This should change everything: using the toxic profile of heat-not-burn products as a performance standard to phase out combustible cigarettes

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INTRODUCTION

Cigarettes are inherently unsafe and no amount of tinkering and product modification over decades has made them safe or even less hazardous. Indeed, evidence suggests they have become more hazardous.[1] But as there are now new substitute nicotine products available, it has been suggested that the viability of phasing out cigarettes should be re-assessed.[2] This paper proposes one way this could be done.

Unlike many other consumer products, no safety standards have been set for cigarettes or other tobacco products. The Framework Convention on Tobacco Control (FCTC) acknowledges the role of regulating the toxicity of tobacco,[3] and the WHO scientific committees on tobacco regulation (TobReg and SACTob) have repeatedly called for such regulations to be developed.[4–7] Despite this, no country or scientific authority has yet set out a path 'to establish actual rather than theoretical control of product design',[7] and parties to the FCTC have yet to receive any guidance on how to do so.[8] In the absence of such regulations, tobacco companies have continued to design their cigarettes without regulatory obligations to address their inherent harmfulness.

Nonetheless, in the absence of any product standards, some of these companies have recently developed and are now marketing nicotine and tobacco products that they describe as reduced risk.[9 10] These include tobacco products variously described as tobacco heating products (THPs) or heat-not-burn (HNB) products, which use battery-powered heating elements rather than combustion to release nicotine and other compounds from a processed tobacco leaf.

The design and marketing of these products is evidence that manufacturers have achieved the technical capacity to reduce the quantity of toxins inhaled through tobacco use. Manufacturers' reports to investors claim that these new tobacco products are economically viable, and that smokers can be persuaded to use them.[11 12] Whether they are meaningfully less harmful than conventional cigarettes is not established.[13]

USING THE TOXIC PROFILE OF HEATED TOBACCO PRODUCTS TO SET A STANDARD FOR CIGARETTES

Both Philip Morris International (PMI) and British American Tobacco (BAT) recently commissioned Labstat International in Kitchener, Canada, to measure the amount of selected toxins produced by their THP/HNB brands 'IQOS' and 'glo'. The results were published in the journal *Regulatory Toxicology and Pharmacology*.[14 15] In both cases, the test methods were based on the Health Canada Intense smoking regime, which was developed by Labstat and subsequently endorsed by TobReg as the preferred test method for setting performance standards.[16] These are the same tests that are performed annually on Canadian cigarette brands as a requirement of federal regulations,[17] and which were previously required under British Columbia law.[18] Both companies requested the laboratory to concurrently measure toxins in the smoke produced by the Kentucky 3R4F reference cigarette. Labstat is member laboratory of the global network of tobacco measurement laboratories, TobLabNet, accredited by WHO.[19]

Labstat measured the presence of 126 (BAT's glo) and 44 (PMI's IQOS) specific chemicals. These chemicals included all but one (eugenol) of the 41 chemicals for which annual testing of cigarette smoke is required by Health Canada,[20] all 39 tobacco smoke toxicants identified for reduction by TobReg,[7] and all 18 of the priority tobacco toxicants identified by the United States Food and Drug Administration.[21]

Table 1 shows the industry's test results for the 38 chemicals from Health Canada's list as well as results from a previous test conducted by the same laboratory on the mainstream smoke of a leading brand of Canadian cigarettes, du Maurier King Size.[22] Results are not shown for eugenol (not tested), tar (not relevant to heated products) or nicotine. The two tobacco heating products produced different results for several toxins: PMI's IQOS produced higher levels for all but 5 of the 38 selected toxic chemicals than did BAT's glo. The differences between these two products, however, were very much smaller than the differences between the heated products and conventional cigarettes. The levels of toxins produced by both the Kentucky reference cigarette and the du Maurier cigarette were from two to more than 500 times greater than either IQOS or glo.

These test results confirm the presence of carcinogens for which it is generally held that there is no safe level of exposure[23] and establish that heated tobacco products cannot be viewed as safe. They also confirm the presence of other chemicals that can cause cardiovascular diseases and other harms, even at low levels of exposure. Were HNB tobacco sticks regulated to the same standard as other consumer products, this information would likely be sufficient to bar them from the market.

The reference point used by the companies for these products, however, is not normal consumer products but rather the conventional cigarette.[11] In presenting these test results, both PMI and BAT emphasise that their new technologies produce 90% lower levels of emissions than are found in the smoke of conventional cigarettes.[14 15] The tobacco companies' use of the test results imply, and will be interpreted as saying, that such products offer a 'less bad' alternative to tobacco smokers than continuing to smoke combustible cigarettes.

NEW POTENTIAL FOR A 'LESS BAD' PERFORMANCE STANDARD FOR CIGARETTES

An alternative perspective is that the companies have now established that they are capable of providing smokers with commercially viable ways of using tobacco that deliver lower levels of toxins and that they could therefore be required by law to do so. The recent test results from PMI and BAT can be used as the basis of a performance standard that could be applied to all inhaled products in order to ensure that the HNB products are the highest risk cigarettes on the market. Setting the standard at

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Table 1 Proposed maximum emission yield performance standard for combustible cigarettes and its relationship to test results published by Philip Morris International (PMI) and British American Tobacco (BAT) for tobacco heated products

Toxic emission	Unit of measure (applies to all values shown in this table)	Test results Combustible cigarette, mean values			Test results Tobacco-heated stick (THS)			Proposed performance standard
		du Maurier KS	Kentucky Reference Cigarette 3R4F		Mean values	Mean values	2 SD from the highest THS value reported by either PMI or BAT	
(IARC carcinogen classification shown in brackets)*	Per stick	Imperial Tobacco Canada[18]	PMI test[14]	BAT test[15]	PMI IQOS[14]	BAT glo[15]		Proposed maximum mean value†
Ammonia	µg	26.5	29.3	32.5	10.5	4.01	3.26	13.76
1-Aminonaphthalene (3)	ng	13.5	21.6	17.6	0.0407	nq	0.0206	0.06
2-Aminonaphthalene (1)	ng	9.75	16.2	13.2	0.0277	nq	0.01818	0.05
3-Aminobiphenyl	ng	2.44	4.18	3.49	0.0112	nq	0.00062	0.02
4-Aminobiphenyl (1)	ng	1.65	2.83	2.29	0.00958	nq	0.0028	0.01
Benzo[a]pyrene (1)	ng	25.31	15	12.9	0.939	nq	0.1592	1.10
Formaldehyde (1)	µg	65.8	85.2	54.1	7.98	3.29	1.008	8.99
Acetaldehyde (2B)	µg	1103	1641	2200	217	111	15.7	232.70
Acetone	µg	558	690	660	35.5	5.96	3.68	39.18
Acrolein (3)	µg	175	156	157	9.63	2.22	1.406	11.04
Propionaldehyde	µg	102	123	132	13.6	5.31	1.324	14.93
Crotonaldehyde (3)	µg	44.2	50.5	42	<3.29	0.567	‡	6.58
Butyraldehyde	µg	66.7	83.5	60.9	20.3	9.78	1.172	21.47
Hydrogen cyanide	µg	296	365	343	<4.37	bdl	‡	8.74
Mercury (3)	ng	10.96	4.77	4.26	2.04	1.28	0.208	2.25
Lead (2B)	ng	48.6	32.1	28.7	<1.62	11.6	0.464	12.06
Cadmium (1)	ng	278	92.9	105	<0.28	bdl	‡	0.56
Nitric oxide (NO)	µg	113	504	495	13.8	9.6	1.934	15.73
Nitrogen oxides (NOx)	µg		560	555	14.1	12.9	1.886	15.99
N-nitrosonornicotine (NNN) (1)	ng		283	263	10.2	24.7	5	29.7
4-(Methyl-nitrosamino)-1-(3-pyridyl)-1-butanone (NNK) (1)	ng		264	281	6.75	24.7	5	29.7
N-nitrosoanatabine (NAT) (3)	ng		270	268	14	37.7	6.8	44.5
N-nitrosoanabasine (NAB) (3)	ng		30.2	24.1	1.92	4.7	0.78	5.48
Pyridine (2B)	µg	39.6	29.7	28.6	6.14	2.21	0.846	6.99
Quinoline	µg	0.773	0.431	0.389	<0.011	nq	‡	0.022
Styrene (2B)	µg	26.5	15.4	16.1	1.05	nq	0.29	1.34
Hydroquinone (3)	µg	177	89.1	84.2	7.2	0.347	0.782	7.98
Resorcinol (3)	µg	3.59	1.79	1.57	<0.055	bdl	‡	0.11
Catechol (2B)	µg	217	89.8	87.4	14.4	3.11	1.36	15.75
Phenol (3)	µg	52.9	14	13.5	1.12	0.174	0.1698	1.29
m+p-Cresol	µg	30.9	12.1	12.2	<0.0646	bdl	‡	0.13
o-Cresol	µg	11.7	4.15	3.94	0.0393	nq	0.01298	0.05
Carbon monoxide (CO)	mg	16.7	30.2	32	0.436	nq	0.1622	0.60
1,3-Butadiene (1)	µg	76.3	98.5	108	0.342	bdl	0.0624	0.41
Isoprene (2B)	µg	417	894	887	2.15	nq	0.404	2.55
Acrylonitrile (2B)	µg	25.5	24.5	19.5	0.158	bdl	0.0244	0.18
Benzene (1)	µg	115	81.1	78.6	0.544	nq	0.0624	0.61
Toluene (3)	µg	199	137	131	1.82	nq	0.326	2.15

Where no SD reported, to allow for uncertainty, proposed performance standard of the mean +2 SD is estimated at twice the highest mean value for THS reported by either PMI or BAT.
*IARC classification of carcinogens: Group 1, Carcinogenic to humans; Group 2A, Probably carcinogenic to humans; Group 2B, Possibly carcinogenic to humans; Group 3, Not classifiable as to its carcinogenicity to humans.
†Maximum mean value based on at least three replicates. This maximum value is equal to the mean +2 SD of the highest tobacco heat stick value reported by either PMI or BAT.
‡No SD reported.
bdl, below detectable levels; IARC, International Agency for Research on Cancer; nq, not quantifiable.

the highest mean plus 2 SD for each of 38 toxic agents would place it at a level that was achieved by all of the THP/HNB sticks that were tested by BAT and PMI and would ensure that all similarly formulated future HNB products would also meet the standard. This proposal for a performance standard based these laboratory measurements commissioned by the tobacco industry is shown in Table 1.

In a country like Canada, where the authority and responsibility to regulate tobacco products has already been assigned to the health minister, and where manufacturers must already use the toxic emissions tests that are the basis of this standard,[24] the regulatory ingredients for this standard are already in place. The consultation process, which is mandatory to regulation-making, can serve to establish the time required for implementation: a phase-in period of 4 to 6 years may be realistic for a new performance standard.

The presence of vaping products and electronic cigarettes creates the opportunity—and maybe even the imperative—to protect the public from the most hazardous forms of nicotine use—combustible cigarettes. Even countries like Turkey, whose prohibition of IQOS has been endorsed by local representatives of WHO, may see a new opportunity for such a performance standard that returns the focus to the products currently on the market.[25]

CONCLUSION

WHO's SACTob Committee has observed that regulation of cigarette design has not

yet moved from the theoretical to the practical.[7] Now there is a way to do so by using a performance standard for inhaled tobacco products.

Such a performance standard may be a complement to other proposals for tobacco product regulation. In the USA, for example, the Food and Drug Administration (FDA) is considering regulating the amount of nicotine in cigarettes, consistent with another TobReg proposal, while permitting modified risk products to be marketed.[26 27] While already sold in many countries, HNB cigarettes are not yet approved for sale in the USA, and their regulatory status in the USA remains to be determined. Philip Morris' twice daily to be allowed to claim these as a less hazardous product was rejected by the US FDA Tobacco Products Scientific Advisory Committee[13] while combustible cigarettes and other tobacco products already on the market enjoy a 'grandfathered' status, which exempts them from such scrutiny. Requiring traditional cigarettes to meet toxic standards would create greater coherence in an FDA-style approach and could serve as an alternative to a reduced-nicotine regulation. PMI and BAT are touting these products as a safer alternative to smoking and are asking for regulatory changes to facilitate the marketing of these new products.[28] In return, they offer no guarantee or commitment to remove their most harmful goods. To the contrary, they have denied such requests by arguing that that they cannot cede the cigarette marketplace to their competitors.[29]

Such a stance clearly calls for a market-driven approach and for a regulatory solution that would apply to all companies. Several observers have proposed just that.[30 31] The proposed standard is a mechanism for doing so.

The performance standard proposed here is not a perfect solution to the tobacco epidemic but is a less bad alternative to the status quo. Some hazards would remain because e-cigarettes and HNB products are toxic products, but, overall, we would be less badly off. As more precise information becomes available on their emissions and hazards, revised performance standards could be set that would apply more specifically to these new products.

Using these technologies as a springboard to better regulations would reduce the disease burden from smoking. It would also help protect public health from the new risks posed by these recent technologies, such as the risk of dual use or the vulnerability of new forms of nicotine becoming a gateway to conventional smoking.

If tobacco companies want to add a new tobacco product to the marketplace, the price to be paid should be to subtract at least one existing one—the combustible cigarette.

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