences in the absolute value or “mass” of nicotine and other smoke constituents. For example, the Canadian regime generates nicotine emissions that range from 1.5 to 3.2 mg for Canadian brands. Therefore, under the Canadian regime, the NNK:nicotine ratios are based on nicotine emissions as low as 1.5 mg for some brands and as high as 3.2 mg for others. To compare NNK ratios from similar doses of nicotine—that is, to ensure that the denominator in the NNK:nicotine ratio is constant across brands—some brands would need to be smoked more intensively than others. Doing so will change the NNK:nicotine ratio in many cases. For example, compared with the ISO regime, the NNK:nicotine ratios of Canadian brands tested under the Canadian method decrease by as much as 29% for some brands and increase by as much as 63% for others.<sup>22</sup> In fact, the NNK:nicotine ratio has been shown to change by as much as 240% across smoking regimes for some international brands.<sup>27</sup> Thus, the toxin:nicotine ratios generated under the Canadian Intense regime do not necessarily reflect differences between brands when used by consumers. If nicotine emissions in machine smoking are equalised in the same way as smokers do, the nicotine ratios would change considerably.

In a sense, the differences between the machine emissions and uptake among populations of human smokers—which for nicotine is essentially constant across brands—can be considered a type of measurement error. The Canadian Intense regime does little to reduce this measurement error relative to the existing ISO regime. This may not be terribly important if the differences between brands for a particular emission are sufficiently large. For example, NNK:nicotine levels show more than a 10-fold difference across brands in different markets, and a sixfold difference within the Canadian market (fig 2).<sup>28</sup> The differences in NNK:nicotine are sufficiently large that a 10-fold difference cannot be attributed simply to how cigarettes perform under a set of machine smoking conditions and is likely to have implications for human exposure.

However, few emissions show the same variability as NNK. For example, as fig 3 shows, the levels of benzene/mg of nicotine exhibit only a twofold difference between the lowest and highest levels among Canadian brands. This presents a challenge for setting upper limits on emissions: as the range of toxin:nicotine ratios decreases, so too does the difference between brands that would fall above an emission limit and be prohibited, and those that would remain on the market. The distinction between brands becomes smaller and the “measurement error” of the machine testing regime becomes more



**Figure 3** Levels of toxins/mg of nicotine among Canadian cigarette brands: 4(methylnitrosamino)-1-(3-pyridyl)-1-butanone (NNK) and benzene (n=89).

prominent. In other words, it is unclear whether these smaller differences have any relationship with smoking behaviour in humans or whether they are simply artefacts of how cigarettes are smoked under machine conditions.

In addition, not all constituents change to the same extent or even in the same direction under different testing regimes—for example, the NNK and benzo[a]pyrene:nicotine ratios decrease under more intense puffing conditions, whereas the nicotine ratio for carbon monoxide increases, as does the overall tar:nicotine ratio.<sup>22</sup> It is unclear to what extent certain emissions can be reduced independently of others.

Manufacturers have also shown their skill in substantially reducing machine emission levels through subtle design changes. Recent evidence from the UK suggests that tobacco manufacturers have adhered to the “10–1–10” limits on ISO emissions simply by increasing the level of filter ventilation so that brands provide deceptively low readings under machine conditions.<sup>29</sup> Filter ventilation is the most prominent, but by no means the only design change available to manipulate yields.

An additional concern about the use of toxin:nicotine ratios is that current proposals fail to take into account the proportion of unprotonated or “free” nicotine. Total nicotine, as measured on the Cambridge filter pad after machine smoking, contains both monoprotonated and “free” nicotine. The proportion of “free” nicotine affects the sensory perceptions of a product (eg, “impact”) as well as the location and rate of nicotine absorption.<sup>30–31</sup> Thus, regulatory limits for toxin:nicotine ratios that fail to take into account the proportion of “free” nicotine may be missing a key element underlying compensatory smoking behaviour.

### BUILDING THE EVIDENCE BASE FOR PRODUCT REGULATION

We consider product regulation to be an important aspect of tobacco control, and reducing cigarette emissions may have a role in this process. However, the existing evidence base must be broadened in three critical fields to direct regulatory strategy and to evaluate the public health potential of these initiatives. Firstly, machine emissions should be considered within the context of biomarkers of human exposure. Unless some consistent relationship can be established between emission standards and levels of exposure (as indicated by biomarkers), emission limits are unlikely to reduce risk. In some cases, biomarker studies can be conducted before regulatory limits are introduced to help identify the magnitude of reductions in machine smoked emissions that are necessary to bring about

reductions in human uptake. For example, if regulators wish to place a limit on NNK:nicotine ratios using existing brands on the market, differences in NNK uptake could be examined within an individual after a switch from a “high” to a “low” NNK:nicotine product. Unless the NNK biomarker (NNAL) is considerably lower when brands below the NNK:nicotine limit are smoked, there is no evidence that the regulatory limit will reduce NNK exposure among humans. One important consideration for this research will be to establish what constitutes a “meaningful” reduction in human exposure.

Secondly, information on the “physical” design parameters of products must be collected, as recommended by the WHO TobReg.<sup>14</sup> Cigarette emissions are most meaningful when considered within the context of these design parameters, which can be manipulated in various ways to alter machine emission levels. For example, filter ventilation is almost perfectly correlated with ISO levels of tar and nicotine.<sup>32–33</sup> ISO standards already exist for several design parameters, including filter ventilation, filter efficiency, draw resistance and paper porosity.<sup>34</sup> Public health regulators should implement mandatory reporting requirements for these physical design parameters to better understand the interaction between product design and smoke constituents, as well as to evaluate how regulatory limits may drive changes in brand design.

Thirdly, patterns of use must be examined to understand the interaction between product design and smoking behaviour in humans, and to identify systematic differences across products. Products that deliver fewer toxins for a fixed volume of smoke and also promote greater smoke intake when used by consumers are not lower-risk products. Likewise, products that deliver higher amounts of toxins, but discourage repeated use might potentially be seen as harm reducing compared with conventional cigarettes. Measures of realistic puffing behaviour and inhalation patterns are, therefore, important for understanding different chemical and biological profiles associated with products.

More generally, the public health community must find a way to develop evidence-based product regulation without setting the evidentiary threshold so high that it acts as a barrier to action. Fortunately, the types of research outlined above are well within the capacity of public health scientists. The tobacco industry can also have an important role in developing this evidence base. Although independent research in these fields is critical, manufacturers should be required to report product information, including emissions, contents, physical design parameters and patterns of use as a condition for selling their

products. Manufacturers are already collecting these data for their own product development and testing purposes (eg, the Philip Morris "total exposure study"<sup>35</sup>), and should be required to make these data public. Canada has already implemented a range of reporting requirements—including reporting of industry research activities—that may serve as a model for other jurisdictions.<sup>36</sup>

### ALTERNATIVE MACHINE SMOKING REGIMES: COMPENSATORY REGIMES

As outlined above, the fundamental limitation of the current ISO testing regime and the regimes under consideration by the ISO Working Group is that they are inconsistent with smoking in humans. In our view, if machine smoking regimes are to be more representative of smoking behaviour in humans, they must overcome this deficiency. The first attempt in this direction has been made by Kozlowski and O'Connor,<sup>10</sup> who recommended adjusting the smoking regime so that brands with lower ISO nicotine emissions are smoked more intensely. For example, with each 0.1 mg decrease in ISO nicotine emission, the puff volume and puff frequency would increase by a set amount in a subsequent round of machine testing. A smoking regime of this type would avoid most of the biases caused by regimes operating with a fixed set of puffing parameters.

Recently, a variation on this model has been proposed, which strives to mimic patterns of human smoking to a greater extent.<sup>ii</sup> Under this regime, the puffing parameters of the smoking machine are set to reach a fixed nicotine "target". In other words, different brands would be machine smoked to generate the same nicotine emission, within a narrow level of tolerance. Thus, each product would have a tailored set of puffing parameters required to achieve this emission.<sup>iii</sup>

This is generally consistent with smoking behaviour in humans, where the smoker determines the nicotine delivery, maintains this delivery across products, and it is the product that determines the puffing behaviour necessary to achieve this delivery. This compensatory regime would produce toxin:nicotine ratios that could be compared across brands without bias for certain designs, and may therefore be more suitable for establishing regulatory limits.

Compensatory regimes also need to address the fact that toxin:nicotine ratios may vary under different smoking intensities.<sup>10</sup> Thus, brands should be tested from time to time, if not routinely, at multiple nicotine targets representing the range of smoking intensity in humans. Testing brands at both a "high" and a "low" nicotine target would allow regulators to detect shifts in toxin:nicotine ratios and to control for them. There is a need to test this alternative regime to determine its feasibility.

### CONSUMER INFORMATION

After nearly 40 years—and after great cost to public health—the public health community is now coming around to the realisation that lower ISO emission cigarettes are not lower-risk products. Unfortunately, many regulators fail to understand the distinction between "product characterisation" and predicting

<sup>ii</sup>Wiebel FJ, Kozlowski L, Hammond D, et al. A novel machine smoking regime for establishing regulatory limits of toxic smoke constituents. World Conference on Tobacco or Health; 13–17 July 2006, Washington DC.

<sup>iii</sup>The different smoking parameters—puff volume, frequency, duration and filter blockage—can be combined in several ways to achieve the same nicotine yield. These machine parameters would, therefore, need to be varied in a systematic way across brands to reach the nicotine "target". For example, to reach the nicotine target, puff frequencies might be varied by intervals of 4 s and puff volumes by 5 ml, keeping ventilation blocking and puff duration constant.

human exposure. At the same time as they insist that cigarette emissions are not measures of risk, various regulators continue to use cigarette emissions in ways that assume a link between the machine emissions and human exposure.<sup>39</sup> Many jurisdictions continue to require that quantitative levels of tar, nicotine and carbon monoxide appear on packages. These numbers continue to be misunderstood and misused by smokers, including smokers in the most affluent and highly educated countries in the world.<sup>2</sup> To date, there is no evidence that quantitative emissions constitute effective consumer information, and several scientific bodies have rightly called for the removal of these emissions from packages.<sup>14 38</sup> In our view, continuing to print emissions on cigarette packages would contravene the spirit of Article 11 of the FCTC, which states that tobacco packaging and labelling "...shall not promote a tobacco product by any means that are ... misleading, deceptive or likely to create an erroneous impression about its characteristics, health effects, hazards or emissions".<sup>13</sup>

For routine consumer information, non-numerical descriptive information on smoke constituents should appear on packages, as is already the case in Brazil, Venezuela and Australia. It is critical to evaluate such descriptive-based approaches, as well as other means of communicating constituent information to smokers. In addition, the tobacco industry should be prohibited from using machine emissions in any of its labelling, advertising or marketing directed at consumers, even if accompanied by "warnings" or disclaimers, such as those that currently appear in the US and Europe.<sup>39</sup>

A change in smoking regimes does not justify a change in this position. The ISO emissions numbers are not deceptive to consumers simply because they are too low, but because they exaggerate the differences between brands. Each of the proposed regimes, including the Canadian regime, will produce a range of emissions that will be equally susceptible to exploitation by the tobacco industry and misunderstanding by the consumer. Simply changing the metric of cigarette emissions provides little insurance against the likelihood that consumers will interpret "lower-emission" brands as lower risk.

### CONCLUSIONS

The current ISO testing regime is an inappropriate standard for evaluating cigarette toxicity and setting regulatory restrictions on cigarettes. All four of the alternatives by ISO TC 126 WG9 have the same fundamental limitations as the existing ISO regime: they continue to generate emissions in ways that are inconsistent with smoking behaviour in humans.

The ISO Working Group has now completed its work and the larger ISO TC 126 committee recently agreed to delay final voting on a new regime until recommendations for Article 9 of the FCTC are developed. The onus is now on the public health community to determine the most appropriate method for emission testing. As only a progress report is planned for the second FCTC conference of the Parties in 2007, guidelines for machine testing may not be put forward until 2008, at the earliest. This timeline provides a window for the public health community to consider alternatives to the Canadian Intense regime that may provide a better basis for setting regulatory limits.

The question remains whether emissions from any machine testing regime can serve as an effective regulatory standard. The "precautionary principle" suggests that the level of toxic emissions in cigarette smoke should be reduced to the extent possible, regardless of whether a public health benefit can be demonstrated. Yet, the benefits of emission regulations need to be weighed against the broader opportunity costs. Emission limits will require considerable resources to implement and

monitor, resources that may exceed the current capacity of regulators. There are also concerns that emission limits would exempt tobacco manufacturers from liability. Most important, it is uncertain how consumers will respond to emission regulation. Despite clear scientific statements to the contrary, consumers may interpret emission limits as an indication that cigarettes are less harmful—much in the same way that they have interpreted emission reductions in the past.<sup>2</sup> In fact, future emission limits may be even more likely to undermine perceptions of risk than in the past: “new” emission reductions would be based on a “superior” machine method, would be more comprehensive in scope, and may have the formal endorsement of the World Health Organization through the FCTC. One can also envision how manufacturers might shape consumer response through packaging and marketing. Overall, regulations that achieve modest reductions in smoke toxicity but result in fewer quitters or more initiators are not effective policy measures.

None of these opportunity costs argue against regulating tobacco products. However, they do suggest that the minimum threshold for intervening may be greater than the precautionary principle alone.

Key questions need to be addressed to evaluate whether emission limits meet this threshold and are appropriate for an FCTC standard. How many emissions will be targeted? Limits that only apply to only a few toxic constituents in tobacco smoke have little chance of reducing a product’s risk. However, regulating a long list of emissions increases the complexity and cost of implementing the standards. Will emission limits be progressively lowered over time? If so, what is the ultimate end point? Most within the public health community would argue that there are no meaningful differences in risk between conventional cigarette brands to begin with. So long as this is the case, there is little or no point in making distinctions between brands that are already on the market. In the end, only limits that reduce the emissions well below current market standards or interfere with the palatability of cigarettes (including the draw “mechanics” of product) have the potential for significant public health benefit.<sup>41</sup> Therefore, emission limits may be effective only when used as “blunt” regulatory tools for mandating substantial changes across all products. Finally, how should the recent findings on free nicotine be incorporated into emission limits that express toxins per mg of nicotine? If the proportion of “free” nicotine is not fixed, perhaps free nicotine should serve as a separate denominator.

As regulatory proposals for reducing emissions evolve, regulators can take immediate and meaningful action in several related areas. We strongly endorse the need to make information on cigarette emissions public to advance the evidence base for effective product regulation; however, this is not to say that quantitative emissions should be communicated directly to consumers. Emission numbers should be removed from packages in jurisdictions where they are currently required and limitations on the use of quantitative emissions should be established before any new smoking regime is adopted. Regulators can also implement comprehensive reporting standards, which would require manufacturers to report physical design parameters and measures of human exposure. We would also encourage regulators to mandate more specific reporting standards for smoke emissions. “Tar” is not a homogeneous substance, and its use as a measure of toxicity obscures critical differences in the amount and importance of individual chemicals in tobacco smoke. Manufacturers should be required to report individual smoke constituents, including “free” nicotine, and known classes of carcinogens such as, but not limited to, tobacco-specific nitrosamines and polynuclear aromatic hydrocarbons. Canada has already introduced

## What this paper adds

The Framework Convention on Tobacco Control includes provisions for testing and regulating cigarette emissions. However, the current international standards for generating cigarette emissions—the ISO machine smoking regime—is widely acknowledged to be an inappropriate method for setting regulatory restrictions. This paper reviews the alternative smoking regimes that were considered by the ISO Working Group WG9 and the World Health Organization, and examines the implications for tobacco control policy and product regulation. In particular, we examine the extent to which the proposed regimes will:

- succeed in “representing” smoking behaviour in humans and generate better predictors of human exposure
- reduce the potential for industry exploitation, particularly in the field of risk communication
- help to establish more effective regulatory limits on cigarette toxicity

comprehensive reporting requirements for cigarette emissions that may serve as a template for other jurisdictions.<sup>14</sup>

Finally, we would urge international agencies to consider a framework for establishing an independent product testing and monitoring laboratory. We strongly support the development of the WHO Tobacco Laboratory Network, but with the addition of an international independent laboratory that could oversee this work.<sup>42</sup> This independent laboratory should be charged with collecting and archiving tobacco products, conducting routine product testing and maintaining a database of product-related information from cigarette manufacturers. A license fee charged to cigarette manufacturers could finance the operations of this laboratory. We would urge the WHO to also consider the appropriate structure for managing the data and making it publicly available to the scientific community. Such a framework would help scientists to incorporate product information into studies of human exposure, as well as to help regulators draw comparisons between brands in different markets. This data repository would be particularly valuable for low-income parties and middle-income parties to the FCTC that lack the capacity and resources to manage the data that would be required under Articles 9 and 10 of the FCTC.

Together, these initiatives would provide an evidence base to direct and evaluate product regulation. In the meantime, we would encourage public health scientists to develop the capacity for alternative machine testing regimes, including those that are more consistent with smoking in humans, as well as other mechanisms for evaluating toxicity. In the longer term, we also believe that a comprehensive testing programme should be extended to cover the effect of all tobacco products, including smokeless tobacco, and that such products should also be brought under a common and coherent system of regulatory control.

We thank Neil Collishaw and Murray Kaiserman for their comments on earlier drafts of this manuscript.

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**Funding:** This review was supported by grants from the National Cancer Institute of the United States (through R01 CA 100362 and through the Roswell Park Transdisciplinary Tobacco Use Research Center, P50 CA111236), Robert Wood Johnson Foundation (045734), Canadian Institutes of Health Research (57897), National Health and Medical Research Council of Australia (265903), Cancer Research UK (C312/A3726) and Canadian Tobacco Control Research Initiative (014578), with additional support from the Centre for Behavioural Research and Program Evaluation, National Cancer Institute of Canada/Canadian Cancer Society.

**Competing interests:** None.

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