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11<sup>th</sup> June, 2018

Prof Hon. Joseph Lee, SBS, JP  
Chairman, Panel on Health Services, Legislative Council  
Legislative Council Complex  
1 Legislative Council Road  
Central, Hong Kong

Dear Chairman Lee,

**Submission regarding Agenda Item IV of the Panel on Health Services Meeting on 19<sup>th</sup> June, 2018**

I am writing with reference to agenda item IV of the Panel on Health Services meeting on 19<sup>th</sup> June, 2018: "Legislative proposal to regulate electronic cigarettes and other new tobacco products". Our submission consists of five parts –

- A. The continuum of risk and need for appropriate regulation
- B. *IQOS* and *Heatstick* product description
- C. Relevant independent scientific evidence on *IQOS* harm reduction potential
- D. *Heatstick* fits within the existing legislative framework under the Dutiable Commodities Ordinance (Cap. 109) and
- E. *Heatstick* is not a cigarette under the Smoking (Public Health) Ordinance (Cap. 371)

We respectfully ask you to table a copy of this submission for the Members' references.

**Executive Summary**

To supplement existing smoking prevention strategies and regulations, several countries are adopting new policies aimed at encouraging smokers who would otherwise continue smoking to switch to better alternatives. *Heatstick* is fundamentally different from cigarettes and, while not risk-free, the use of *Heatstick* in conjunction with *IQOS* presents less risk of harm and can present less risk of tobacco-related diseases than cigarettes for smokers who switch completely. Over 20 independent expert groups or institutions from around the world have also verified elements of Philip Morris International's robust science behind *IQOS* harm reduction potential, including the German Federal Institute for Risk Assessment, the UK Committee on Toxicity, and the US Food and Drug Administration. *Heatstick* fits within the existing excise tax legislation in Hong Kong as "All other manufactured tobacco except tobacco intended for the manufacture of cigarettes", and should not be classified as a cigarette for regulatory purposes.

**A. The continuum of risk and need for appropriate regulation**

Today, there are a variety of non-combustible products that while not risk-free, have the potential to present less risk of harm than continued smoking for smokers who switch completely. These products have one thing in common – they deliver nicotine without burning tobacco, which significantly reduces consumers' exposure to many of the harmful and potentially harmful compounds associated with smoking related disease.<sup>1</sup>

<sup>1</sup> See, e.g., Ludicke, F., Effects of Switching to the Menthol Tobacco Heating System 2.2, Smoking Abstinence, or Continued Cigarette Smoking on Clinically Relevant Risk Markers: A Randomized, Controlled, Open-Label, Multicenter Study in Sequential Confinement and

Not all tobacco products are the same. Regulators increasingly recognize that there is a continuum of risk for tobacco and nicotine-containing products. Cigarettes are the highest risk product, and while quitting is the best option, non-combustible products are likely to be less risky than cigarettes for those smokers who will not quit. As outlined in the US Food and Drug Administration (FDA) comprehensive approach to tobacco control, Commissioner Scott Gottlieb said:

*A centerpiece of this comprehensive regulatory plan is acknowledging that nicotine, while highly addictive, is delivered through products on a continuum of risk. And it's the delivery mechanism – not the nicotine itself – that is truly the issue at-hand.<sup>2</sup>*

According to Action on Smoking and Health UK, “almost all of the harm from smoking comes from the inhalation of tobacco smoke rather than nicotine.”<sup>3</sup> Therefore, products that deliver nicotine without combustion have the potential to reduce individual risk compared to smoking cigarettes, and if they prove to be an acceptable alternative for adult smokers, can ultimately reduce population harm.

While there is no substitute for quitting, we believe that encouraging those who would otherwise continue to smoke to switch to potentially less harmful alternatives, can bring significant public health benefits. This is important because there are still approximately 1 billion smokers globally, including over 615,000 smokers in Hong Kong.

Philip Morris Asia Limited (PMAL) and Philip Morris International (PMI) are committed to a future in which non-combustible products, such as heat-not-burn products (HnB), replace cigarettes and other forms of combustible tobacco – a future in which we no longer sell cigarettes. In pursuit of this goal, PMI has hired over 400 scientists and experts and invested more than USD 4.5 billion to develop, substantiate and build manufacturing capacity for a wide portfolio of non-combustible products. We are designing all these products to provide alternatives for adult smokers to have a better choice.

Achieving this vision requires more than research and the development of less harmful alternatives to cigarettes. Legislation and regulation have fundamental roles to play. In addition to measures intended to prevent the initiation of smoking and encourage cessation, providing smokers with access to and non-misleading information about products that are potentially less harmful than cigarettes present a significant public health opportunity. For example, according to the FDA:

*With appropriate product regulation, new technology, and product innovation – including new medicinal nicotine products and electronic nicotine delivery systems (ENDS) – could present an opportunity for more smokers to quit combustible tobacco and stay quit. Our plan takes new steps to foster innovation in nicotine delivery, where such innovation could truly make a positive public health impact.<sup>4</sup>*

Several countries are adopting new policies to supplement existing policies and regulations aimed at encouraging smokers who would otherwise continue smoking to switch to better alternatives. In July 2017, the US FDA announced a new approach to regulating the harms of combustible tobacco by increasing restrictions on cigarettes and by allowing “greater flexibility” for non-combustible products.<sup>5</sup> In announcing the plan, US FDA Commissioner Scott Gottlieb stated:

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Ambulatory Settings (Part 2), Nicotine & Tobacco Research, February 2017, <https://academic.oup.com/ntr/article/2978029/Effects>; Goniewicz, M. L., et al., Exposure to Nicotine and Selected Toxicants in Cigarette Smokers Who Switched to Electronic Cigarettes: A Longitudinal Within- Subjects Observational Study, Nicotine & Tobacco Research, August 2016, <https://academic.oup.com/ntr/article-abstract/19/2/160/2631650/Exposure-to-Nicotine-and-Selected-Toxicants-in>.

<sup>2</sup> US FDA Commissioner Scott Gottlieb, Remarks by Dr. Gottlieb on the Regulation of Nicotine, 17 October 2017, <https://www.fda.gov/NewsEvents/Speeches/ucm581314.htm>.

<sup>3</sup> Action on Smoking and Health, Nicotine and Addiction, <http://ash.org.uk/download/nicotine-and-addiction/>

<sup>4</sup> US Food and Drug Administration, HEALTHY INNOVATION, SAFER FAMILIES: FDA'S 2018 STRATEGIC POLICY ROADMAP, January 2018, <https://www.fda.gov/AboutFDA/ReportsManualsForms/Reports/ucm591993.htm>

<sup>5</sup> US Food and Drug Administration, HEALTHY INNOVATION, SAFER FAMILIES: FDA'S 2018 STRATEGIC POLICY ROADMAP, January 2018, <https://www.fda.gov/AboutFDA/ReportsManualsForms/Reports/ucm591993.htm>

*Envisioning a world where cigarettes would no longer create or sustain addiction, and where adults who still need or want nicotine could get it from alternative and less harmful sources, needs to be the cornerstone of our efforts.<sup>6</sup>*

The UK is another example of a country where regulators are examining regulating smoke-free products differently than cigarettes. In July 2017, the UK Government released “The Tobacco Control Plan for England”. The plan sets forth the Department of Health’s vision of tobacco control for the next five years, and also formalizes the shift in Government policy for England. The plan notes:

*In addition, there has been the development and very recent introduction of novel tobacco products that claim to reduce the harm of smoking. We welcome innovation that will reduce the harms caused by smoking and will evaluate whether products such as novel tobacco products have a role to play in reducing the risk of harm to smokers.<sup>7</sup>*

The appropriate regulation of these alternatives is an important element of the success of policies intended to encourage adult smokers who would otherwise continue smoking to switch to better alternatives. By providing adult smokers with access to better products and factual information, adult smokers can make better choices.

#### **B. IQOS and Heatstick product description**

*IQOS* is an electronic device that generates a nicotine-containing aerosol by heating a specially designed tobacco stick (*Heatstick*), at controlled temperatures below 350 degrees Celsius. By heating tobacco rather than burning it, *IQOS* produces an aerosol, not smoke, containing significantly lower levels of toxicants than cigarette smoke.

##### Product Description

The *IQOS* system is presented as follows:



**Figure 1                      The three components of the IQOS system**

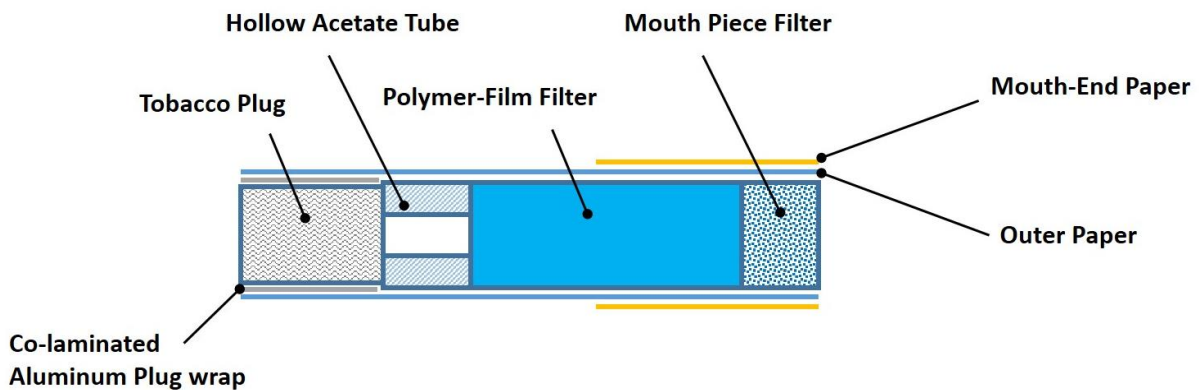
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<sup>6</sup> US FDA, FDA’s new plan for tobacco and nicotine regulation, July 2017, available at <https://www.fda.gov/TobaccoProducts/NewsEvents/ucm568425.htm>.

<sup>7</sup> UK Department of Health, Towards a smoke-free generation: Tobacco control plan for England, July 2017, <https://www.gov.uk/government/publications/towards-a-smoke-free-generation-tobacco-control-plan-for-england>.

As shown above, the IQOS system has three components, i.e.:

- The **Charger** that is used to recharge the Holder after each use;
- The **Holder** into which the *Heatstick* is inserted and which heats the tobacco in the *Heatstick* by means of an electronically-controlled heater; and
- The **Heatstick** which contains specially processed tobacco and two filter sections. The *Heatstick* has been designed specifically and exclusively for use with the Holder (heating device) of the IQOS. The *Heatstick* comprises a number of elements that are different than cigarettes.



**Figure 2** Illustration of cross-sectional diagram of the *Heatstick* showing major components

### **Heatstick Components**

The **tobacco plug** is made of specific blend of tobacco leaves. They're carefully processed to create a uniform mixture that's formed into a sheet and then crimped. The entire process is designed to produce the highest possible homogeneity of the tobacco. The tobacco plug is specifically formulated for heating and is not designed for smoking. When heated, water and glycerin evaporate and re-condense into small droplets to generate a visible tobacco aerosol.

The **co-laminated aluminum plug wrap** prevents any attempt to ignite the tobacco plug with a flame, and therefore the *Heatstick* is not capable of being smoked by itself.

The **hollow acetate tube** is made of cellulose acetate fibers with a plasticizer, wrapped in a non-porous paper over-wrap. The hollow acetate tube prevents the tobacco plug from being pushed into the *Heatstick* when the tobacco plug is inserted in the heater.

The **polymer-film filter** is made from polymer-film wrapped in a non-porous paper over-wrap which is made of wood cellulose fibers. In this section of the *Heatstick*, vaporized compounds are cooled down to yield an acceptable aerosol temperature.

The **mouth piece filter** is made of cellulose acetate fibers with plasticizer, wrapped in a non-porous paper over-wrap. It is a filter which provides sufficient rigidity when the mouth piece filter is held between the lips of the *Heatstick* user.

The **outer paper** holds the various *Heatstick* components together.

The **mouth-end paper** is added on the mouth end to prevent the lips of a consumer from sticking to the *Heatstick* mouth piece filter.

## Use of the *Heatstick* and *IQOS*

The *Heatstick* is inserted into the Holder and the user turns on the electronics by means of a switch to initiate the heating of the tobacco plug.

Once the initial heating phase is complete, the *Heatstick* is ready to be used. The Holder follows an in-use heating profile that is designed to provide a consistent sensory experience. The *Heatstick* generates a tobacco aerosol and thereby enables the user to inhale and exhale the tobacco aerosol.

After the cycle of use is complete, the *Heatstick* must be removed from the Holder. The Holder is then placed in the Charger where it is recharged. A new *Heatstick* must be used for the next use.

## Main distinguishing physical and operational characteristics of the *Heatstick*

The following characteristics are specific to the *Heatstick* and distinguishes it from cigarettes:

- I. The electronically-controlled heating, in combination with the uniquely processed tobacco, prevents combustion from occurring. When used, the *IQOS'* heating mechanism ensures that the tobacco is not heated above 350°C. The *Heatstick's* content of water and glycerine facilitates the unique low-temperature (in contrast with the burning described in the next paragraph) heating use of the *Heatstick* which results in the emission of a tobacco aerosol fundamentally different from the smoke emitted from a cigarette when it is used. More specifically, the *Heatstick's* aerosol is made up of about 90% water and glycerine, and contains no carbon-based solid particles. Cigarette smoke, on the other hand, contains solid particles, and only about 50% of its mass consists of water and glycerine. In addition, the *Heatstick* is not smoked; it does not combust and produces no smoke or ash. By way of comparison, during the natural smolder period of a lit cigarette in between puffs, temperatures of between 600 to 800°C occur in the center of the burning cone. During a puff the temperature increases to more than 900°C at the periphery of the burning zone. The combustion of tobacco results in the formation of smoke (which contains a range of chemical compounds), heat and ash.
- II. 'Tar' applies to products that burn tobacco like cigarettes. *IQOS* heats the tobacco in the *Heatstick* instead of burning it, therefore tar measurements do not apply, and what really matters is the composition of the aerosol. While it is possible to measure NFDPM<sup>8</sup> in the *Heatstick* aerosol, it is completely different in composition from cigarette smoke 'tar'; as a result, comparing the two would be misleading, as concluded by researchers from the German Federal Institute for Risk Assessment (BfR)<sup>9</sup>.

*"Although the NFDPM value for HNB products can be formally calculated as for the conventional cigarettes, direct comparisons would be misleading".<sup>10</sup>*

Ultimately, we are of the view that NFDPM or "tar" yields do not provide a meaningful assessment of the relative risks of tobacco products. In fact, the EU has prohibited the printing of "tar" yields on cigarette packs. (Directive 2014/40/EU<sup>11</sup>). The World Health Organization has also stated very clearly: "Tar need not be measured, as it is not a sound basis for regulation, and the levels can be misleading."<sup>12</sup>

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<sup>8</sup> 'Tar' can be referred by a technical term as nicotine-free dry particulate matter (NFDPM)

<sup>9</sup> *Bundesinstitut für Risikobewertung* (BfR) is a public body under the German Federal Ministry for Food and Agriculture, responsible for providing scientific advice to the German government.

<sup>10</sup> Mallock et al., Levels of selected analytes in the emissions of "heat not burn" tobacco products that are relevant to assess human health risks, *Archives of Toxicology*, May 2017, <https://link.springer.com/article/10.1007%2Fs00204-018-2215-y>

<sup>11</sup> See DIRECTIVE 2014/40/EU OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 3 April 2014

<sup>12</sup> WHO, Report on the Scientific Basis for Tobacco Product Regulation: Fifth Report of a WHO Study Group (2015), link [here](#)

### C. Relevant independent scientific evidence on IQOS harm reduction potential

PMI has conducted a systematic assessment of IQOS incorporating elements of multiple disciplines, including aerosol chemistry and physics, *in vitro*, *in vivo* and systems toxicology, clinical studies, as well as pre-and post-market assessments of consumer perception, behavior, and actual use of IQOS.

We are committed to sharing our results as the development and scientific assessment of our products advance and would be happy to do so also with the Panel on Health Services. The results of all our studies, across the causal chain of events, are coherent with this reduction in toxicant emission and consistently demonstrate that the tobacco aerosol generated by using IQOS is less toxic than cigarette smoke. Therefore, the totality of the evidence clearly demonstrates that IQOS presents less risk of harm and can present less risk of tobacco-related disease than cigarettes.<sup>13</sup>

So far, over 20 independent studies and reviews on IQOS validate different elements of our assessment approach or otherwise reach positive conclusions. For the Panel's reference, a detailed list of independent third-party studies and assessments of IQOS is attached at Annex A. Examples include –

- (A) Results of a study published by the US FDA Southeast Tobacco Laboratory on January 25, 2018: It was recognized that our IQOS reduces the formation of harmful and potentially harmful chemicals (compared to the convention tobacco, formation was significantly reduced by greater than 90% for acrolein and benzopyrene more than 80% for formaldehyde).
- (B) Results of a study published by the UK Committee on Toxicity in December 2017: *"[I]t is likely that there is a reduction in risk, though not to zero, to health for smokers who switch completely to heat-not-burn products."*
- (C) Results of a study published by the Public Health England (PHE) on February 6, 2018: It was recognized that *"Compared with cigarettes, heated tobacco products are likely to expose users and bystanders to lower levels of particulate matter and harmful and potentially harmful compounds (HPHC). The extent of the reduction varies between studies."*
- (D) Results of a study published by the National Institute of Public Health Japan on September 14, 2017: It was recognized that *"The concentration levels of hazardous compounds in the mainstream smoke of IQOS are much lower than those in conventional combustion products."*
- (E) Results of a study published by the German Federal Institute for Risk Assessment (BfR) on July 12, 2017: It found that *"levels of major carcinogens are markedly reduced in the emissions of the analyzed HNB product in relation to the conventional tobacco cigarettes and that monitoring these emissions using standardized machine smoking procedures generates reliable and reproducible data which provide a useful basis to assess exposure and human health risks."*
- (F) Results of a study published by the All-Russia Scientific Research Institute (study conducted by request of Russian Government) on December 12, 2017: It was recognized that the "content of toxic components in the vapour from the novel technology is, indeed, 90 or more percent less than in that from the other products tested."
- (G) Results of a study published by the China National Tobacco Quality Supervision and Test Centre (CNTQSTC) on January 8, 2018: It was recognized that, *"THS 2.2 [IQOS] resulted in lower HPHC levels compared to 3R4F [reference cigarette]. Except for carbonyls, ammonia, and NAB, the reduction rate is more than 90%."*

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<sup>13</sup> Philip Morris Products S.A., Tobacco Heating System (IQOS) Briefing Document, December 2017, <https://www.fda.gov/downloads/AdvisoryCommittees/CommitteesMeetingMaterials/TobaccoProductsScientificAdvisoryCommittee/UCM593108.pdf>

**D. Heatstick fits within the existing legislative framework under the Dutiable Commodities Ordinance (Cap. 109)**

It is our opinion that *Heatstick* should be classified as “all other manufactured tobacco except tobacco intended for the manufacture of cigarettes” under the Dutiable Commodities Ordinance (Cap. 109) (“DCO”) as supported by a joint legal opinion of Mr. Benjamin Yu SC and Mr. Jin Pao.

Under the DCO, various rates of duties are payable on four identified categories of tobacco products set out in Part II of Schedule I of the DCO: (i) cigarettes; (ii) cigars; (iii) Chinese prepared tobacco; and (iv) all other manufactured tobacco except tobacco intended for the manufacture of cigarettes.

According to the DCO, tobacco products are categorized as follows:

Category	
Cigarette	Any roll of tobacco capable of being smoked by itself not being a cigar
Cigar	Any roll of tobacco capable of being smoked by itself and which has an outer wrapper of natural tobacco, or predominately contains broken or threshed leaf and has a binder of reconstituted tobacco and an outer wrapper of reconstituted tobacco fitted spirally
Chinese Prepared Tobacco	Tobacco prepared in the traditional Chinese manner from tobacco leaf grown in China
All other manufactured tobacco except tobacco intended for the manufacture of cigarettes	Tobacco product that does not fall within the above definitions

Since the *Heatstick* is not rolled up in tobacco and is not tobacco prepared in the traditional Chinese manner from tobacco leaf grown in China, *Heatstick* cannot fall within the definition of “cigar” and “Chinese prepared tobacco”.

The *Heatstick* cannot be classified as “cigarettes” under the DCO either. The term “cigarette” is defined under the DCO as “any roll of tobacco capable of being smoked by itself not being a cigar”. As explained in part B. above, the features of the *Heatstick* are distinctly different from that of a cigarette which can be smoked directly and straight away after lighting, and can therefore be smoked “by itself”.

Unlike a cigarette, the *Heatstick* is not capable of being used “by itself” because it needs to be inserted into the Holder and heated for a period of time to the required temperature before the user can inhale the aerosol generated from the heating of tobacco. Throughout the consumption process, the *Heatstick* must be used in conjunction with the Holder for it to be heated within a precisely controlled temperature. If removed from the Holder, the *Heatstick* will not be able to function as designed, no aerosol will be produced, and the *Heatstick* will be spent.

The *Heatstick* cannot function without IQOS. The *Heatstick* is fitted with a particular type of aluminium foil (see Figure 2 above) which renders it impracticable to light with a flame and to directly inhale and exhale from the product itself. The *Heatstick* is designed and intended to be used, and can only be used, exclusively in conjunction with IQOS.

Also, as indicated in part B, the *Heatstick* is made of specific blend of tobacco leaves, which include various tobacco types that are grounded and formed into a reconstituted sheet together with binders and humectants. We consider that the term “reconstituted tobacco” is wide enough to include the tobacco material contained in the *Heatstick*, and that the product should accordingly be classified as “manufactured tobacco” under the DCO.

In conclusion, we believe *Heatstick* should be classified as “other manufactured tobacco except tobacco intended for the manufacture of cigarettes” under Part II, Schedule I of the DCO and should be taxed as such.

**E. *Heatstick* is not a cigarette under the Smoking (Public Health) Ordinance (Cap. 371)**

Under the Smoking (Public Health) Ordinance (Cap. 371) (the “SPHO”), “*tobacco product*” is defined to include any of the following four product categories: cigarette; cigarette tobacco; cigar; or pipe tobacco. “*Cigarette*” is defined under the SPHO as tobacco rolled up in paper or in any other material except tobacco in such form as to be capable of immediate use for smoking.

Turning to the analysis of this definition, we note that *Heatstick* clearly contains tobacco which is rolled up in “*any other material except tobacco*”. The most critical issue is whether the *Heatstick* is in such form “*as to be capable of immediate use*”. As already explained in part B, the *Heatstick* is to be used in conjunction with IQOS. Before the *Heatstick* can be ready for use, a user needs to first insert the *Heatstick* into the Holder. The Holder needs to be switched “on” and the *Heatstick* needs to be heated to the required temperature, which takes about 20 seconds. The *Heatstick*, once heated to the correct temperature, is then maintained at a constant temperature range within the Holder. After the heating process is completed, the user will be able to inhale the aerosol which is produced by the *Heatstick* through that heating process. Once removed from the Holder, the *Heatstick* will not be able to function and no aerosol will be produced. After it has been used in this way, the Holder must be recharged, using the Charger, which takes approximately five minutes. The consumer can insert a new *Heatstick* and go through the same process to repeat the experience. In simple words, the process to consume a *Heatstick* requires time and the use of the Holder.

Under the circumstances, the *Heatstick* is not “*capable of immediate use*”. Unlike a “*cigarette*” which can be smoked directly and straight away without first assembling it into another product, the *Heatstick* needs to be inserted into the *Holder* and heated, and then used throughout the consumption experience in conjunction with the IQOS device, without which the *Heatstick* cannot function. As this requirement is not met, the *Heatstick* does not classify as a “*cigarette*” under the SPHO.

\* \* \* \* \*

We hope this submission provides sufficient information on topics that are of critical importance for the discussion and to help arrive at a decision that can contribute positively to the Hong Kong society by allowing smokers who would otherwise continue smoking access to better alternatives soonest. We would be glad to provide further information regarding this matter when requested. Thank you for your kind attention to this matter.

Yours sincerely,



Kittipong Jangkamolkulchai (Dr)  
Head of Corporate Affairs (Hong Kong & Macau)  
Philip Morris Asia Limited



## Annex A

### Third-party studies and assessments of IQOS

Study	Conclusion	Type of Study
Aerosol Chemistry		
Nicotine Delivery to the Aerosol		
Farsalinos et al., Nicotine Delivery to the Aerosol of a Heat-Not-Burn Tobacco Product: Comparison With a Tobacco Cigarette and E-Cigarettes, Nicotine & Tobacco Research, 16 June 2017, <a href="#">here</a> .	<i>“The HnB product delivers nicotine to the aerosol at levels higher than ECs but lower than a tobacco cigarette when tested using Health Canada Intense puffing regime. No change in HnB nicotine delivery was observed at prolonged puff duration with the same puff volume, unlike ECs which deliver more nicotine with longer puff duration.”</i>	Independent study.
Formation		
Li et al., Chemical Analysis and Simulated Pyrolysis of Tobacco Heating System 2.2 Compared to Conventional Cigarettes, Nicotine & Tobacco Research, 8 January 2018, <a href="#">here</a> .	<i>“THS 2.2 resulted in lower HPHC levels compared to 3R4F. Except for carbonyls, ammonia, and NAB, the reduction rate is more than 90%.”</i>	Independent study.
Bekki et al., Comparison of Chemicals in Mainstream Smoke in Heat-not-burn Tobacco and Combustion Cigarettes, National Institute of Public Health (Japan), September 2017, <a href="#">here</a> .	<i>“The concentration levels of hazardous compounds in the mainstream smoke of IQOS are much lower than those in conventional combustion cigarettes.”</i>	Independent study.
Farsalinos, Toxicant exposure: Heated tobacco products vs. e-cigarettes, Presentation at Global Forum on Nicotine 2017, 16 June 2017, <a href="#">here</a> .	<i>“Significantly lower toxic emissions than smoking, but higher than new-generation e-cigarettes.”</i>	Independent study and comparison of results with PMI data.
Mallock et al. (German Federal Risk Assessment Institute (BfR)), Levels of selected analytes in the emissions of “heat not burn” tobacco products that are relevant to assess human health risks, Archives of Toxicology, 5 May 2018, <a href="#">here</a> .	<i>“We show that nicotine yield is comparable to typical combustible cigarettes, and observe substantially reduced levels of aldehydes (approximately 80–95%) and VOCs (approximately 97–99%). Emissions of TPM and nicotine were found to be inconsistent during the smoking procedure. Our study confirms that levels of major carcinogens are markedly reduced in the emissions of the analyzed HNB product in relation to the conventional tobacco cigarettes and that monitoring these emissions using standardized machine smoking procedures generates reliable and reproducible data which provide a useful basis to assess exposure and human health risks.”</i> BfR also “confirm[ed] absolute values for selected toxicants in the emissions of [IQOS] that are in agreement with data published by the manufacturer.”	Independent study and comparison of results with PMI data.
US FDA’s Southeast Tobacco Laboratory (STL), October 2017, <a href="#">here</a> .	<i>“Preliminary assessment of the data indicates that the levels of acrolein, formaldehyde, and benzo[a]pyrene in the IQOS aerosol measured by STL are higher than the values reported by the applicant, however, these three HPHCs are still significantly lower than the levels in the mainstream smoke of the reference cigarette 3R4F. Greater than 90% reduction was observed from acrolein and benzo[a]pyrene, and greater than 80% reduction was observed for formaldehyde in the aerosol compared to 3R4F. The levels of tar and</i>	Independent study and comparison of results with PMI data.

	<p><i>nicotine determined by STL were similar to the levels reported by the applicant. Finally, levels of ammonia, NNN, and NNK in the HeatSticks tobacco filler measured by STL were similar to the levels reported by the applicant. [...] The independent testing performed by STL confirmed the lower levels of selected HPHCs in the aerosol from the HeatSticks compared to mainstream cigarette smoke."</i></p>	
<p>Setyan, A., et al. (Swiss EMPA Institute), Physico-chemical characterization of particles and volatile organic compounds emitted by electronic cigarettes and heat-not-burn products, compared to a reference tobacco cigarette, 2018, Abstract (<a href="#">here</a>)</p>	<p><i>"Particles emitted by all the products were totally dominated by submicron particles. However, those emitted by the conventional cigarette were slightly larger than those from the Puritane [e-cigarettes] and IQOS (mode at 220 nm for 3R4F, vs. 150 nm for Puritane and IQOS... VOCs concentrations were 6 times higher than with the conventional cigarette than with the Puritane and IQOS... A wide range of mono-aromatic (mainly benzene-and furan-derivatives) and oxygenated compounds were identified in gaseous emissions of the conventional cigarette. Most of these compounds were also present in the IQOS, but in much lower concentrations. ..."</i></p>	<p>Independent study.</p>
<p>The All-Russia Scientific Research Institute for Tobacco and Tobacco Products (study conducted by request of Russian Government) (<a href="#">here</a>)</p>	<p><i>"The research results showed that the content of toxic components in the vapour from the novel technology is, indeed, 90 or more percent less than in that from the other products tested."</i> (unofficial translation).</p>	<p>Independent study.</p>
<p>Talih, S., et al., Is IQOS designed to convert combustible cigarette users? Investigation of Free-Base and Total Nicotine, and Reactive Oxygen Species, Poster 5-118 at SRNT 2018</p>	<p><i>"ROS [reactive oxygen species] levels were lower in the IQOS aerosol relative to the cigarette."</i></p>	<p>Independent study.</p>
<p>Dutch National Institute for Public Health and the Environment (RIVM), IQOS Factsheet, 15 May 2018 (<a href="#">Factsheet (Dutch)</a>; <a href="#">Factsheet English</a>; <a href="#">Summary (English)</a>)</p>	<p><i>"The use of heatsticks with the IQOS is harmful to health, but probably less harmful than smoking tobacco cigarettes."</i> (Summary)</p> <p><i>"Obviously, the fewer harmful substances a person is exposed to, the less harmful it is for the health. A lower amount of substances in the emissions from heated tobacco than in a tobacco cigarette does not mean that the product is proportionately less harmful, however. The quantity of a substance that is inhaled only determines part of the harmful effect."</i> (Factsheet)</p> <p><i>"The research referred to in the scientific literature were mainly carried out by or on behalf of the producer, Philip Morris. The quantities measured by RIVM in the emissions are similar to these quantities."</i> (Factsheet)</p> <p><i>"The substances that the RIVM measured are comparable to those contained in the data from Philip Morris."</i> (Factsheet)</p>	<p>Independent study and comparison of results with PMI data.</p>

	<p><i>“The emissions created when heating and burning tobacco clearly differ in composition. This is because the temperature of a lit cigarette, at least 600 - 700 degrees, is much higher than the temperature reached in a device that heats tobacco (up to 300 degrees). Which substances are formed depends on the temperature.”</i> (Factsheet)</p> <p><i>“With heated tobacco, the way of smoking and the temperature do not appear to influence the amount of nicotine contained in the emissions. With an equal number of puffs, the amount of nicotine contained in the emissions is the same for various types of tobacco and with the different ways of smoking.”</i> (Factsheet)</p>	
<b>Indoor Air Quality and Risk to Bystanders</b>		
Protano, C., et al., Second-hand smoke exposure generated by new electronic devices (IQOS and e-cigs) and traditional cigarettes: submicron particle behavior in human respiratory system, Ann Ig, 2016 ( <a href="#">here</a> )	<i>“During smoking, SMPs released by traditional and hand-rolled cigarettes and deposited in the respiratory tract of a passively exposed subject are four-times higher than those released by electronic and heat-not-burn devices. After smoking, SMPs generated by traditional and hand-rolled cigarettes remain high until the end of the experiment (about six times higher than background) while, for electronic and heat-not-burn devices, SMPs values return immediately very similar to background...”</i>	Independent study.
Ruprecht, A.A., et al., Environmental pollution and emission factors of electronic cigarettes, heat-not-burn tobacco products, and conventional cigarettes, Aerosol Science and Technology, 21 March 2017, ( <a href="#">here</a> )	<i>“While polycyclic aromatic hydrocarbons (PAHs) were mostly non-detectable in the iQOS smoke, certain n-alkanes, organic acids (such as suberic acid, azelaic acid, and n-alkanoic acids with carbon numbers between 10 and 19) as well as levoglucosan were still emitted in substantial levels from iQOS (up to 2–6 mg/h during a regular smoking regimen). Metal emissions were reduced in iQOS smoke compared to both electronic cigarettes and conventional cigarettes and were mostly similar to the background levels. Another important finding is the presence of carcinogenic aldehyde compounds, including formaldehyde, acetaldehyde, and acrolein, in iQOS smoke, although the levels were substantially lower compared to conventional cigarettes”</i>	Independent study.
Prodanchuk et al., Potential risk assessment of the electrically heated tobacco system (EHTS) use, Modern Problems of Toxicology Food and Chemical Safety, October 2017, <a href="#">here</a> .	<i>“Recognized reduced risk potential for active and passive smokers’ health while using EHTSs in comparison with conventional filtered cigarette smoking is based in reduced level of air pollution in the room, where these products were used.”</i>	Independent study.
<b>Toxicity</b>		

Leigh et al., Cytotoxic Effects Of A Tobacco Heat-Not-Burn System On Human Bronchial Epithelial Cells, Abstract presented at SRNT 2018, <a href="#">here</a> .	<i>"Using limited cytotoxic measures, the IQOS system showed significantly reduced cytotoxicity as compared to combustible tobacco cigarettes. While more comprehensive testing is needed to determine long term effects of inhaling aerosol from HnB products, this new product may be a potential harm reduction tool for smokers unwilling to quit smoking or smokers not interested in switching to e-cigarettes."</i>	Independent study.
<b>Reduced Exposure</b>		
Kazan Federal University (study conducted by request of Russian Government) ( <a href="#">here</a> ) (unpublished). Results published in a comment to FDA <a href="#">here</a> . Press release, 7 May 2018, <a href="#">here</a> .	<i>"Results of the study in humans demonstrate that the impact of tobacco smoke HPHCs is reduced almost to the level of smoking abstinence when using THS. At the same time, THS has moderately good flavor, sensation, perception and the level of nicotine intake. Based on the study data, no signs of possible new or increased risks related to THS in comparison to CC use by adult smokers were discovered. Thus, this product can be considered as a CC substitution for the nicotine-dependent adult smokers. After a full transition from cigarettes to THS this product would potentially help to reduce the risks of smoking-related diseases."</i>	Independent study.
Gale et al., Changes in Biomarkers of Exposure on Switching from a Conventional Cigarette to Tobacco Heating Products: A Randomised, Controlled Study in Healthy Japanese Subjects, BAT, Poster 5-1888 at SRNT 2018, <a href="#">here</a> .	<i>"This clinical study demonstrated that when smokers switched from smoking combustible cigarettes to using tobacco heating products (glo or IQOS), their exposure to smoke toxicants was significantly decreased. In many cases, this was to the same extent as that seen when subjects quit smoking completely."</i>	Independent study.
Tobacco Products Scientific Advisory Committee (TPSAC), 25 January 2018, <a href="#">here</a> .	TPSAC agreed, by a vote of 8-1, that <i>"Scientific studies have shown that switching completely from cigarettes to the IQOS system significantly reduces your body's exposure to harmful or potentially harmful chemicals."</i>	Conclusion based on review of PMI and FDA data.
<b>Reduced Risk</b>		
UK Committee on Toxicity, Toxicological evaluation of heat-not-burn products, 12 December 2017, <a href="#">here</a> .	<i>"[I]t is likely that there is a reduction in risk, though not to zero, to health for smokers who switch completely to heat-not-burn tobacco products."</i>	Independent study.
PHE, Evidence review of e-cigarettes and heated tobacco products 2018, 6 February 2018, <a href="#">here</a> .	<i>"The available evidence suggests that heated tobacco products may be considerably less harmful than tobacco cigarettes and more harmful than EC."</i>	Review of the literature/evidence.
Stephens, Comparing the cancer potencies of emissions from vapourised nicotine products including e-cigarettes with those of tobacco smoke, Tobacco Control, 4 August 2017, <a href="#">here</a> .	<i>"The cancer potencies of the HnB prototype device that heated various tobacco blends lie between one and two orders of magnitude less than tobacco smoke but higher than the preponderance of EC emissions"</i>	Study "us[es] published chemical analyses of emissions and their associated inhalation unit risks."
Kvasha, Evaluation of electronic nicotine delivery system (ENDS) effects on cardiovascular disease risk, based on endothelium function as factor of its	<i>"Thus, it was outlined in our work, that switching to electronic nicotine delivery systems, both tobacco and liquid-based, and nicotine delivery with the elimination of the harmful effects of cigarette smoke"</i>	Independent study.

determination, Ukrainian Health, 8 July 2017, <a href="#">here</a> .	<i>prevents impairment of oxygen transport function of the blood, injury of the vascular endothelium and development of proatherogenic alterations in lipid metabolism and blood lipoproteins. In case of dual use, their shielding effect occurs in its reduced form.</i>	
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<b>Intended and Unintended Use</b>		
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Tabuchi et al., Awareness and use of electronic cigarettes and heat-not-burn tobacco products in Japan, Addiction, 14 November 2015, <a href="#">here</a> .	<i>“Approximately half the respondents in a Japanese internet survey were aware of e-cigarettes and heat-not-burn tobacco products, 6.6% had ever used. More than 70% of ever users used non-nicotine e-cigarettes, the sale of which is not legally prohibited, even to minors, in Japan, and 33% of them used nicotine e-cigarettes; 3.5% of never smoking men and 1.3% of never smoking women had ever used e-cigarettes. Corresponding figures for use in the last 30 days were 0.6% and 0.3%, predominantly non-nicotine e-cigarettes.”</i>	Analysis of internet survey results.
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