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Electronic cigarettes: what is new in the year 2019?

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Introduction

The use of electronic cigarettes (e-cigs), also referred to as vaping, has been marketed as a safe alternative to tobacco use, both entities similarly serving to deliver the stimulant nicotine. E-cigs, packaged in a liquid form stored in a cartridge, which can be loaded onto a battery-operated electronic heating device, can heat up into a vapour that users breathe in. The liquid in the cartridge contains not only nicotine but also the necessary organic solvents isopolypropylene glycol and vegetable glycerin, as well as various flavours intended to appeal to users, especially young people. E-cigs thus delivers nicotine in aerosol via controlled heating of liquid while avoiding tobacco leaves and burning.

A growing epidemic in e-cigarette use in the U.S.

The alarming rise in the use of e-cigs among US adolescents is seen by the US Food and Drug Administration (FDA) as reaching epidemic proportions. Currently, 3.2% of the adult population in the US, while 3.6 million junior-high and high-schoolers, are e-cig smokers.[1] The most recent US statistics showed that the vaping prevalence among 8th, 10th and 12th graders (equivalent to secondary school years 2, 4, and 6, respectively) has doubled in each of the 3 grades from 2017 to 2019; the prevalence of use during the previous 30 days was more than 1 in 4 in 12th graders, more than 1 in 5 in 10th graders and more than 1 in 11 in 8th graders.[2] This trend signifies a failure of current measures, be they at the governmental, community or school level, in the US in curbing the vaping popularity. Nicotine addiction in the young is particularly problematic as nicotine is a powerful central nervous system stimulant that provides users with instantaneous gratification and leads to long-term addiction that is difficult to overcome once established.

Carcinogenicity of nicotine seen in a mouse model of e-cigarette use

Tobacco smoke, which delivers numerous carcinogens generated during tobacco curing and burning, has become the leading cause of human cancers, including lung cancer and bladder cancer.

Measuring the level of nitrosamines, the breakdown products of nicotine, in body fluids has been a gold standard for assessing the potential carcinogenic effect of tobacco smoke. When a similar method is adopted to assess the carcinogenic potential of e-cigs, it has been noted that the levels of these nicotine breakdown products are only 5% of the levels found in tobacco smokers, which suggests nicotine nitrosation does not take place in e-cig smoke (ECS). This finding has supported the recommendation by some public health experts that e-cigs are 95% safer than traditional cigarettes.[1]

Nevertheless, it is not clear whether the marker of carcinogenicity could be equally applied to traditional smoking and e-cig smoking. A group of researchers at New York University have shown that instead of measuring body levels of nitrosamines, the study of DNA damages may shed better light on the carcinogenicity induced by ECS. An animal model showed mice exposed to short-term (12 weeks) ECS sustained extensive DNA damage in lung and bladder mucosa and diminished DNA repair in the lungs, similar to DNA changes observed in human lung epithelial and bladder urothelial cells upon exposure to nicotine and its nitrosation products. The research group went on to study the potential carcinogenicity of nicotine using the same mouse model. Three groups of mice were subjected to the following chamber conditions 4 hours each day and 5 days per week for 54 weeks:

1. Exposure to ECS generated from nicotine juice at concentration of 36 mg/mL dissolved in isopolypropylene glycol and vegetable glycerin at 1:1 ratio, with a nicotine aerosol concentration of 0.196 mg/m3 (n=45)

2. Exposure to aerosol inhalation which is free from nicotine but at comparable level of the vehicle solvent isopolypropyline glycol and vegetable glycerin (n=20)

3. Exposure to ambient filtered air (n=20)

At the end of 54 weeks of exposure, it was found that 22.5% of group 1 surviving mice (9 out of 40) developed adenocarcinoma of the lung in comparison to groups 2 (zero incidence) and 3 (one out of 18) ($p<0.05$); similarly, 57.5% of group 1 mice developed bladder urothelial hyperplasia vs 1 in group 2 and 0 in group 3 ($p<0.001$). The researchers concluded that the DNA damage induced by metabolites of nicotine nitrosation products are likely the major causes for lung as well as bladder carcinogenesis in mice.[1]

Mysterious vaping illness in the US

In July 2019, the Wisconsin Department of Health Services and the Illinois Department of Public Health received reports of pulmonary disease associated with the use of e-cigs. This led to a coordinated public health investigation that resulted in a report of 53 case patients published in the New England Journal of Medicine.[3] Case patients were defined as those with a history of vaping within 90 days before symptom onset and had pulmonary infiltrates on imaging not attributable to other causes.

The key findings of these 53 case patients were as follows:

- Median age: 19 years of age (range 16-53); male: 83%
- Respiratory symptoms: 98%; gastrointestinal symptoms: 81%; constitutional symptoms: 100%
- Bilateral infiltrates on chest imaging: 100%
- Hospitalization: 94%
- Intubation and mechanical ventilation: 32%
- Death: 1 case patient
- History of having used tetrahydrocannabinol: 84%[3]

The outbreak of this mysterious pulmonary condition pushed the US authorities to establish stricter regulations on e-cigs. In the US, it is illegal for vendors to sell e-cigs to those <18 of age; in some states and cities, the age limit is 21. However, a good proportion of those with this pulmonary condition were younger than 21. The US FDA in September 2019 announced the plan to remove flavoured e-cig devices from the market. San Francisco, a smart city, was ahead in the game as it was the first US city to ban e-cig sales in June 2019.[4] Following the eruption of lung injuries, US states that have banned sales of flavoured e-cigs include New York, Michigan, Rhode Island and Massachusetts.[5] The latest figures with regard to the surge of this mysterious lung condition were reported in Nature on 17 October 2019: 1,300 case patients and 26 deaths.[6]

Four imaging patterns correlated with pathological findings have been reported based on 19 case patients: acute eosinophlic pneumonia, diffuse alveolar damage, organizing pneumonia and lipoid pneumonia suggestive of various forms of lung injuries in response to inhalational insult.[7]

Various scientific postulations as the culprit of such lung injuries arising from vaping have been put forth. Because of the diverse vaping practices, plausible culprits include:

- tetradhydrocannabinol, although this was absent in 16% of the original case series of 53 patients;
- various chemicals included in the flavourings, among which the most infamous appears to be the cinnamaldehyde, a chemical that can kill lung cells;[5]
- the oils carrying the nicotine or the tetrahydrocannabinol, leading to a syndrome called lipoid pneumonia, etc.

Given the wide range of chemicals vapers are exposed, there is a chance we may never be able to track down a single cause for the outbreak of this respiratory illness, says a pulmonologist at Harvard's School of Public Health.[6]

Surprisingly, in a latest report of vaping-associated lung injury, Larsen et al. described the pathological analysis of lung tissue taken from 17 affected vapers. Against their expectation, they did not find exogenous lipoid pneumonia nor eosinophilic changes. They noted general lung damage and inflammation; the authors hence postulated that vaping-associated lung injury represents a form of airway-centered chemical pneumonitis from one or more inhaled toxic substances, the exact toxin remaining elusive up to this point.[8]

E-cigarettes are more addictive than traditional cigarettes!

In addition to the harms of carcinogenesis and direct toxic lung injury from e-cig smoke as detailed above, one recent study highlights the hidden danger of e-cigs: vapers can be more nicotine-addicted than users of traditional cigarette smoking.

In a joint Polish and Canadian study, a group of highly educated young adults at a mean age of 22.4 were recruited into this study, including 30 cigarette smokers, 30 exclusive e-cig users and 30 dual users. A 25-item questionnaire collected information related to the patterns and attitudes towards the use of cigarettes and e-cigs. Nicotine dependence was also assessed via standard tools. It was found that nicotine dependence levels were over 2 times higher among e-cig users compared to traditional smokers. The authors postulated that likely these young smokers were using the more advanced e-cig devices which can deliver high doses of nicotine and that the younger brain may be more prone to nicotine addiction.[9] The absence of the social stigma of traditional smoking may, I surmise, also encourage more intense use of e-cigs and hence higher level of addiction.

Conclusion

2019 has been a remarkable year in the US as far as vaping is concerned. It is a year in which multiple authorities are saying NO to e-cigs. It is also a year in which there is an outpouring of scientific data on the harms of e-cigarette smoke, be it a mouse model showing the carcinogenic effects of nicotine or over 2,000 patients (and 26 deaths) with a vaping lung disease that remains to be clearly defined and delineated. The ability of e-cigs to induce powerful nicotine addiction in highly educated young adults is not to be ignored. It is high time that the Hong Kong SAR Government imposes a total ban of e-cigarettes, taking a good lesson from the American experience.

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By email and by hand

Dear Sirs

Smoking (Public Health) (Amendment) Bill 2019 (the "Bill")

We act for British-American Tobacco Company (Hong Kong) Limited.

As the Secretary for Commerce and Economic Development may be aware, the Secretary for Food and Health has recently introduced the Bill in the Legislative Council to, amongst other things, ban the import, manufacture, sale, distribution and advertisement of Alternative Smoking Products (as defined in the Bill).

There are various legal issues with the Bill which are problematic, including the fact that it is contrary to the Government's established free trade policy in Hong Kong. British American Tobacco (together with its subsidiaries, the "**BAT Group**") has invested in a range of potentially reduced-risk products, including its tobacco heating products (such as *glo* and Neostiks) and electronic cigarettes (such as Vype). It is currently legal to import and sell these products in Hong Kong. However, if the Bill is passed it will become illegal to do so. A blanket ban on all import of these products will disproportionately restrict the free movement of goods and impermissibly threatens Hong Kong's constitutionally guaranteed status as a free port as protected under Articles 114 and 115 of the Basic Law. The blanket ban will also be in breach of the General Agreement on Tariffs and Trade ("**GATT**") of the World Trade Organisation ("**WTO**"), of which Hong Kong is a member, and international bilateral agreements signed by Hong Kong.

We have previously issued detailed written submissions regarding the Bill to the Bills Committee on 8 April 2019 (LC Paper No. CB(2)1175/18-19(11)). In those submissions, BAT Group has outlined its concerns on issues caused by the Bill which include disproportionate restrictions to free movement

of goods and inconsistency with Hong Kong's international trade obligations – these concerns are contained in sections 8 and 10 of the submissions. We enclose a copy of the submissions for your reference.

We also submitted a letter to the Bills Committee on 21 June 2019, which builds on our prior submissions and included our responses to questions raised by the Legislative Council's Legal Service Division. In particular, it elaborates further on the international laws violated by the Bill and includes a legal opinion by Professor Petros Mavroidis, an expert in the field of international economic law, on the incompatibility of the Bill with international law. We enclose a copy of this letter for your reference.

Further breaches of international obligations

In addition, there are further international obligations which the Government has disregarded and/or failed to comply with in introducing the Bill, which we set out below.

First, the rights and protections provided to intellectual property owners under the Agreement on Trade-Related Aspects of Intellectual Property Rights (the "**TRIPS Agreement**") are relevant. We have previously raised concerns about the WTO-inconsistent discrimination between foreign-produced Alternative Smoking Products and traditional, Hong Kong-produced combustible tobacco products. From the intellectual property perspective, the TRIPS Agreement also imposes obligations on WTO Members including Hong Kong to not discriminate in protection of intellectual property. For example, Articles 3 and 4 of the TRIPS Agreement take the National Treatment and Most-Favoured-Nation Treatment non-discrimination rules of the GATT and apply them "*with regard to the protection of intellectual property*" of nationals of other WTO Members. In respect of trademarks, Article 15.4 of the TRIPS Agreement makes clear that the nature of the product shall not be an obstacle to registration. And Article 27.1 of the TRIPS Agreement also makes patent rights enjoyable without discrimination as to the field of technology. Therefore, given that combustible tobacco products and their corresponding trademarks, patents, goodwill and other intellectual property rights are permitted and protected in Hong Kong, the ban of Alternative Smoking Products violates not only the GATT with respect to the products but could also be inconsistent with the TRIPS Agreement with respect to their intellectual property rights.

Second, the proposed ban on Alternative Smoking Products breaches bilateral investment treaties, for example the Investment Promotion and Protection Agreement ("**IPPA**") between Hong Kong and the United Kingdom. That treaty outlines the various types of "investment" that are covered by the treaty protections in the definition of that term in Article 1(e)(iv) as *"every kind of asset and in particular…intellectual property rights, goodwill, technical processes and know-how*". Therefore, intellectual property rights must be afforded the substantive protections in that treaty, which include "*fair and equitable treatment*" covering any impairment by unreasonable or discriminatory measures of the use or enjoyment of the investment (Article 2(2)) and the protection against unlawful expropriation without just compensation (Article 5). As explained in our prior submissions to the Bills Committee, this Bill is not only unreasonable but also irrational and effects a complete deprivation of intellectual property, in breach of the IPPA.

Third, under Article 2.9 of the Agreement on Technical Barriers to Trade, Hong Kong, as a member of WTO, is required to notify other WTO members, through the WTO Secretariat, at an early appropriate stage of proposed technical regulations that may have a significant effect on other WTO members' trade. The Bill prohibits import of goods from other WTO members bearing certain characteristics (e.g. goods capable of generating aerosol from tobacco) and constitutes a technical

regulation for this purpose.[1] However, insofar as we are aware, the Government has failed to comply with this important obligation to notify other WTO members of the Bill and allowing them adequate time to provide comments on the Bill.

Fourth, Article V of GATT requires there to be freedom of transit through the territory of each contracting party, via the routes most convenient for international transit, and must not cause any unnecessary delays. It has been held that this requires WTO members to extend "*unrestricted access via the most convenient routes for the passage of goods in international transit whether or not the goods have been trans-shipped, warehoused, break-bulked, or have changed modes of transport*".[2] The proposed section 15DD in Clause 23 of the Bill, however, does not permit transhipment of Alternative Smoking Products to be stored temporarily in Hong Kong pending export unless the product remains in a vessel (if transported by sea) or in the aircraft or air transhipment cargo (if transported by air). Nevertheless, we are instructed that the majority of the tobacco related cargos come to Hong Kong by land and/or sea and would need to be removed from the vehicle or vessel pending the next transit or transhipment. This would be prohibited if the Bill is passed, resulting in an impermissible restriction on access to the most convenient routes for the passage of goods in international transit protected under GATT Article V. Such restriction would also be inconsistent with existing arrangements under various Free Trade Agreements. This includes the preferential tariff treatment for such transhipment cargo in Hong Kong between Mainland China and certain countries (such as Korea and Australia) as provided by the Free Trade Agreement Transhipment Facilitation Scheme which seeks to facilitate, rather than to ban, such transhipment. It would be irrational to impose such restriction when such transhipment cargo has no domestic implication.

We understand from the Commerce and Economic Development Bureau's ("**CEB**") Mission Statement that it is CEB's mission to enhance Hong Kong's position as a leading international trade and business centre, foster a business-friendly environment and attract investment to Hong Kong. The anti-free trade move proposed by the Bill threatens Hong Kong's position as a leading international trade and business centre and deprives of foreign investments in Hong Kong. We therefore write to bring this matter to the Secretary for Commerce and Economic Development's attention, including the serious breaches of international law as described above, and respectfully urge him to consider making submissions to the Secretary for Food and Health and the Bills Committee.

We also note that the Hong Kong government has attempted to rely on the World Health Organisation's Framework Convention on Tobacco Control ("**FCTC**") to justify its proposed ban of Alternative Smoking Products.[3] This reliance on the FCTC, which covers "tobacco products", to support the proposed ban of e-cigarettes and other products is however misplaced. We enclose to this letter a legal opinion by Professor Jan Wouters, a leading international trade law and public international law scholar, which argues conclusively for the lack of applicability of the FCTC to alternative nicotine delivery systems such as e-cigarettes. Professor Wouters' opinion is based on his review of the customary international legal principles of treaty interpretation and counters the attempts to extend the FCTC beyond its limited coverage of traditional tobacco products, based on the following reasons:

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1 Appellate Body Report, *European Communities – Measures affecting asbestos and Asbestos-containing products*, AB-2000-11, WT/DS135/AB/R.

2 Panel Report, *Colombia – Indicative prices and restrictions on ports of entry*, WT/DS366/R at paragraph 7.401.

3 See Legislative Council Brief, File Ref: FH CR 1/3231/19 (13 Feb. 2019), at para. 9, and paras. 15-16 of Annex B.

- The history of the FCTC confirms that alternative nicotine delivery systems (such as e-cigarettes and heated tobacco products ("**HTPs**")) were not covered by the FCTC at the time of adoption, since they did not exist as such.
- General rules of treaty interpretation confirm that, because they do not contain tobacco, e-cigarettes fall outside the scope of application of the FCTC based on (1) the ordinary meaning of the treaty's terms, (2) the current state of scientific knowledge and (3) the FCTC's object and purpose.
- HTPs, by contrast, meet the first part of the definition of covered tobacco products since they contain tobacco. However, they do not meet the second part of the definition, which requires that the tobacco products "are manufactured to be used for smoking, sucking, chewing or snuffing". HTPs do not involve burning or combustion, as recognised by public health authorities, and thus no burnt tobacco is "smoked" and instead an aerosol is vaped. The context as well as the object and purpose of the FCTC confirm that HTPs do not fall within the FCTC's scope of application.
- No subsequent action by the FCTC Conference of the Parties ("**COP**") amounts to a subsequent agreement or subsequent practice that brings non-tobacco products such as e-cigarettes within the remit of the FCTC.
- For HTPs, a single reference that appears to reflect the view that these products are covered "tobacco products" in one recital of the preamble of a single FCTC COP decision (FCTC/COP8/(22)) neither can amend the clear text of the treaty nor can be sufficient to amount to a subsequent agreement or subsequent practice within established international legal rules of treaty interpretation. Rather, FCTC Parties' widely divergent practice with respect to HTPs confirms that no such agreement exists (e.g. some parties promoted their use as part of a harm reduction strategy, while others treat them as ordinary tobacco products).

A proper interpretation of the FCTC that gives meaning and effect to the harm reduction principle enshrined in the plain language of its definition of tobacco control, and in line with the object and purpose of the treaty, requires that alternative nicotine delivery systems products not be banned but rather treated more favourably from a regulatory and taxation standpoint than combustible tobacco products (such as cigarettes). This would support adult consumers of combustible products to switch to alternative nicotine delivery systems.

If you have any questions, please feel free to contact our Mr Dominic Geiser or Mr Truman Mak.

Yours faithfully,

Herbert Smith Freehills

Encls

cc: Clerk to Bills Committee on Smoking (Public Health) (Amendment) Bill 2019
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By email and by hand

Dear Sirs

Submission on the Smoking (Public Health) (Amendment) Bill 2019

We act for British-American Tobacco Company (Hong Kong) Limited ("**BATHK**").

We write in connection with the deputation meeting of the Bills Committee (the "**Bills Committee**") in relation to the Smoking (Public Health) (Amendment) Bill 2019 (the "**Bill**") on 13 April 2019 (the "**Meeting**"). Amongst other things, the Bill seeks to ban the import, manufacture, sale, distribution and advertisement of Alternative Smoking Products (as defined in the Bill).

BATHK strongly opposes the Bill. The Bill is irrational and is not evidence-based – it bans products that are potentially less harmful than conventional cigarettes, including tobacco heating products ("**THPs**") and electronic cigarettes ("**e-cigarettes**"), and effectively ignores the potential harm reduction benefits associated with the use of such products. The Bill is also unconstitutional and contravenes the Basic Law in that it violates the fundamental human right of privacy and right of private property, disproportionately restricts the free movement of goods and impermissibly threatens Hong Kong's guaranteed status as a free port. The Bill is inconsistent with Hong Kong's international trade obligations. Furthermore, the Government has failed to follow a proper process with the Bill, in breach of BATHK's legitimate expectation and its duty to consult.

Please find below a detailed submission of BATHK on the Bill for consideration by members of the Bills Committee at the Meeting. We should be grateful if you could kindly table a copy of this submission for the Meeting.

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1. EXECUTIVE SUMMARY

1.1 British American Tobacco ("**BAT**") has long been working to develop potentially reduced-risk products ("**PRRPs**") that could help reduce the public health impact of smoking. To that end, it has invested in a range of PRRPs, including THPs and e-cigarettes. They are different to conventional cigarettes – they do not combust, and therefore, they produce significantly fewer toxicants than conventional cigarettes. The reduced-risk potential of THPs and e-cigarettes as compared to conventional combustible cigarettes has been widely recognised by public authorities (see section 2 below).

1.2 Under the current legislative framework, it is legal to import and sell THPs and e-cigarettes in Hong Kong, subject to certain regulations, such as payment of duties and registration. The Government has also previously agreed that these products should continue to be available for sale and consumption in Hong Kong, and proposed in June 2018 that they should be regulated in a way similar to conventional cigarettes. The Chief Executive also explained to the members of the Legislative Council on 12 July 2018 that these products, "*which* [are] *less harmful medically*", should be regulated, and expressed her concerns over a blanket ban being imposed, including concerns relating to Hong Kong's trade obligations (see section 3 and paragraphs 4.1 to 4.2 below).

1.3 However, notwithstanding her concerns, and without providing any scientific justification or conducting any prior consultation with the industry or the general public, the Chief Executive drastically changed her position and unilaterally announced on 10 October 2018 in her 2018 Policy Address that the Government will introduce the Bill. The Bill is effectively a blanket ban of Alternative Smoking Products in Hong Kong, and extends even to their private use (see paragraphs 4.3 to 4.7 below).

1.4 BATHK submits that the Bill is irrational and disproportionate in banning products that emits substantially less toxicants than conventional cigarettes whilst at the same time allowing people to smoke conventional cigarettes. An approach that denies harm reduction benefits to consumers is not rational, ethical or appropriate for the protection of public health. There are alternative regulatory approaches that are available to support smokers in quitting conventional smoking, while minimising the potential risks presented by their use, as proposed by many experts and implemented in other countries (see section 5 below).

1.5 BATHK also submits that:

1.5.1 The Bill is **unconstitutional** in that:

(A) It disproportionately restricts the fundamental human right of privacy protected under Article 14 of the Hong Kong Bill of Rights, Article 17 of the International Convention on Civil and Political Rights ("**ICCPR**") and Article 39 of the Basic Law, by imposing a blanket ban on Alternative Smoking Products, regardless of one's age, the place or the purpose for which they are to be consumed. The Bill would prevent a conventional smoker from exercising his or her freedom to consume these products (which are endorsed by leading health regulators and experts around the world as potentially less harmful alternatives to cigarettes) in private, in order to switch away from smoking conventional cigarettes (see section 6 below).

(B) It amounts to a complete deprivation of private property protected under Articles 6 and 105 of the Basic Law, including BATHK and BAT's goodwill, registered trademarks, patents, and investments in its Alternative Smoking Products. Such deprivation is not necessary to achieve any legitimate aim of the Bill. It also exposes the Government to significant risks of claims and liabilities for compensation (see section 7 below).

(C) It disproportionately restricts the free movement of goods and impermissibly threatens Hong Kong's constitutionally guaranteed status as a free port under Articles 114 and 115 of the Basic Law, without any legitimate necessity to achieve the objectives sought to be pursued in the Bill (see section 8 below).

1.5.2 The Bill is **in breach of due process,** by denying BATHK's legitimate expectation that the Government will regulate, rather than impose a blanket ban on, Alternative Smoking Products and that the Government would follow fair and proper regulatory processes, such as conducting a formal public consultation and Regulatory Impact Assessment to properly consider the impacts, costs and benefits of the Bill, before introducing significant tobacco control reform (see section 9 below).

1.5.3 The Bill is **inconsistent with Hong Kong's international obligations** by breaching the General Agreement on Tariffs and Trade ("**GATT**") of the World Trade Organisation ("**WTO**") and Hong Kong's bilateral treaties, including, *inter alia*, the Investment Promotion and Protection Agreement ("**IPPA**") signed between Hong Kong and the United Kingdom (see section 10 below).

1.6 BATHK therefore respectfully urges the Government to withdraw this Bill which is irrational, in breach of due process and inconsistent with Hong Kong's international obligations. It should then conduct a public consultation in relation to these matters and review the responses received before deciding to introduce any regulatory reform. In doing so, it should engage with manufacturers of such products, as well as other stakeholders. BATHK would be happy to share their insights on best practices from their dealings with different types of regulatory frameworks around the world.

2. INTRODUCTION

2.1 BATHK is a member of the BAT group of companies and is responsible for the importation, distribution and sale of tobacco products in Hong Kong.

2.2 BAT has long been working to develop PRRPs that can help potentially reduce the public health impact of smoking and has invested in a range of PRRPs, including THPs and e-cigarettes. BAT is one of the major suppliers of these products in a number of countries. BATHK has already commenced preparation to launch these products, in particular *glo*, one of BAT's THPs, in Hong Kong based on the proposed regulation of these new tobacco products by the Government which was submitted to the Panel on Health Services of Legislative Council (the **"Health Panel"**) in June 2018.

THPs

2.3 THPs are devices that heat rather than burn tobacco. Unlike conventional cigarettes (which combust tobacco at a temperature higher than 800°C), THPs heat tobacco (typically at a temperature between 240-350 °C) to produce a nicotine-containing aerosol that is inhaled. Unlike the smoke emitted from a lit cigarette, THPs' aerosol is composed mainly of water, humectant (e.g. glycerol), nicotine and flavourings.

2.4 *Glo* is composed of an electronic battery powered device which heats specially designed tobacco sticks, Neostiks, to approximately 240°C. The consumer inserts the Neostik into the *glo* device and turns it on by means of a button which initiates the heating of the tobacco. Once the initial heating phase is completed, the Neostik is ready to be consumed.

2.5 When used as directed and intended, Neostiks neither ignite nor burn. The electronically-controlled heating, in combination with the uniquely processed tobacco, prevents combustion from occurring. The Neostiks are not smoked; they do not combust and produce no ash. The reduction in temperature, and the fact there is no burning, results in the production of aerosol containing fewer as well as a lower level of toxicants, the majority of which are at significantly lower levels than in cigarette smoke. This offers the potential for significant harm reduction when compared to cigarettes. Indeed, the science BAT has done to date on *glo* shows that it emits approximately 90-95% less toxicants[1] than the smoke of a reference cigarette in terms of the nine harmful toxicants the World Health

[1] 'British American Tobacco publishes a series of studies supporting the reduced-risk potential of glo' published by Dr Marina Murphy of British American Tobacco in November 2017; 'Tobacco heating products overview of the scientific assessment of glo' prepared by British American Tobacco (available in enclosure 5 in LC Paper No. CB(2)1402/17-18(01) (Revised)). Also see Forster et al., (2017) Assessment of novel tobacco heating product THP 1.0. Part 3: Comprehensive chemical characterisation of harmful and potentially harmful aerosol emissions. This is an independently peer-reviewed study, published in the journal of Regulatory Toxicology and Pharmacology.

Organisation ("**WHO**") recommends to reduce in cigarette smoke.[2] There is also a substantial reduction in the number and level of second hand environmental toxicants emission for *glo* use compared to cigarette smoking.

2.6 The reduced-risk potential of THPs as compared to conventional combustible cigarettes has been recognised by public authorities and experts. For example:

2.6.1 In 2018, Public Health England ("**PHE**"), an executive body of the UK Department of Health, published an evidence review of e-cigarettes and THPs in which it concluded that "[c]*ompared with cigarette smoke, heated tobacco products are likely to expose users and bystanders to lower levels of particulate matter and harmful and potentially harmful compounds.*"[3]

2.6.2 In 2017, the UK Committee on Toxicity of Chemicals in Food, Consumer Products and the Environment ("**COT**") published a toxicological evaluation of two THPs on the market in the UK, in which it found that "[i]*nvestigations on both products showed a decrease in the harmful and potentially harmful compounds (HPHCs) in the aerosol generated by the device to which the user would be exposed, compared to the HPHCs in the mainstream smoke from a conventional cigarette. For both products, there were some HPHCs where the reduction was approximately 50%, but the reduction in a number of other HPHCs was greater than 90%, with many of the compounds being below the limits of detection or quantification for the assays used.*"[4]

2.6.3 A study by Caponnetto et al.[5] which investigated carbon monoxide in the exhaled breath ("**eCo**") of participants after use of two THPs found "*no eCO elevations during inhalation testing with HTPs* [Heated Tobacco Products] *under investigation in any of the study participants. Our findings concur with findings from e-cigarette studies as well as from manufacturer and independent data on HTPs.*" The authors concluded that "*it is our opinion that non-combustible nicotine sources – that are significantly less harmful than conventional cigarettes – can be a viable solution for those who, for whatever reason, cannot or do not want to give up nicotine, or who want to cut back on smoking or quit altogether. Therefore, switching to combustion-free products has the potential to act as a gateway out of smoking. The personal preference for a particular product (e.g., e-cigarette vs HTP vs smokeless tobacco products) can play a critical role in increasing the likelihood of successfully abstaining from cigarette smoking…As for e-cigarettes, health professionals should consider all the options available to a smoking patient and opt for the ones that provide the greatest probability of quitting for good, including HTPs.*"

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2 This is a comparison between the smoke from combusted tobacco in a standard 3R4F reference cigarette (approximately 9 mg tar) and the vapour from heated tobacco in glo, in terms of the nine types of harmful components the WHO recommends to reduce. See also (1) Statement on the toxicological evaluation of novel heat-not-burn tobacco products by Committee on Toxicity – COT2017/04; December 2017; and (2) Toxicological evaluation of novel heat-not-burn tobacco products – non-technical summary.

3 PHE (2018), *Evidence review of e-cigarettes and heated tobacco products 2018: A report commissioned by Public Health England*.

4 COT (2017), *Statement on the toxicological evaluation of novel heat-not-burn tobacco products*.

5 Caponnetto et al. (2018), *Carbon monoxide levels after inhalation from new generation heated tobacco products*.

E-cigarettes

2.7 E-cigarettes contain no tobacco at all, do not rely on combustion, and, as a consequence, no smoke or tobacco tar is formed when the e-liquid is "vaped". BAT launched its first vapour product, Vype e-cigarette, in 2013 and is one of the world's leading e-cigarette companies.

2.8 An increasing number of health experts agree that vaping e-cigarettes is less harmful than smoking conventional cigarettes. For example:

2.8.1 A recent systematic review of the scientific literature undertaken by the National Academies of Sciences, Engineering, and Medicine for the U.S. Food and Drug Administration concluded, *inter alia*, that: "[t]*here is conclusive evidence that completely substituting e-cigarettes for combustible tobacco cigarettes reduces users' exposure to numerous toxicants and carcinogens present in combustible tobacco cigarettes.*"[6]

2.8.2 The PHE (2018) report recognised that "[v]*aping poses only a small fraction of the risks of smoking and switching completely from smoking to vaping conveys substantial health benefits over continued smoking. Based on current knowledge, stating that vaping is at least 95% less harmful than smoking remains a good way to communicate the large difference in relative risk unambiguously so that more smokers are encouraged to make the switch from smoking to vaping*" and that there have been "*no identified health risks of passive vaping to bystanders*" (emphasis added).[7]

2.8.3 The Scottish National Health Service in collaboration with several other public health bodies and NGOs, including Action on Smoking and Health Scotland, Cancer Research UK, and the UK Centre for Tobacco and Alcohol Studies, published a statement in 2017 in which it stated that "[t]*here is now agreement based on the current evidence that vaping e-cigarettes is* ***definitely less harmful*** *than smoking tobacco. Although most e-cigarettes contain nicotine, which is addictive, vaping carries less risk than smoking tobacco. Thus, it would be a good thing if smokers used them* ***instead*** *of tobacco.*"[8] (emphases in original)

2.8.4 A study funded by Cancer Research UK (2017) found that people who swapped smoking regular cigarettes for e-cigarettes or nicotine replacement therapy for at least six months had much lower levels of toxic and cancer causing substances in their body than people who continued to use conventional cigarettes.[9]

2.8.5 A study by Levy et al., (2017)[10] modelled the population impact in the future if more smokers in the US switched to e-cigarettes. They estimated that taking into account several parameters such as cessation, initiation and relative harm, switching cigarette smokers to e-cigarette use over a 10-year period would lead to 1.6 to 6.6 million fewer premature deaths in the US under a pessimistic and

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6 The National Academies of Sciences, Engineering, and Medicine (2018), *Public Health Consequences of E-Cigarettes*.

7 PHE (2018), *Evidence review of e-cigarettes and heated tobacco products 2018: A report commissioned by Public Health England*, at Chapter 4.

8 http://www.healthscotland.scot/publications/e-cigarettes-consensus-statement.

9 Shahab et al., (2017) *Nicotine, Carcinogen, and Toxin Exposure in Long-Term E-Cigarette and Nicotine Replacement Therapy Users.* Ann Intern Med, *390-400.*

10 Levy et al., (2017) *Potential deaths averted in USA by replacing cigarettes with e-cigarettes.* Tobacco Control. Aug 30.

optimistic scenario respectively. The authors concluded that "*a strategy of replacing cigarette by e-cigarette use can yield substantial gains, even with conservative assumptions about related risks. Most important, an e-cigarette substitution strategy provides the justification to redouble efforts to target cigarette use, as it is called for by the WHO Framework Convention for Tobacco Control.*" (emphasis added)

2.9 In view of the reduced harm from the use of e-cigarettes, an increasing number of governments and public health authorities support the use of e-cigarettes as an effective way for people to quit smoking. For example:

2.9.1 The PHE (2018) report found that "[i]*n the first half of 2017, quit success rates in England were at their highest rates so far observed and for the first time, parity across different socioeconomic groups was observed. It is plausible that EC* [e-cigarettes] *have contributed to this*" and that "[w]*hile caution is needed with these figures, the evidence suggests that ECs have contributed tens of thousands of additional quitters in England.*"[11]

2.9.2 The UK National Health Service supports the use of e-cigarettes in quit-attempts, referring to e-cigarettes on its "Stop smoking treatments" website, and stating that "*research has found that e-cigarettes can help you give up smoking, so you may want to try them rather than the medications listed above...*"[12].

2.9.3 A briefing note by Cancer Research UK (2016), "E-Cigarettes in Stop Smoking Services" recommends that "[S]*top Smoking Services are currently seeing a reduction in the number of clients and one contributing factor is likely to be the increase in e-cigarette use. These services should be accepting of e-cigarette use and support those who wish to use them alongside behavioural support as an aid to stop smoking.*" [13] (emphasis added)

2.9.4 The Royal College of Physicians has stated that "*smokers who use nicotine products as a means of cutting down on smoking are more likely to make quit attempts. Promoting wider use of consumer nicotine products, such as e-cigarettes, could therefore substantially increase the number of smokers who quit.*"[14]

2.9.5 Health Canada's current tobacco control strategy states "*[t]raditional cessation approaches are not the only tools available to help Canadians transition away from smoking cigarettes, the most deadly nicotine delivery system. A harm reduction approach aims to reduce the negative consequences of cigarette smoking by recognizing the potential benefits of using less harmful alternatives*". It adds "***Vaping is less harmful than smoking.*** *Completely replacing cigarettes with a vaping product will significantly reduce a smoker's exposure to toxic and*

11 PHE (2018), *Evidence review of e-cigarettes and heated tobacco products 2018: A report commissioned by Public Health England*, at Chapter 4.

12 http://www.nhs.uk/conditions/smoking-(quitting)/Pages/Treatment.aspx .

13 Cancer Research UK (2016), *E-Cigarettes in Stop Smoking Services*. Available at: https://www.cancerresearchuk.org/sites/default/files/e-cig_in_sss_0.pdf.

14 UK Royal College of Physicians (2016), Nicotine without smoke: Tobacco harm reduction.

cancer-causing chemicals. Adults can access vaping products containing nicotine as a less harmful alternative to smoking."[15] (emphasis in the original)

2.9.6 The New Zealand Ministry of Health states that "[s]*mokers switching to vaping products are highly likely to reduce their health risks and for those around them*" and "[s]*top smoking services should support smokers using vaping products to quit.*[16]

2.10 For a detailed illustration of the reduced risk potential of PRRPs, please refer to BATHK's previous submission to the Health Panel dated 16 May 2018 (LC Paper No. CB(2)1402/17-18(01) (Revised)).

3. THE CURRENT REGULATORY FRAMEWORK

3.1 Tobacco products are currently regulated under the Smoking (Public Health) Ordinance (Cap. 371) ("**SPHO**"). Under Part 3 of the SPHO, it is permissible to sell cigarettes and tobacco products in Hong Kong, provided that certain packaging and tar yield requirements are complied with.

3.2 THPs are a type of tobacco product. Under the current regulatory regime, it is **legal** to import and sell THPs in Hong Kong, provided that appropriate duty is paid. BATHK has therefore already commenced preparation to launch one of its THPs, i.e. *glo*, in Hong Kong.

3.3 As e-cigarettes do not contain tobacco, they are not regulated under the SPHO. However, e-cigarettes that contain nicotine may potentially be regulated under the Pharmacy and Poisons Ordinance (Cap. 138). Nevertheless, it is still **legal** to import and sell e-cigarettes containing nicotine in Hong Kong provided that the relevant regulations are complied with.

4. THE BILL

4.1 On 12 June 2018, the Food and Health Bureau issued a Legislative Paper to the Health Panel in relation to its proposal to regulate e-cigarettes and new tobacco products (including THPs) in a way similar to the current regulatory regime of cigarettes and tobacco products, i.e. the provisions in the SPHO.[17] In doing so, the Government agreed that the import and sale of e-cigarettes and THPs **should be legally permitted**, subject to similar regulations that apply to conventional cigarettes and tobacco products.

4.2 On 12 July 2018, the Chief Executive explained to the members of the Legislative Council of the Government's proposal to regulate new tobacco products. The Chief Executive stated that:

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15 Health Canada (2018), *Overview of Canada's Tobacco Strategy*, see: https://www.canada.ca/en/health-canada/services/publications/healthy-living/canada-tobacco-strategy/overview-canada-tobacco-strategy.html.

16 New Zealand Ministry of Health (2018), *Ministry of Health position statement – Vaping products*, see: https://www.health.govt.nz/our-work/preventative-health-wellness/tobacco-control/vaping-and-smokeless-tobacco.

17 LC Paper No. CB(2)1578/17-18(05) (https://www.legco.gov.hk/yr17-18/english/panels/hs/papers/hs20180619cb2-1578-5-e.pdf).

> "*... the Food and Health Bureau is proposing to strengthen regulation, such that these products are being regulated, at least on par with the conventional cigarettes for the protection of public health.*
>
> *Right now, the Secretary for Food and Health is consulting the sector, listening to various views, and we hope to take into account these views and introduce amendments to the Smoking (Public Health) Ordinance in the coming legislative session.*
>
> *But as far as a complete ban is concerned, Hong Kong does have to recognize her trade obligations in an international environment, because if conventional cigarettes are even more harmful, but they are allowed to be sold in Hong Kong under certain regulation, to go into a total ban of another form of tobacco product which is less harmful medically would raise many challenges. So, we have to really strike a balance.*"[18] (emphasis added)

4.3 The proposal was tabled at the Health Panel, and deliberations were based on the said proposal.

4.4 Notwithstanding these remarks by the Chief Executive, on 10 October 2018, without any prior consultation with the members of the tobacco industry or the general public, the Chief Executive unilaterally announced in her 2018 Policy Address that the Government would submit proposed legislative amendments to ban the import, manufacture, sale, distribution and advertisement of e-cigarettes and other smoking products. This is a complete change of position from the Chief Executive's remarks that were made only three months earlier which confirmed the Government's intention to regulate, not ban, such products.

4.5 The Bill and related Legislative Brief were then introduced to the Legislative Council and the Bills Committee in February and March 2019 respectively without consulting the Health Panel again.

4.6 Although the Bill does not specifically restrict the possession, purchase and use of Alternative Smoking Products, once implemented, it would be practically impossible for any individual to legally possess, purchase or use any of these products in Hong Kong (and in the case of existing users, at least when they have consumed all of the existing products that they have legally purchased) given that they would no longer be able to legally purchase them in Hong Kong or import them into Hong Kong for private use. In other words, the Bill is effectively a blanket ban on the use of Alternative Smoking Products in Hong Kong. This not only represents a drastic change in the Government's position but it is also inconsistent with the approach taken by leading countries around the world, such as in most countries in Europe, the UK, the US, Japan, S. Korea, Canada and New Zealand.

4.7 For the reasons explained below, it is clear that the Bill is unconstitutional, irrational, in breach of due process and inconsistent with Hong Kong's international trade obligations.

5. THE BILL IS IRRATIONAL

5.1 BATHK submits that the Bill is irrational. Rather than being evidence-based, the Bill is being driven by an irrational and outdated concept of an '*abstinence-only*' approach to tobacco control that ignores both the potential public health benefits that tobacco harm reduction strategies can bring, and undermines individual freedoms. There are alternative

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[18] https://www.legco.gov.hk/yr17-18/english/counmtg/hansard/cm20180712a-translate-e.pdf.

regulatory approaches that are available to support smokers in quitting conventional smoking, while minimising the potential risks presented by their use, as proposed by many experts and implemented in other countries.

5.2 Internationally, it is accepted that most of the harm associated with tobacco is caused by inhaling the smoke produced by the combustion of tobacco and not nicotine itself.[19] There is also recognition that different tobacco and nicotine products can have vastly different risk profiles, and that PRRPs have an important role in reducing the projected harms of smoking. For example, the findings of the 2007 report of the Royal College of Physicians (one of the oldest and most prestigious medical societies in the world) were unequivocal: "[i]*n this report we make the case for harm reduction strategies to protect smokers. We demonstrate that smokers smoke predominantly for nicotine, that nicotine itself is not especially hazardous, and that* ***if nicotine could be provided in a form that is acceptable and effective as a cigarette substitute, millions of lives could be saved.***" (emphasis added)[20]

5.3 Sweanor[21] et al. summarised the global public health implications of tobacco harm reduction, stating: "*The relative safety of smokeless tobacco and other smokefree systems for delivering nicotine demolishes the claim that abstinence-only approaches to tobacco are rational public health campaigns*" and concluded that "***Applying harm reduction principles to public health policies on tobacco/nicotine is more than simply a rational and humane policy. It is more than a pragmatic response to a market that is, anyway, already in the process of undergoing significant changes. It has the potential to lead to one of the greatest public health breakthroughs in human history by fundamentally changing the forecast of a billion cigarette-caused deaths this century.***" (emphasis added)[22]

5.4 A recent letter from a group of 72 independent specialists in nicotine science, policy and practice, calling on the WHO to embrace innovations in technology in the fight against diseases caused by smoking, also states: "[i]*n the field of tobacco control and public health, the world has changed significantly since the Framework Convention on Tobacco Control was signed in 2003. It is impossible to ignore or dismiss the rise of Alternative Nicotine Delivery Systems (ANDS). These are established and new technologies that deliver nicotine to the user without combustion of tobacco leaf and inhalation of tobacco smoke. These technologies offer the prospect of significant and rapid public health gains through 'tobacco harm reduction'. Users who cannot or choose not to quit using nicotine have the option to switch from the highest risk products (primarily cigarettes) to products that are, beyond reasonable doubt, much lower risk than smoking products (e.g. pure nicotine products, low-toxicity smokeless tobacco products, vaping or heated tobacco products). We believe this strategy could make a substantial contribution to the Sustainable*

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19 For a detailed discussion of the reduced risk potential of THPs and e-cigarettes, please refer to BATHK's previous submission to the Health Panel of the Legislative Council dated 16 May 2018 (LC Paper No. CB(2)1402/17-18(01) (Revised)).

20 Royal College of Physicians (2007). 'Harm reduction in nicotine addiction: helping people who can't quit. A report by the Tobacco Advisory Group of the Royal College of Physicians'.

21 David Sweanor, J.D., is a renowned public health advocate and Advisory Committee Chair of the University of Ottawa Centre for Health Law, Policy and Ethics. He has over 30 years' experience in public health policy, including spearheading the development of efforts to reduce cigarette smoking in Canada and globally.

22 Sweanor D, Alcabes P, Drucker E (2006), Tobacco harm reduction: how rational public policy could transform a pandemic, International Journal of Drug Policy 18 (2007) 70-74.

Development Goal to reduce premature deaths through non-communicable diseases (SDG Target 3.4)."[23]

5.5 The concept of tobacco harm reduction is also firmly embedded in the WHO Framework Convention on Tobacco Control ("**FCTC**"). Specifically, in defining tobacco control, Article 1(d) of the FCTC recognises that "*tobacco control*" concerns not just "*a range of* [tobacco] *supply, demand*" measures, but also the adoption of "*harm reduction strategies that aim to improve the health of a population by eliminating or reducing their consumption of tobacco products and exposure to tobacco smoke*". Accordingly, the Government, as a party to which the FCTC applies (through China), is obliged to consider harm reduction measures as part of an overall tobacco control strategy.

5.6 The Bill is also irrational in the following aspects:

5.6.1 As explained in paragraphs 2.5 and 2.8 above, the use of THPs (such as *glo* and Neostiks) and e-cigarettes result in the emission of substantially less toxicants than conventional cigarettes. It is unreasonable, and indeed illogical, for the Government to adopt a blanket ban on all Alternative Smoking Products, whilst at the same time allowing people to smoke conventional cigarettes;

5.6.2 The Bill implements a blanket ban on all Alternative Smoking Products, the definition of which is extremely wide under the current Bill and does not take into account the specific health impacts of each such product. For example, it is wide enough to cover a device which generates an aerosol that contains no tobacco whatsoever;

5.6.3 The Government has not considered or responded to the significant volume of scientific evidence of the harm reduction benefits offered by THPs and e-cigarettes. BATHK has previously made public submissions to the Health Panel on 16 May 2018 enclosing a large volume of evidence which has apparently not been considered.[24] The Government has not explained why a blanket ban is required and favoured over regulation, notwithstanding the evidence submitted; and

5.6.4 We note that the Government only chose to conduct testing on one of the THPs among the many different THPs manufactured by different manufacturers and available in the international market, and each product could be very different and carry different risk levels. For example, whilst the Government noted that iQOS (the only product tested) burns the tobacco stick at about 260°C, we are instructed that BAT's *glo* would heat Neostiks at a lower temperature of approximately 240°C and consequently would be likely to produce fewer toxicants and lower levels of those toxicants. The substance and composition of Neostiks may also be different with that of iQOS. BATHK in fact provided samples of its THPs (i.e. *glo* and Neostiks) to the Government for laboratory testing in April 2018. However, all samples were returned untested by the Government in November 2018. The Government's approach in relying on only one product to impose a blanket ban on other products from a range of different manufacturers (which they have ignored and refused to test) is plainly unfair to other market participants, and is irrational. This approach also illustrates that the Government

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23 Abrams et al. (2018), 'Letter from seventy-two specialists in nicotine science, policy and practice'.

24 LC Paper No. CB(2)1402/17-18(01): https://www.legco.gov.hk/yr17-18/english/panels/hs/papers/hs20180521cb2-1402-1-e.pdf.

has not properly considered the health effects of all types of Alternative Smoking Products before deciding to introduce the Bill.

6. BREACH OF THE FUNDAMENTAL HUMAN RIGHT OF PRIVACY

The Bill is a clear restriction on the right to privacy

6.1 The right to privacy is a fundamental human right protected by Article 14 of the Hong Kong Bill of Rights, Article 17 of the ICCPR and Article 39 of the Basic Law, which provide, *inter alia*, that "[n]*o one shall be subjected to arbitrary or unlawful interference with his privacy*".

6.2 Privacy is the "*secluded part of every person's life in which, without outside interference, he or she may act independently*".[25] The Hong Kong Court has recognised that the concept of "privacy" under the ICCPR is indistinguishable to the concept of "private life" under Article 8 of the European Convention of Human Rights.[26]

6.3 The European Court of Human Rights has considered the nature of the right to privacy / private life as follows:

6.3.1 "[t]*he concept of "private life" is a broad term... It covers the physical and psychological integrity of a person*";

6.3.2 "*the notion of personal autonomy is an important principle underlying the interpretation of* [the guarantees of right to private life]";

6.3.3 "*The very essence of the* [European Convention of Human Rights] *is respect for human dignity and human freedom... the Court considers that it is under Article 8 that notions of the quality of life take on significance*"; and

6.3.4 "*The Court would observe that the ability to conduct one's life in a manner of one's own choosing may also include the opportunity to pursue activities perceived to be of a physically or morally harmful or dangerous nature for the individual concerned. The extent to which a State can use compulsory powers or the criminal law to protect people from the consequences of their chosen lifestyle has long been a topic of moral and jurisprudential discussion, the fact that the interference is often viewed as trespassing on the private and personal sphere adding to the vigour of the debate. However, even where the conduct poses a danger to health, or arguably, where it is of a life-threatening nature, the case-law of the Convention institutions has regarded the State's imposition of compulsory or criminal measures as impinging on the private life of the applicant within the scope of Article 8(1) and requiring justification in terms of the second paragraph*" (emphasis added).

6.4 In other words, a person's autonomy in respect of one's own private life is constitutionally guaranteed in Hong Kong. A person should be free to conduct one's own life in a manner of one's own choosing. This includes, for example, the food and drink that one consumes, as well as the activities that one chooses to do, even if the food/drink might negatively impact one's own health or if the activity might pose danger to one's own life.

6.5 The Government now intends to implement the Bill which is effectively a blanket ban on the use of Alternative Smoking Products. This has the practical effect of prohibiting an

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25 *Democratic Party v Secretary for Justice* [2007] 2 HKLRD 804.

26 *Democratic Party v Secretary for Justice* [2007] 2 HKLRD 804.

individual (capable of understanding the risks involved in the same and exercising his or her own autonomy) from using Alternative Smoking Products, even privately in one's own home, and even when alone (and therefore not affecting any members of the public). Whilst the use of these products might affect one's own health, the same is also true for smoking conventional cigarettes and the consumption of food or drink, notably alcohol, neither of which are banned. Indeed in this case, the proposed ban cannot be justified in any way because the Hong Kong Government is denying smokers the opportunity to move away from conventional cigarettes to PRRPs. The intended ban clearly intrudes such person's autonomy and human dignity and is in clear violation of the fundamental human right to privacy.

6.6 Indeed, the UK Supreme Court (whose decisions are highly persuasive in Hong Kong) has recently held that a comprehensive ban on smoking in a hospital (in which convicts with mental disorder were detained) engaged the right to private life under Article 8 of the ECHR.[27] The present case is even stronger – the Bill seeks to impose a comprehensive ban on the use of products that are potentially less harmful than the use of conventional cigarettes.

6.7 We wish to note that the Bill gives rise to an issue that is of fundamental public importance and with far-reaching implications. The issue is not just relevant to the ban on Alternative Smoking Products. The Bill sets precedent and opens a gateway to any future proposal of the Government to ban other personal activities, including private consumption of unhealthy food/alcohol and the private participation of life-threatening activities, with the same purported rationale – to restrict Hong Kong residents from taking part in activities that the Government considers harmful, even in circumstances where the individual concerned understands and accepts the risk involved in the activities and where the activities do not affect any other people. Hence, the Government's purported restriction of the right to privacy under this Bill must be carefully considered.

<u>The restriction on the fundamental right to privacy is disproportionate</u>

6.8 Since the Bill imposes a restriction on the fundamental right to privacy, the Government must discharge the burden to demonstrate that the restriction is proportionate, i.e.:[28]

6.8.1 the restriction must pursue a legitimate aim;

6.8.2 the restriction must also be rationally connected to that legitimate aim;

6.8.3 the restriction must be no more than necessary to accomplish that legitimate aim; and

6.8.4 the social benefit gained is not outweighed by the detrimental impact of the restriction.

6.9 In respect of the aim of the Bill, the Government noted the following in its Legislative Council Brief for the Bill:

6.9.1 "*4. The Food and Health Bureau submitted a proposal to the Legislative Council ("LegCo") Panel on Health Services ("HS Panel") on the regulation of alternative smoking products in June 2018. The proposal was heavily criticised by the*

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27 *McCann v State Hospitals Board for Scotland* [2017] 1 WLR 1455.

28 *Hysan Development Company Limited and Others v Town Planning Board and Another* (FACV 21/2015, 26 September 2016).

medical professions, education sector, parents and many members of the public. They were worried that allowing the sale of alternative smoking products with restrictions would not be adequate to protect public health, and would bring about very negative impact and pose health risks on children and adolescents in particular. A non-binding motion was passed at the HS Panel meeting on 19 June 2018, urging the Government to impose a full ban." (emphasis added);

6.9.2 "*5. Meanwhile, there is increasing evidence that both e-cigarettes and HNB products are definitely harmful to health and may bring about gateway effects...*" (emphasis added);

6.9.3 "*7. International studies have also concluded that the tar and nicotine yields in HNB products are comparable to conventional cigarettes. Even Philip Morris International's ("PMI") in vivo clinical data failed to show a statistically detectable difference between iQOS (short for "i Quit Ordinary Smoking", the HNB product developed by PMI) and conventional cigarette users for 23 of the 24 biomarkers of potential harm among American adults....*" (emphasis added);

6.9.4 "*8. While awaiting studies on the gateway effect of the newly introduced HNB products to accumulate, a US study examined consumers' perception about iQOS in Japan and Switzerland. Through expert interviews, product and marketing analysis and focus groups, the study concluded that iQOS was marketed as a "sophisticated, high tech and aspirational" product. Youth and young adults are more interested in such product positioning and this approach raises concern about youth appeal...*" (emphasis added);

6.9.5 "*9. On the other hand, WHO has tightened its guidelines on tobacco control. Further to the seventh session of the Conference of the Parties ("COP") to the WHO Framework Convention on Tobacco Control ("FCTC") which proposed, in November 2016, to its Contracting Parties to consider applying regulatory measures to, inter alia, prohibit the manufacture, importation, distribution, sale, presentation, etc., of e-cigarettes, the eighth session held in October 2018 proposed the same for HNB products.*"

6.10 It appears that the aim of the Bill is to:

6.10.1 Prevent children and adolescents from using Alternative Smoking Products (the "**Children Concern**");

6.10.2 Prevent the opening of a gateway to the consumption of conventional cigarettes (the "**Gateway Concern**");

6.10.3 prevent access to products with tar and nicotine yields that are comparable to conventional cigarettes (the "**Harm Concern**"); and/or

6.10.4 Respond to the alleged guideline of the WHO to prohibit Alternative Smoking Products (the "**FCTC Concern**").

6.11 However, in respect of:

6.11.1 The Children Concern – it is essential to have careful regard for the evidence and to properly assess to risks and benefits of any proposed intervention. Such an assessment would need to include, identifying the extent and patterns of any youth usage; assessing the extent to which any such usage is harmful, including whether the use is merely experimental or long term; and assessing the extent to

which any increased usage of PRRPs is displacing more harmful cigarette use by youth and adult smokers. In failing to undertake such an assessment, the Government cannot demonstrate that the Bill is adequate, necessary or proportionate. Indeed, contrary to the position asserted by the Chief Executive, the PHE (2018) report found that "[d]*espite some experimentation with these devices among never smokers, EC are attracting very few young people who have never smoked into regular use*" and that "*EC use among never smokers in GB remains very rare at less than 1%, similar to the level of use of NRT. Among never smokers who have ever used EC, a minority have used nicotine-containing liquids and the vast majority have not progressed to regular use.*"[29] A US study published by Kozlowski et al., (2017)[30] also concluded that "*risks for youth posed by e-cigarettes likely fall far short of those feared by the products' opponents*" and that, currently "*youth use of e-cigarettes is unlikely to increase the ranks of future cigarette smokers.*" Other studies also indicate that regular youth use is concentrated in young people who smoke[31] and there is evidence that young people use vaping products to reduce harm and to quit smoking[32]. In the 2018 United States Annual Review of Public Health, the authors also note: "[u]*nder all but the most implausible scenarios, population simulation modeling estimates millions of life years saved by employing the principles of harm minimization and switching smokers to safer ANDS products.*"[33] In any event, it is clear that a blanket ban of these products is not necessary at all and is excessive. A prohibition of sale of these products based on the age, **similar to the restriction imposed on sale of conventional cigarettes, would be more than sufficient to achieve this purpose**;

6.11.2 The Gateway Concern – the Government only claimed that the use of THPs "*may bring about gateway effects*" (emphasis added) and stated in paragraph 28 of Annex B of the Legislative Council Brief that "[t]*he presence of nicotine from the heating of real tobacco in HNB should bring about possibly stronger gateway and renormalisation effect, despite the lack of scientific evidence at this stage*" (emphasis added). In other words, the Government has openly admitted that there is currently no scientific evidence on any alleged gateway effect from the use of THPs. To the contrary, evidence suggests that e-cigarettes and THPs have provided a gateway out of smoking for millions of smokers. As a number of public health experts recently noted in a letter calling on the WHO to reject prohibition and embrace 'tobacco harm reduction' and risk-proportionate regulation of tobacco and nicotine products: "[m]*illions of smokers have moved from cigarettes to less harmful alternatives where the laws allow it. Where ANDS*

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29 McNeill A, Brose LS, Calder R, Bauld L & Robson D., *Evidence review of e-cigarettes and heated tobacco products 2018. A report commissioned by Public Health England.* London: Public Health England, 2018

30 Kozlowski et al. (2017), *Adolescents and e-cigarettes: Objects of concern may appear larger than they are.* Drug & Alcohol Dependence, 174:209-14.

31 Villanti et al. (2016), *Frequency of Youth E-Cigarette and Tobacco Use Patterns in the United States: Measurement Precision is Critical to Inform Public Health*, Vol. 19, Nicotine and Tobacco Research. Oxford University Press.

32 Shiffman S and Sembower MA (2017), *PATH Data: Harm Reduction is Teens' Top Reason for Using e-cigarettes.*

33 Abrams et al (2018), *Harm Minimization and Tobacco Control: Reframing Societal Views of Nicotine Use to Rapidly Save Lives*, Annu. Rev. Public Health 2018. 39:193–213.

have been popular, we have seen rapid declines in adult smoking, for example in the United Kingdom, Sweden, the United States, and in Japan where cigarette consumption fell by 27 percent in the two years between first quarter 2016 and the same period in 2018 following the introduction of heated tobacco products."[34];

6.11.3 The Harm Concern – as stated in paragraphs 2.6 and 2.8 above, the reduced-risk potential of Alternative Smoking Products as compared to conventional combustible cigarettes has been widely recognised by international public authorities. Although the Government appears to disagree with this view, the Government admitted in paragraph 7 of the Legislative Council Brief that certain THPs are at least "*comparable to conventional cigarettes*", as opposed to being more harmful. The Government has not explained what "*comparable*" means (e.g. whether the Government considers a difference of, say 30%, to be "*comparable*"). In any event, even if, on the Government's view (which is disagreed by BATHK), they are "*comparable*", the Government has not provided any justification as to why THPs should be banned whilst "*comparable*" conventional cigarettes should be permitted; and

6.11.4 The FCTC Concern – other than prohibition, the FCTC Conference of the Parties in fact also proposed its Contracting Parties to consider other types of regulation as appropriate (such as restrictions or regulations) on new generation products such as THPs. It did not require Contracting Parties to only consider prohibition as the only means.

6.12 Further, in considering whether the restriction is proportionate, it is important to bear in mind that:

6.12.1 The right to privacy is a fundamental human right concerning a person's dignity and autonomy, a right which must be respected by the Government. The role of the Government is to protect the welfare of the general public, but not to interfere with an individual's autonomy; and

6.12.2 The Bill effectively imposes a blanket restriction on the use of Alternative Smoking Products. A person is prohibited from using these products at all regardless of one's age, the place or the purpose for which they are to be consumed. A person cannot even exercise one's freedom to consume these products alone, in private, for the purpose of switching away from smoking conventional cigarettes. The extent of the constitutional right which the Bill seeks to restrict is therefore very significant.

6.13 In view of the above, it is clear that the Bill disproportionately infringes the fundamental human right to privacy, and is therefore unconstitutional.

7. DEPRIVATION OF CONSTITUTIONALLY PROTECTED PROPERTY RIGHTS

7.1 The Court of Final Appeal acknowledged that Articles 6 and 105 of the Basic Law expressly protect private property rights.[35] These rights are fundamental to a capitalist economy which is protected by Article 5 of the Basic Law.

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34 Abrams et al. (2018), 'Letter from seventy-two specialists in nicotine science, policy and practice'.

35 *Hysan Development Company Limited and Others v Town Planning Board and Another* (FACV 21/2015, 26 September 2016).

7.2 In *Michael Reid Scott v The Government of HKSAR*,[36] the Court found that property for the purposes of Article 105 of the Basic Law is a very wide concept and requires a "*wide and purposive interpretation*". Similar to property rights protected under Article 1 of the First Protocol to the Convention for the Protection of Human Rights and Fundamental Freedoms, the protection of property rights clearly extends to intangible properties, such as goodwill in a business.[37]

7.3 Although BATHK has not yet completed its launch of its THPs, *glo*, as explained in paragraph 2.2 above, these products are currently widely available for purchase outside Hong Kong (including in countries such as Japan and Korea) and can be brought into Hong Kong legally by individuals as long as appropriate duties are paid. **It has been held that a manufacturer of goods sold abroad, but whose goods were brought into the local jurisdiction by private individuals, would be considered as having established sufficient market within the local jurisdiction to have its goodwill protected in the local market.**[38] The goodwill attached to *glo* and Neostiks is therefore constitutionally protected in Hong Kong. The trademarks of *glo* and Neostiks are also registered under Trade Mark Ordinance (Cap. 559), and hence, legally protected as personal property in Hong Kong together with the registered patents.

7.4 If the Bill is passed, BATHK would not be permitted to sell, nor could Hong Kong residents legally purchase or import, and thus use, *glo* or Neostiks in Hong Kong. All of BAT and BATHK's goodwill, patents, and investments in *glo* and Neostiks will become of no meaningful or economic use, and hence, worthless in Hong Kong. Hence, the Bill does not merely restrict BAT and BATHK's property rights – it goes as far as to completely deprive BAT and BATHK of their goodwill, trademarks and investments in *glo* and Neostiks, which are property rights constitutionally protected under Articles 6 and 105 of the Basic Law. As such, similar to the infringement of the right to privacy, the Government must demonstrate that the Bill is proportionate to the extent of it imposing restrictions on those constitutional rights.

7.5 As demonstrated in paragraphs 6.8 to 6.13 above, it is clear that the Bill is disproportionate. In this connection, we wish to add that the restriction of property rights to be imposed by this Bill is even more disproportionate than the Government's previous reform relating to the increase in size of the graphic health warnings on cigarette packets – BATHK will be effectively denied the right to apply any of the *glo* and Neostiks trademarks (which are specific to THPs) at all to its THPs. There would remain absolutely no commercial value or utility in these trademarks in BAT/BATHK's Hong Kong market if the blanket ban was implemented.

7.6 Apart from the protection mentioned above, Article 105 of the Basic Law also requires the Government to protect the "*right to compensation for lawful deprivation of their property*" (emphasis added). This means that, even if the Bill is proportionate, the Government will still be liable to pay compensation for the complete deprivation of BAT and BATHK's goodwill, trademarks and investments in *glo* and Neostiks. The same also applies to other Alternative Smoking Products manufactured by other tobacco companies, exposing the Government to significant risks of claims and substantial liabilities.

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36 HCAL 188/2002, 7 November 2003.

37 See for example, *R (Nicholds) v Security Industry Authority* [2007] 1 WLR 2067 at [73].

38 *La SociÉtÉ Anonyme Des Anciens ÉTablissements Panhard Et Levassor v Panhard Levassor Motor Company, Limited* [1901] 2 Ch. 513.

8. BREACH OF HONG KONG'S CONSTITUTIONALLY GUARANTEED STATUS AS A FREE PORT

8.1 Articles 114 and 115 of the Basic Law expressly guarantee Hong Kong's status as a free port and protect free trade and free movement of goods:

Article 114

The Hong Kong Special Administrative Region shall maintain the status of a free port and shall not impose any tariff unless otherwise prescribed by law.

Article 115

The Hong Kong Special Administrative Region shall pursue the policy of free trade and safeguard the free movement of goods, intangible assets and capital.

8.2 The Bill imposes a blanket ban on all import of smoking products. It is indisputable that the Bill engages Articles 114 and 115.

8.3 Indeed, prohibitions on the sales/import of tobacco and alcohol products have been found to engage the European counterpart to Articles 114 and 115 of the Basic Law, i.e. Article 34 of the Treaty on the Functioning of the European Union ("**TFEU**"), which provides that "*Quantitative restrictions on imports and all measures having equivalent effect shall be prohibited between member states.*"

8.4 For example, in *R (Sinclair Collis Ltd) v Secretary of State for Health*[39], a prohibition on the sale of tobacco from automatic vending machines in the United Kingdom was found to engage Article 34 TFEU for impeding on the claimant's ability to import tobacco vending machines into the United Kingdom. The European Court of Justice (the "**ECJ**") similarly found in *Rosengren and Others v Riksaklagaren*[40] that a ban imposed by the Swedish Government on the importation of alcoholic drink by private individuals into Sweden engaged Article 34 TFEU.

8.5 Where the free movement of goods is restricted, the ECJ held that "*it is for the national authorities to demonstrate that those rules are consistent with the principle of proportionality, that is to say, that they are necessary in order to achieve the declared objective, and that that objective could not be achieved by less extensive prohibitions or restrictions, or by prohibitions or restrictions having less effect on intra-Community trade*" (emphasis added).[41]

8.6 Applying this proportionality analysis, the ECJ in *Rosengren* found that the Swedish Government could not show that the complete ban on import of alcoholic drink by private individuals was necessary in order to achieve the declared objective of protecting public health, or that the public goal could not be achieved by a less extensive prohibition, such as a restriction based on age. Hence, the ban was held to be a disproportionate restriction on the free movement of goods, and therefore, unconstitutional.

8.7 Similar considerations apply to the Bill. As explained in paragraphs 6.8 to 6.13 above, it is plainly not necessary to impose a blanket ban on these products. Less extensive restrictive measures are available, including age restriction on sale and use (held in *Rosengren* to be an alternative means) and appropriate marketing restriction.

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39 [2012] QB 394.
40 (Case C-170/04) [2007] ECR I-4071.
41 *Rosengren and Others v Riksaklagaren* (Case C-170/04) [2007] ECR I-4071 at [50].

8.8 As such, the Bill disproportionately restricts the free movement of goods protected under the Basic Law, and impermissibly threatens Hong Kong's constitutionally guaranteed status as a free port.

9. BREACH OF DUE PROCESS

9.1 The Government's previous representation to regulate new tobacco products, rather than ban them outright, gave rise to a legitimate expectation that it will still be legal to import and sell Alternative Smoking Products in Hong Kong. In reliance of this legitimate expectation, BATHK has commenced preparation for the launch of its THPs, namely, *glo* and Neostiks, in Hong Kong and incurred considerable expenses as a result.

9.2 The Government's unilateral and complete change in position in October 2018 represents a clear departure from the legitimate expectation. The Government has not at any time sought to consult BATHK or other members of the tobacco industry. The introduction of the Bill is therefore in breach of due process.[42]

9.3 Further, the Bill represents a significant departure from the Government's existing policy on regulation of tobacco and nicotine products. BATHK, as well as other members of the tobacco industry, has a legitimate expectation that the Government would follow fair and proper regulatory processes, such as conducting a formal public consultation and Regulatory Impact Assessment (to properly consider the impacts, costs and benefits of the Bill) before any significant tobacco control reform such as the Bill. However, the Government had neither produced any consultation document for the public to consider the Bill nor invited the public to submit their views on the same before introducing the Bill, which deviates from the long-established standards and consultation practices adopted by the Food and Health Bureau. Moreover, notwithstanding that the Government first introduced its proposal to regulate Alternative Smoking Products in the Health Panel, it proceeded to introduce the Bill directly in the Legislative Council without any attempt to consult with members of the Health Panel.

9.4 The Bill is therefore introduced by the Government in breach of due process and the legitimate expectation of BATHK.

10. INCONSISTENCY WITH HONG KONG'S INTERNATIONAL OBLIGATIONS

10.1 As referred to in paragraph 4.2 above, the Chief Executive explained to the members of the Legislative Council on 12 July 2018 that:

"*But as far as a complete ban is concerned, Hong Kong does have to recognize her trade obligations in an international environment, because if conventional cigarettes are even more harmful, but they are allowed to be sold in Hong Kong under certain regulation, to go into a total ban of another form of tobacco product which is less harmful medically would raise many challenges. So, we have to really strike a balance.*" (emphasis added)

10.2 In other words, the Chief Executive is aware that the Bill, constituting a blanket ban of Alternative Smoking Products, is inconsistent with Hong Kong's trade obligations.

10.3 Indeed, as will be illustrated below, the Bill is:

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42 *Ng Siu Tung & Others v Director of Immigration* (2002) 5 HKCFAR 1.

10.3.1 In breach of the GATT of the WTO;

10.3.2 In breach of Hong Kong's bilateral treaties, including the IPPA signed between Hong Kong and the United Kingdom; and

10.3.3 In any event not required by the WTO FCTC.

The Bill is in breach of the GATT

10.4 Article XI of the GATT of the WTO, of which Hong Kong is a member, provides that:

"*No prohibitions or restrictions other than duties, taxes or other charges, whether made effective through quotas, import or export licences or other measures, shall be instituted or maintained by any contracting party on the importation of any product of the territory of any other contracting party or on the exportation or sale for export of any product destined for the territory of any other contracting party.*"

10.5 Unlike the current legislative regime for conventional cigarettes which includes the imposition of duties (which is permissible under Article XI), the Bill constitutes a complete and absolute ban on the importation of Alternative Smoking Products. This is clearly captured by Article XI.

10.6 Further, in view of the following factors, the Bill cannot be saved by the general exceptions permitted under Article XX(b) of the GATT for measures that are necessary to protect human health:

10.6.1 The threshold for the "necessity" test is high – the WTO Appellate Body has recognised that a "necessary" measure is "*located significantly closer to the pole of **'indispensable'** than to the opposite pole of simply 'making a contribution to'*" (emphasis added).[43]

10.6.2 The WTO Appellate Body has recognised that an import ban is "*by design as trade-restrictive as can be*" and that "*when a measure produces restrictive effects on international trade as severe as those resulting from an import ban, it appears to us that it would be difficult for a panel to find that measure necessary unless it is satisfied that the measure is apt to make a material contribution to the achievement of its objective*" (emphasis added).[44]

10.6.3 To demonstrate that an import ban brings about a material contribution or is indispensable to the achievement of its objective, the Government has to support it by evidence, data, quantitative projections or qualitative reasoning based on a set of hypothesis that are tested and supported by sufficient evidence.[45] The Government has, however, adduced none of these. To the contrary, there is a significant volume of evidence showing that THPs and e-cigarettes emit significantly lower level of toxicants than conventional cigarettes and are potentially less harmful alternative to conventional smokers (see paragraphs 2.5

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43 Appellate Body Report, *Korea – Measures Affecting Imports of Fresh, Chilled and Frozen Beef*, WT/DS161/AB/R, WT/DS169/AB/R (11 December 2000), para. 161; see also Appellate Body Report, *Brazil – Measures Affecting Imports of Retreaded Tyres*, WT/DS332/AB/R (3 December 2007), para. 141.

44 Appellate Body Report, *Brazil – Measures Affecting Imports of Retreaded Tyres*, WT/DS332/AB/R (3 December 2007), para 150.

45 Appellate Body Report, *Brazil – Measures Affecting Imports of Retreaded Tyres*, WT/DS332/AB/R (3 December 2007), para 151.

and 2.8 above). These all point against any suggestion that the Bill brings about any material contribution or is indispensable to the protection of public health.

10.6.4 Further, less restrictive alternative measures are available, such as setting appropriate product safety standards and ensuring that robust laws are put in place that prevent the sale of Alternative Smoking Products to minors. The availability of these far less restrictive alternative measures plainly illustrates that it is not necessary to implement a blanket ban on the import of Alternative Smoking Products.

10.7 In light of the above, the Government faces considerable difficulties to justify that an import ban of these potentially reduced risk products is necessary to protect public health. The Bill is therefore in breach of the GATT.

The Bill is in breach of international bilateral agreements

10.8 The Bill is also in breach of the bilateral agreements signed by Hong Kong. For example, the IPPA signed between Hong Kong and the United Kingdom provides that:

10.8.1 "*Investments and returns of investors of each Contracting Party shall at all times be accorded fair and equitable treatment... Neither Contracting Party shall in any way impair by unreasonable or discriminatory measures the... use, enjoyment... of investment in its area of the other Contracting Party*" (IPPA Article 2(2)).

10.8.2 "*Investors of either Contracting Party shall not be deprived of their investment... except lawfully, for a public purpose related to the internal needs of that Party on a non-discriminatory basis and against compensation.*" (IPPA Article 5).

10.9 For reasons explained in section 5 above, the Bill is not only unreasonable but also irrational. The unreasonable measure to be introduced by the Bill, which results in effectively a complete deprivation of the investments of foreign investors, such as BAT (which is based in the United Kingdom), is in clear breach of IPPA Article 2(2).

10.10 Further, IPPA Article 5 requires any lawful deprivation of foreign investment to be compensated. For reasons similar to paragraph 7.6 above relating to Article 105 of the Basic Law, the Bill would expose the Government to potentially significant liability for compensation to foreign investments in Alternative Smoking Products.

11. OTHER POLICY CONSIDERATIONS

11.1 Apart from the above legal issues, BATHK wishes to highlight the following policy considerations, all of which militate against the introduction of the Bill:

11.1.1 There is ample evidence from many developed government departments or authoritative bodies on the reduced risk potential of Alternative Smoking Products, indicating that these products can be a less harmful option for many conventional cigarette users;[46]

11.1.2 The WHO FCTC Conference of the Parties merely recommended in the eighth session that Contracting Parties should consider regulatory measures as

[46] For a detailed discussion of the reduced risk potential of THPs and e-cigarettes, please refer to our previous submission to the Health Panel dated 16 May 2018 (LC Paper No. CB(2)1402/17-18(01) (Revised)).

appropriate to local laws. Hong Kong has one of the lowest rates of smoking around the world.[47] Further, Hong Kong adult consumers are sensible and can and should not be unfairly prevented from making their own decision as to what products to consume. The current proposed extreme measure does not suit Hong Kong local circumstances;

11.1.3 There are around 40 countries around the world (mostly developed countries) that have allowed the sales of these Alternative Smoking Products;

11.1.4 As stated in paragraph 5.6.4 above, the Government's testing of THPs was tilted towards one company's product, and excluding BAT's THPs. In any event, the Government has not disclosed the testing methodology. It should be noted that the testing methodology for THPs should not be equivalent to those adopted for conventional cigarette;

11.1.5 As stated in paragraph 6.11.2 above, the Government has produced no evidence of the alleged gateway and renormalization effects from THPs. Further, many of the surveys or researches conducted by the Government on the Alternative Smoking Products are not published despite repeated requests by various parties. BATHK urges the Government to fully publish all relevant surveys, reports or studies quoted by the Government in the Bill with full transparency to the members of the Bills Committee and members of the public; and

11.1.6 BAT never targets its products, whether conventional cigarette or Alternative Smoking Products, to minors. The Children Concern does not justify a blanket ban of these products as it can be sufficiently addressed by restricting sales of the Alternative Smoking Products to minors in Hong Kong.

12. CONCLUSION

12.1 In view of the above, the Bill is clearly irrational and disproportionate, violates the fundamental human right of privacy and right of private property, disproportionately restricts the free movement of goods, impermissibly threatens Hong Kong's guaranteed status as a free port, is in breach of due process and inconsistent with Hong Kong's international obligations. Before deciding to introduce this Bill, the Government should first conduct a public consultation in relation to these matters.

12.2 Rather than banning these new technologies, the Government should develop regulatory solutions for bringing high quality PRRPs including Alternative Smoking Products to market and supporting smokers who want to switch from conventional smoking. Any legitimate concerns about safety and quality, access by young people etc., can be addressed by product regulations of which there is growing experience in other countries, including in Europe, the UK, the US, Canada and New Zealand. A real opportunity exists for the Government to drive change that could benefit the lives of millions of smokers, rather than creating a legacy of further failed tobacco policy and potential harm to consumers and the economy.

47 https://www.info.gov.hk/gia/general/201803/22/P2018032200255.htm.

12.3 BATHK therefore respectfully urges the Government to withdraw the Bill and to work with all stakeholders to establish an evidence-based, appropriate regulatory regime that properly reflects the risk profile of Alternative Smoking Products and respects the constitutionally protected rights and freedom of Hong Kong residents.

Yours faithfully,

Herbert Smith Freehills

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Your ref

Date
21 June 2019

By email and by hand

Dear Sirs

Smoking (Public Health) (Amendment) Bill 2019

We act for British-American Tobacco Company (Hong Kong) Limited.

We refer to the letter from the Secretary for Food and Health to the Assistant Legal Adviser of the Legislative Council dated 15 May 2019 (LC Paper No. CB(2)1431/18-19(04)), in particular paragraphs 2 to 8 thereof which were made in response to our letter dated 18 February 2019 (the "**Response**"). The purpose of this letter is to comment on and provide BATHK's views in relation to the Response. We should be grateful if you could kindly table a copy of this letter for consideration by the members of the Bills Committee for the meeting on 25 June 2019.

Unless otherwise specified, terms defined in our previous submission dated 8 April 2019 (LC Paper No. CB(2)1175/18-19(11)) (the "**April Submission**") shall have the same meaning herein for ease of reference.

For the reasons detailed below, BATHK is of the view that the Response is inaccurate and misleading, in particular because it contains an incorrect statement of the relevant legal principles. Notwithstanding the Response, BATHK considers that the Government has failed to justify its proposal to restrict fundamental human rights and disregard Hong Kong's international obligations through the implementation of the Bill.

1. INCORRECT APPLICATION OF THE PROPORTIONALITY TEST

1.1 The Government stated in paragraph 4 of the Response that "[t]*he proposed full ban is not*

disproportionate to the accomplishment of that legitimate aim [i.e. for the protection of public health], *as there are no less restrictive measures that can achieve the very high level of public health protection*".

1.2 With all due respect, this is clearly inconsistent with the Government's position that was made public only four months before the Chief Executive's decision to introduce the Bill. In the Food and Health's Legislative Paper dated 12 June 2018, the Government stated that it had "*critically reviewed the scientific evidence, overseas practices and WHO recommendations*" and was of the view that Alternative Smoking Products should be subject to regulation, as opposed to an outright ban. This illustrates that the Government, after detailed study of the evidence, agreed that a less restrictive measure (namely, a regulatory regime) can still achieve the "*very high level of public health protection*" sought by the Government. This analysis applies equally to the analysis under Hong Kong's international WTO obligations discussed below, where the availability of less restrictive alternatives contradicts the claim of justification under Article XX of GATT.

1.3 In applying the proportionality test, the Government failed to assess the impact of the Bill on public health **overall**. The Government merely considered the alleged "*health risks and the gateway and renormalisation effects posed by*" Alternative Smoking Products (which are in any event not substantiated for reasons explained in paragraph 6.11.2 of the April Submission) without taking into account two important factors that would also affect public health, namely:

1.3.1 the potential benefits that Alternative Smoking Products can contribute to public health; and

1.3.2 the fact that the use of conventional cigarettes will still be permitted for sale after the implementation of the ban of Alternative Smoking Products that are potentially less harmful (and indeed, the Government could not provide any evidence that Alternative Smoking Products are more harmful than conventional cigarettes).

1.4 As stated in the April Submission, there is growing evidence on the harm reduction benefits offered by the use of THPs and e-cigarettes. These products are a potentially less harmful option for many conventional cigarette users and a means to assist smokers to quit smoking, thereby reducing the health impact caused by conventional cigarettes (and thereby facilitating the protection of public health).

1.5 Indeed, governments in major developing countries took into account these public health benefits when formulating policies on THPs and/or e-cigarettes. For example:

1.5.1 The New Zealand Government decided to regulate, rather than ban, e-cigarettes and other tobacco products. The Ministry of Health further "*encourages smokers who want to use vaping products to quit smoking to seek the support of local stop smoking services*...[which] *must support smokers who want to quit with the help of vaping products*";[1]

1.5.2 The Government of Canada enacted the Tobacco and Vaping Products Act on 23 May 2018 which legalised, *inter alia*, the manufacturing and sale of vaping products in Canada – which is the exact opposite of the total ban proposed by the Hong Kong Government;

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[1] New Zealand Ministry of Health (2018), *Ministry of Health position statement – Vaping products*, see: https://www.health.govt.nz/our-work/preventative-health-wellness/tobacco-control/vaping-and-smokeless-tobacco.

1.5.3 The US Food and Drug Administration announced on 30 April 2019 that it has authorised the marketing of one of the THPs, recognising that authorising these products for the US market "*is appropriate for the protection of the public health because, among several key considerations, the products produce fewer or lower levels of some toxins than combustible cigarettes*".[2] It further explained that this decision is based on a comprehensive analytical standard (notably absent in the Government's Response) which:

> *"requires the FDA to consider the risks and benefits to the population as a whole, including users and non-users of tobacco products. Importantly this includes youth. The agency's evaluation includes reviewing a tobacco product's components, ingredients, additives and health risks, as well as how the product is manufactured, packaged and labeled. The review for the ... products took into account the increased or decreased likelihood that existing tobacco product users will stop using tobacco products, and the increased or decreased likelihood that those who do not use tobacco products will start using them*" (emphasis added); and

1.5.4 The United Arab Emirates previously banned the sales of e-cigarettes. However, after conducting a review of data on alternative smoking products, the United Arab Emirates lifted its ban following the new rule UAE.S 5030 in April 2019.[3]

1.6 In contrast, the Hong Kong Government has failed to take into account these harm reduction benefits that have been widely recognised by major governments around the world. It is important to note that whilst a total ban of these products might potentially reduce the associated health risks, it will at the same time remove all the harm reduction benefits that these products can contribute to public health. It would be wrong and irresponsible for the Government to selectively highlight the risks whilst ignoring the benefits in assessing whether the Bill would, on balance, make a meaningful contribution to the objective of protecting public health.

1.7 The Government also took an overly simplistic view in concluding that a total ban would reduce risks to public health. As mentioned in paragraph 1.3 above, the use of Alternative Smoking Products is not the only factor that would affect public health. Each factor carries different weight in terms of its effect on public health. Given that there are many more existing users of conventional cigarettes and that conventional cigarettes are more harmful than Alternative Smoking Products, the use of conventional cigarettes would, in fact, likely be the dominant factor that would affect public health. The Government has not conducted any study to assess how this dominant factor might affect public health in circumstances where Alternative Smoking Products are banned.

1.8 In particular, by imposing a blanket ban over Alternative Smoking Products while continuing to permitting the sale of conventional cigarettes, the Government might be sending a confusing and/or misleading message to the general public that it is safer (because it is legal) to smoke conventional cigarettes rather than to use Alternative Smoking Products (which will be banned). This may result in an undesirable effect of

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2 US Food & Drug Administration (2019), 'FDA permits sale of IQOS Tobacco Heating System through premarket tobacco product application pathway', see: https://www.fda.gov/news-events/press-announcements/fda-permits-sale-iqos-tobacco-heating-system-through-premarket-tobacco-product-application-pathway.

3 The National, 'UAE to allow sale of e-cigarettes and vaping devices': see: https://www.thenational.ae/uae/health/uae-to-allow-sale-of-e-cigarettes-and-vaping-devices-1.826798.

encouraging the public, especially previous conventional smokers who may have switched to Alternative Smoking Products, to switch back to conventional cigarettes.

1.9 On the other hand, there is evidence that the smoking population has decreased rapidly and markedly in jurisdictions where Alternative Smoking Products are legally permitted. As stated in the April Submission, a number of public health experts recently noted in a letter to the WHO, calling on it to reject prohibition and embrace 'tobacco harm reduction' and risk-proportionate regulation of tobacco and nicotine products, that "[m]*illions of smokers have moved from cigarettes to less harmful alternatives where the laws allow it. Where ANDS have been popular, we have seen rapid declines in adult smoking, for example in the United Kingdom, Sweden, the United States, and in Japan where cigarette consumption fell by 27 percent in the two years between first quarter 2016 and the same period in 2018 following the introduction of heated tobacco products.*"[4] In view of the evidence available, a ban of Alternative Smoking Products would be unlikely to have any **net** positive effect on public health overall, and hence could not satisfy the proportionality test.

1.10 As mentioned in the April Submission, the Government has the burden to demonstrate that any proposed restriction on fundamental rights is proportionate by passing the four-stage proportionality test. The Government, by failing to properly assess the impact of the full ban on the overall public health in Hong Kong (in particular the fact that a full ban on Alternative Smoking Products would unfairly eliminate the harm reduction benefits associate with these products and would in turn permit the continued use of more harmful, conventional cigarettes), cannot demonstrate that the ban is rationally connected to the protection of public health, which is the second stage of the proportionality test. In any event, for reasons already detailed in the April Submission (in particular paragraphs 6.11 and 6.12 thereof), a total ban is not necessary to protect public health and banning a potentially less harmful type of products would not give rise to any social benefit (or at the very least, any such benefit would be outweighed by the detrimental impact in restricting fundamental human rights concerning a person's dignity and autonomy), failing both the third and fourth stages of the proportionality test.

2. DEPRIVATION OF PROPERTY

2.1 As stated in the April Submission, the Bill amounts to deprivation of property which requires compensation from the Government. In response, however, the Government merely stated that "*it is the Government's assessment that the Bill would not give rise to deprivation of property requiring real value compensation under the Basic Law*" without giving any reasons to explain how it arrived at this assessment.

2.2 Further, the Government's argument that the Bill would likely satisfy the proportionality test under Articles 6 and 105 of the Basic Law (which is denied by BATHK), even if accepted by the Court, does not absolve the Government from its obligation to provide compensation. Although property rights protected under Articles 6 and 105 of the Basic Law may be subject to restrictions that are reasonably proportionate, Article 105 expressly provides for a right to compensation for "*lawful deprivation of their property*", i.e. a deprivation of property that passes the proportionality test.

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[4] Abrams et al. (2018), 'Letter from seventy-two specialists in nicotine science, policy and practice'.

3. BREACH OF HONG KONG'S CONSTITUTIONALLY GUARANTEED STATUS AS A FREE PORT

3.1 The Government purports to rely on the Smokeless Tobacco Products (Prohibition) Regulations to justify the Bill's restriction on the free movement of goods protected under Articles 114 and 115.

3.2 However, this is wholly misconceived for the following reasons:

3.2.1 The Smokeless Tobacco Products (Prohibition) Regulations were introduced prior to the implementation of the Basic Law. According to Article 8 of the Basic Law, all laws previously in force in Hong Kong shall be maintained only if they do not contravene the Basic Law. Whether the Smokeless Tobacco Products (Prohibition) Regulations are consistent with Articles 114 and 115 is still a question to be tested in Court.[5] The fact that the Smokeless Tobacco Products (Prohibition) Regulations exist, of itself, does not mean that that or another similar import ban is justified; and

3.2.2 The Government failed to cite any authority that Articles 114 and 1115 can be restricted in the way proposed by the Bill.

4. BREACH OF INTERNATIONAL OBLIGATIONS

4.1 The Government is also incorrect in stating that the proposed full ban under the Bill does not engage Article XI of GATT. The authorities have clearly established that the term "prohibition" under Article XI refers to a "*legal ban on the trade or importation of a specified commodity*".[6] It is beyond doubt that the ban of Alternative Smoking Products engages Article XI and further that it violates the provision without any justification under Article XX of GATT. Alternatively, even if the proposed ban were to be considered an internal measure banning sales (which does not seem to be the case for the Bill given it expressly provides for a ban on imports), rather than an external measure banning imports, the Government's proposal would still violate Article III of GATT without justification.

4.2 Further, enclosed to this letter is a legal opinion by Professor Petros Mavroidis, a respected international trade and WTO legal scholar, which explains that imposing an import and sales ban on Alternative Smoking Products while permitting combustible tobacco products to be legal for sale, import, distribution and consumption would be in breach of WTO obligations. The legal opinion specifically refers to the proposed ban in Hong Kong as one of the examples of such ban. We respectfully request that this legal opinion be consulted carefully before the Government undertakes any action that would be illegal under international law. We provide Professor Mavroidis' conclusions in summary form here:

> *"In summary form, our conclusion is that an import ban on* [Alternative Nicotine Delivery Systems or "ANDS"] *violates Article XI of GATT, since it constitutes a prohibition on importation, and thus a prohibited zero import quota. In addition, assuming the measure is characterized as domestic sales ban, our conclusion remains that a sales ban on ANDS, while no ban has been imposed on* [Traditional Cigarettes or "TCs"], *violates Article III of GATT. Our conclusion is*

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5 The Court can and has after the implementation of the Basic Law declared some pre-1997 legislations to be incompatible with the Basic Law. See, for example, *Secretary for Justice v Yau Yuk Lung Zigo and Another* (2007) 10 HKCFAR 335.

6 Appellate Body Report, *China – Measures related to the exportation of various raw materials*, AB-2011-5 WT/DS394/AB/R at paragraph 319.

based on the fact that ANDS and TCs are like products and a ban on imported ANDS, while allowing the sale of domestic TCs, amounts to Less Favourable Treatment for imported like products. As we explain in this Note, there is no need to inquire into the regulatory intent of the discriminatory ban on ANDS since any modification of the conditions of competition to the detriment of imported like products is prohibited.

Finally, we consider that the regulating Member will fail in trying to justify its measures under the general exceptions of Article XX of GATT, irrespective of whether the established violation concerns Article III or XI of GATT. There are good reasons to believe that the regulating Member will not meet the necessity-requirement, as it has to do in order to mount a successful defence of its otherwise GATT-inconsistent measure. The lack of contribution of the ban to the protection of health and the availability of less restrictive alternatives to a ban such as information campaigns and labelling render the ban unnecessary, it seems. In any case, even if the regulating Member were to be successful in demonstrating the "necessity" of the ban on ANDS, its measure will fail the requirements of the chapeau of Article XX of GATT. This is so because, the ban is a disguised restriction on trade and applied in a manner that constitutes unjustifiable discrimination: in the name of protecting human health (and/or public morals), the regulator will be banning the sale of certain goods while not banning the sale of like goods that are at least as harmful to health and probably much more harmful to health. Thus, it will find it impossible to explain why its decision to ban some and not other (more harmful) products, is rationally connected with the health objective of the measure. In sum, the measure is in violation of the GATT/WTO commitments of the regulating Member. The precautionary principle is of no relevance to the applicable GATT/WTO obligations and cannot, therefore, be invoked to save the measure." (emphasis added)

4.3 Other than Articles XI and III of GATT and the obligations explained in the April Submission, there are further international obligations which the Government has disregarded and/or failed to comply with in introducing the Bill:

4.3.1 First, Article V of GATT requires there to be freedom of transit through the territory of each contracting party, via the routes most convenient for international transit, and must not cause any unnecessary delays. It has been held that this requires WTO members to extend "*unrestricted access via the most convenient routes for the passage of goods in international transit whether or not the goods have been trans-shipped, warehoused, break-bulked, or have changed modes of transport*".[7] The proposed section 15DD in Clause 23 of the Bill, however, does not permit transhipment of Alternative Smoking Products to be stored temporarily in Hong Kong pending export unless the product remains in a vessel (if transported by sea) or in the aircraft or air transhipment cargo (if transported by air). Nevertheless, we are instructed that the majority of the tobacco related cargos come to Hong Kong by land and/or sea and would need to be removed from the vehicle or vessel pending the next transit or transhipment. This would be prohibited if the Bill is passed, resulting in an impermissible restriction on access to the most convenient routes for the passage of goods in international transit protected under GATT Article V; and

7 Panel Report, *Colombia – Indicative prices and restrictions on ports of entry*, WT/DS366/R at paragraph 7.401.

4.3.2 Second, under Article 2.9 of the Agreement on Technical Barriers to Trade, Hong Kong, as a member of WTO, is required to notify other WTO members, through the WTO Secretariat, at an early appropriate stage of proposed technical regulations that may have a significant effect on other WTO members' trade. The Bill prohibits import of goods from other WTO members bearing certain characteristics (e.g. goods capable of generating aerosol from tobacco) constitutes a technical regulation for this purpose.[8] However, insofar as we are aware, the Government has failed to comply with this important obligation to notify other WTO members of the Bill and allowing them to provide comments on the Bill.

In view of the above, and for reasons explained in the April Submission, the Government has incorrectly applied the proportionality test and failed to assess the overall impact of a full ban on public health. Notwithstanding that the Government acknowledged the existence of other less restrictive measures (such as the regulatory regime proposed by the Government in June 2018) which could also achieve a very high level of public health protection, the Government disregarded those measures and instead insisted on introducing the Bill that disproportionately restricts fundamental human rights and the free movement of goods guaranteed by the Basic Law. The Government also failed to comply with Hong Kong's international obligations in introducing the Bill. BATHK therefore respectfully urges the Government to withdraw the Bill and to work with all stakeholders to establish an evidence-based, appropriate regulatory regime that properly reflects the risk profile of Alternative Smoking Products and respects the constitutionally protected rights and freedom of Hong Kong residents.

Yours faithfully,

Herbert Smith Freehills

Encl

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[8] Appellate Body Report, *European Communities – Measures affecting asbestos and Asbestos-containing products*, AB-2000-11, WT/DS135/AB/R.

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Alternative Nicotine Delivery Systems (ANDS) such as e-cigarettes and heated tobacco products

Legal Opinion on Consistency of their Ban with WTO Law

Petros C. Mavroidis

Terms of Reference and Executive Summary

I am a professor of WTO Law at Columbia Law School, New York and at the University of Neuchâtel. I am associate editor of the Journal of World Trade, on the editorial board of The World Trade Review, and several Columbia Law journals. I recently served as chief co-rapporteur at the American Law Institute (ALI) for the project "Principles of International Trade Law: The WTO" (2013).

I am the author and editor of several books on international trade law. My most recent publication is The Regulation of International Trade, MIT Press, 2016, which won the 2017 Certificate of Merit in a Specialized Area of International Law from the Executive Council of the American Society of International Law (ASIL). I have also written around 80 articles referenced in peer-reviewed journals, and 80 chapters in books. A full CV is attached.

I was asked to opine on the consistency of a measure that would ban the importation and sale of novel tobacco products such as heated tobacco products as well as other new types of "electronic nicotine delivery systems" including e-cigarettes ("ENDS"). E-cigarettes are handheld devices that heat a liquid containing nicotine and flavours that are heated to form a vapour, which is inhaled to simulate the experience that smokers have but do not involve tobacco and often do not even look like a traditional cigarette. Heated tobacco products only heat tobacco and generate a nicotine-containing vapour. These products produce an aerosol that provides nicotine as well as a sensation similar to that of smoking traditional cigarettes (TC), but do not involve the burning of tobacco, and are thus non-combustible products.

Both novel products come under the generic term of "Alternative Nicotine Delivery Systems" (ANDS), a term that has been used by health experts for grouping these non-combustible products.[1] Recently, independent health experts have found that ANDS play an important role in a harm reduction strategy, precisely because they function as a less harmful alternative to smoking TCs.[2] Health experts, consequently, have called for a positive, less restrictive

[1] See, "Letter from seventy-two specialists in nicotine science, policy and practice - Innovation in tobacco control: developing the FCTC to embrace tobacco harm reduction", 1 October 2018, p. 2, Available at https://clivebates.com/documents/WHOCOP8LetterOctober2018.pdf.

[2] There are various studies, which support the view that ANDS, while addressed primarily to smokers and aiming to act as substitute for TCs, are less of a health concern than TCs, see, for example, https://www.annualreviews.org/doi/10.1146/annurev-publhealth-040617-013849. This observation is important for various parts of the legal analysis included in this Note. How can, to provide but an illustration, a measure be judged necessary to protect human health, if it addresses the lower risk for human health (that represented from

regulatory approach to ANDS. Indeed, it goes beyond the scope of this legal opinion, but it appears that the international legal regime on the right to health would indeed require a less rather than a more restrictive regime for these products. Depriving smokers of this less harmful alternative would go against the internationally protected right to health of those that smoke.[3] In sum, there is no doubt, as these letters as well as a recent scientific study also demonstrate,[4] that ANDS may provide an alternative to traditional cigarettes, since the risk to human health is likely to be reduced.

An import and sales ban is under consideration against ANDS in, for example, Singapore and Hong Kong (China).

For the purposes of this Note, I use the English translation of the Singaporean law as an accurate description of the measure, the consistency of which with the relevant WTO law I will analyse as an example.

The question is whether the ban on ANDS is consistent with the relevant WTO law. As the measure stands, it would be characterized as import embargo, since the letter of the law leaves us in no doubt that imports of ANDS will not be allowed in Singapore.

One cannot exclude, nevertheless, that a panel characterizes the measure as a domestic sales ban of ANDS. In this case, the domestic sales ban, would simply be enforced at the border (and would cover imported ANDS).

The legal test for consistency of an import ban, and a domestic sales ban, under the GATT, is not identical. We will be examining the consistency of the measure with WTO law under either scenario.

In addition, if the measure does not take the form of a simple ban, but, rather, the form of a technical regulation that lays down product characteristics of tobacco products and related

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consumption of ANDS), while leaving un-addressed the higher risk emanating in the consumption of the substitute product, namely, TCs?

[3] See, "Letter from seventy-two specialists in nicotine science, policy and practice - Innovation in tobacco control: developing the FCTC to embrace tobacco harm reduction", 1 October 2018, Available at https://clivebates.com/documents/WHOCOP8LetterOctober2018.pdf.

[4] https://journals.sagepub.com/doi/pdf/10.1177/2397847318773701.

products, such as arguably ANDS, the consistency of the measure could also be examined under the disciplines of the Agreement on Technical Barriers to Trade (TBT Agreement). Very similar considerations relating to discrimination and the requirement that the measure be "necessary" to fulfil the legitimate health objective as discussed in this note would apply under, in particular Articles 2.1 and 2.2 of the TBT Agreement respectively. In particular, Article 2.2 requires that a technical regulation not be more trade restrictive than necessary. Given the potential contribution to harm reduction offered by ANDS as highlighted by independent health experts, a measure that effectively bans ANDS or that imposes the same restrictions that are justified on TCs would have a very trade restrictive effect on these novel products in an emerging market. Therefore, even applying the same restrictions on ANDS as are applied to TCs necessarily appears to be violating this important provision given its highly trade restrictive character of a measure that would go against the health objective of harm reduction. Given that we are considering a straightforward ban on ANDS, we will not further address the TBT Agreement in this Note.

In summary form, our conclusion is that an import ban on ANDS violates Article XI of GATT, since it constitutes a prohibition on importation, and thus a prohibited zero import quota. In addition, assuming the measure is characterized as domestic sales ban, our conclusion remains that a sales ban on ANDS, while no ban has been imposed on TCs, violates Article III of GATT. Our conclusion is based on the fact that ANDS and TCs are like products and a ban on imported ANDS, while allowing the sale of domestic TCs, amounts to Less Favourable Treatment for imported like products. As we explain in this Note, there is no need to inquire into the regulatory intent of the discriminatory ban on ANDS since any modification of the conditions of competition to the detriment of imported like products is prohibited.

Finally, we consider that the regulating Member will fail in trying to justify its measures under the general exceptions of Article XX of GATT, irrespective of whether the established violation concerns Article III or XI of GATT. There are good reasons to believe that the regulating Member will not meet the necessity-requirement, as it has to do in order to mount a successful defence of its otherwise GATT-inconsistent measure. The lack of contribution of the ban to the protection of health and the availability of less restrictive alternatives to a ban such as information campaigns and labelling render the ban unnecessary, it seems. In any case, even if the regulating Member were to be successful in demonstrating the

"necessity" of the ban on ANDS, its measure will fail the requirements of the chapeau of Article XX of GATT. This is so because, the ban is a disguised restriction on trade and applied in a manner that constitutes unjustifiable discrimination: in the name of protecting human health (and/or public morals), the regulator will be banning the sale of certain goods while not banning the sale of like goods that are at least as harmful to health and probably much more harmful to health. Thus, it will find it impossible to explain why its decision to ban some and not other (more harmful) products, is rationally connected with the health objective of the measure. In sum, the measure is in violation of the GATT/WTO commitments of the regulating Member. The precautionary principle is of no relevance to the applicable GATT/WTO obligations and cannot, therefore, be invoked to save the measure.

To the extent that there exists a more general regime under public international law in favour of a right to health, it seems clear that this measure is inconsistent with such a right as it deprives smokers of products that are likely to be less harmful to health and that fulfil a similar end use. This was highlighted in a letter of seventy-two independent health experts, as discussed below.

1. Import Ban on ANDS

Since we deal with an import ban, the relevant provision is Article XI of GATT. Consequently, the legal question before us is, whether an import ban on ANDS is consistent with this provision.

Article XI.1 of GATT reads:

> No prohibitions or restrictions other than duties, taxes or other charges, whether made effective through quotas, import or export licences or other measures, shall be instituted or maintained by any contracting party on the importation of any product of the territory of any other contracting party or on the exportation or sale for export of any product destined for the territory of any other contracting party.

Since the early GATT case France-Import Restrictions, it is clear that measures expressed in numbers (e.g., 1,000 tons of widgets; or, 1,000 litres of widgets) are considered quotas, that is, one of the three forms that a quantitative restriction can revert into.

In *India – Quantitative Restrictions*, the panel (§5.129), when interpreting the term "restriction" appearing in the body of Article XI of GATT, clarified that this term covers both import- as well as export restrictions. We quote the relevant passage:

> [T]he text of Article XI:1 is very broad in scope, providing for a general ban on import or export restrictions or prohibitions 'other than duties, taxes or other charges'. As was noted by the panel in Japan –Trade in Semi-conductors, the wording of ArticleXI:1 is comprehensive: it applies 'to all measures instituted or maintained by a [Member] prohibiting or restricting the importation, exportation, or sale for export of products other than measures that take the form of duties, taxes or other charges.' The scope of the term 'restriction' is also broad, as seen in its ordinary meaning, which is 'a limitation on action, a limiting condition or regulation'.

A ban on imports of ANDS is obviously a covered "prohibition" on importation, as it imposes a zero quota.

There is no need to demonstrate that the measure has had certain trade effects, even if it would be quite obvious that a measure that bans all imports has an effect on trade.

Nor does the regulatory intent matter. In other words, it is irrelevant that a Member such as Singapore did not seek to protect a domestic industry.

Standing case law already from the GATT-era (Japan – Trade in Semi-conductors; US – Superfund) has confirmed the above, and has consistently held that there is no room for reviewing the regulatory intent within the four corners of complaints under Article XI of GATT.

This analysis leads to the conclusion that an import ban of ANDS is not consistent with WTO Members' obligations under Article XI of GATT.

Conclusion under GATT Article XI

A ban on imports of ANDS is a violation of Article XI of GATT.

2. Sales Ban on ANDS

The challenged measure could be re-phrased, as we have suggested in the introduction to this Note, and presented as a sales (as opposed to an import-) ban. The Interpretative Note ad Article III of GATT reads:

> Any internal tax or other internal charge, or any law, regulation or requirement of the kind referred to in paragraph 1 which applies to an imported product and to the like domestic product and is collected or enforced in the case of the imported product at the time or point of importation, is nevertheless to be regarded as an internal tax or other internal charge, or a law, regulation or requirement of the kind referred to in paragraph 1, and is accordingly subject to the provisions of Article III.

If the measure, thus, were re-designed to read that "sales of ANDS are prohibited within the sovereignty of ...", it could be enforced at the border with respect to imported ANDS, just like an import embargo. It will, in other words, operate as an import ban, even though the legal nature of the measure suggests that it qualifies as a behind the border non-tariff barrier.

Contrary to the scenario discussed under Section 1, the measure, as re-phrased here, applies to both imported, as well as domestic goods.

In this scenario, the relevant legal question is whether there is treatment less favourable for imported goods when compared to treatment afforded to domestic "like" goods.

A sales ban is a domestic (behind the border) measure, and as such, it must observe the discipline embedded in Article III.4 of GATT. A sales ban as envisaged here is covered by the disciplines of Article III.4 since it is undoubtedly a law, regulation or requirement affecting commerce (i.e. the products' internal sale, offering for sale, purchase, transportation, distribution or use).

The sequence established (in the sense of order of analysis), is to first examine what is the class of goods that are considered "like", and then, examine if imported goods have been afforded "less favourable treatment" (LFT).

2.1 Are ANDS and Traditional Cigarettes Like/Directly Competitive or Substitutable (DSC) Goods?

For the purposes of our discussion, we assume that the claim is that the sales ban concerns ANDS (domestic and imported), and does not concern domestic and imported traditional cigarettes (TCs). So, while TCs irrespective of origin can be sold in a given market, ANDS cannot.

The question we address here is whether an imported ANDS, and a domestic TC are like products. In this vein, we can draw strong parallels with *EC – Asbestos*, the leading case under Article III.4 of GATT, which dealt with a dyad of goods of this sort.

The term "like products" appears in both Article III.2 as well as III.4 of GATT. The former provision distinguishes between "like" and "directly competitive products". Both terms refer to the competitive relationship between domestic and imported goods, the first to an intense, and the second to a looser competitive relationship. In *Japan – Alcoholic Beverages II*, the Appellate Body held that two goods are like, if they are in a strong competitive relationship. The latter could be evidenced, for example, when two goods share the same elaborate classification. In this case, the Appellate Body held that, sharing the same six-digit classification, was enough of an indication supporting a finding of likeness (pp. 23-24). In a subsequent case, in *Philippines – Distilled Spirits*, the Appellate Body underscored that it was not necessary to share the same six-digit classification for two goods to be like. What mattered was that they were in a strong competitive relationship (§§182, and 226 *et seq.*).

In our case, TCs and ANDS do not share the same six-digit classification. The former come under HS 2402, whereas ANDS can come under various headings. In fact, there is still quite a bit of debate on where these new products should be classified. This debate is still ongoing before the World Customs Organization (WCO).

As per the ruling on *Philippines – Distilled Spirits* though, the fact that ANDS and TCs do not share the same six-digit classification, is not determinative of whether the goods are

"like" one another.[5] More important than classification, the adjudicator will have to look into other criteria before concluding whether this is or is not the case, such as, among others, physical characteristics, end uses, and consumer preferences.

We submit that in this case, the answer is clear. In *EC – Asbestos*, the Appellate Body held that the term "like" in Article III.4 of GATT should be understood as encompassing not only "like" as per Article III.2 of GATT, but also directly competitive or substitutable ("DCS") goods as per the same provision (§§98-100). Consequently, even goods in looser competitive relationship can still be considered "like" as per Article III.4 of GATT.

Competitive relationship is of course, a matter of appreciation by consumers. Case law has consistently underscored that, in the context of claims discussed under Article III of GATT, it is consumers that will decide whether two goods are competing with each other. Products' physical characteristics, end uses, and, of course preferences of consumers are key factors, as per standing case law, in deciding on the competitive relationship across two goods. ANDS, on the one hand, and TCs, on the other, share the same end use of delivering nicotine. "Satisfying an addiction to nicotine" and "creating a pleasurable experience associated with the taste of the cigarette and the aroma of the smoke" are end-uses of TCs that were recognized by the Appellate Body in *US – Clove Cigarettes*. Similarly, satisfying nicotine cravings and creating a pleasurable experience with the taste and aroma of the vapour are end-uses that apply to ANDS.[6] There is ample empirical evidence to this effect. The Appellate Body has ruled that the evidence on end-uses (and of consumer preferences) of the products is especially relevant in cases where the evidence relating to properties, nature and quality of the products indicates that the products at issue are physically different.[7]

What about price? Consumers, after all, are typically characterised by scarcity of monetary resources, and purchases by definition comport an opportunity cost. In *Korea – Alcoholic Beverages*, the Appellate Body relegated them to second order concern (§§114 et seq.). So,

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[5] Nor is it so that because of a "like" product conclusion, the tariff classification of these products needs to be the same. Tariff classification is not what is driving the likeness determination and vice versa. The fact that products are "like" product does not in any way require that they be treated the same for tariff classification purposes. The latter is simply a matter of customs law and principles which focus on the physical characteristics of the product rather than their competitive relationship.

[6] Appellate Body Report, *US – Clove Cigarettes*, para. 132.

[7] Appellate Body Report, *EC – Asbestos*, para. 118.

while important, it is not the decisive concern in the eyes of the Appellate Body. At any rate, the fact that consumers use these products to serve a similar end-use and the fact that they are normally sold through similar distribution channels at similar retail places suggests that the two goods we discuss here (ANDS, TCs) are like goods.

And what about health concerns? How do they influence choice by consumers? In *EC – Asbestos*, the Appellate Body held that a reasonable consumer would always prefer a health-promoting over a health-impairing good (that could share the same intended function), and hence the two goods should be regarded unlike. In that case, the Appellate Body was dealing with construction material some made of asbestos (health-impairing), and some of fibres (health-promoting).

Would this reasoning apply here to support a conclusion that ANDS and TCs are not "like" products? The short answer is no. In *EC – Asbestos*, the Appellate Body was dealing with a different situation: consumers knew that some construction material is carcinogenic and some is not. This is not the case here. Both TCs and ANDS represent a risk to human health, even if the risk is of a different nature and degree.

Therefore, and since both products serve the same purpose, reasonable consumers will treat TCs and ANDS as like goods. Since imported ANDS and domestic TCs are like goods, the question we need to now address is whether the ban on ANDS constitutes LFT. We turn to this issue in what now follows.[8]

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[8] Although like products require similar treatment in terms of taxation and laws and regulations affecting the sale of the product, it would not be correct to conclude that different excise tax treatment or a different regulatory regime could not be necessary, adequate and proportionate. In fact, in the situation under examination, it would seem permissible and rational to apply a different, more favourable tax and regulatory regime to potentially less harmful, "like products", such as ANDS, since such a different treatment would be justified as necessary for the protection of health and any distinctions would be related to this objective of health protection given the role played by ANDS in a harm reduction strategy. In fact, precisely because of that, most countries have been imposing significantly less burdensome taxes for these different, but competitively "like products" and have not imposed the same strict regulations on ANDS as have been applied to TCs, since this would mean the failure of the new categories. By way of example, most recently, the US FDA in its decision to allow the sales of Heated Tobacco Products in the United States as "appropriate" to protect public health and allowed for forms of advertising via social media different from what is the case for TCs. See, https://www.fda.gov/tobacco-products/premarket-tobacco-product-applications/premarket-tobacco-product-marketing-orders A more lenient regulatory treatment has also been proposed in Canada. See https://www.newswire.ca/news-releases/new-tobacco-and-vaping-products-legislation-receives-royal-assent-683483681.html Canada's Bill S-5 allows for more flavours for vapour than for cigarettes (which is none including no menthol) as well as some advertising freedoms that are not afforded to combustibles such as sponsorships and celebrity endorsements. This different, more favourable approach can be justified in light of the text of Article XX of the GATT that nothing prevents the adoption of measures necessary to protect health.

2.2 Does the Sales Ban Afford Less Favourable Treatment to Imported ANDS?

Case law has established that the LFT-requirement embedded in Article III.4 of GATT incorporates the categoric imperative of Article III.1 of GATT to avoid applying domestic measures so as to afford protection to domestic production, without requiring a demonstration of such protectionist intent or effect. In *EC – Bananas III*, the Appellate Body held to this effect that (§ 216):

> Article III:4 does not specifically refer to Article III:1. Therefore, a determination of whether there has been a violation of Article III:4 does not require a separate consideration of whether a measure afford[s] protection to domestic production.

In *EC – Seal Products*, the Appellate Body was evaluating the consistency of a measure conditioning access of seal products upon the satisfaction of certain process-related requirements. In §§5.109-110 of its report, the Appellate Body dismissed the relevance of regulatory intent, when discussing whether the challenged measure was affording LFT to imported (like) goods in the following manner:

> The proposition that distinctions may be drawn between imported and like domestic products without necessarily according less favourable treatment to the imported products implies only that the "treatment no less favourable" standard, under Article III:4, means something more than drawing regulatory distinctions between imported and like domestic products. There is, however, a point at which the differential treatment of imported and like domestic products amounts to "treatment no less favourable" within the meaning of Article III:4. The Appellate Body has demarcated where that point lies, in the following terms:
> [T]he mere fact that a Member draws regulatory distinctions between imported and like domestic products is, in itself, not determinative of whether imported products are treated less favorably within the meaning of Article III:4. Rather, what is relevant is whether such regulatory differences distort the conditions of competition to the detriment of imported products. If so, then the differential treatment will amount to treatment that is "less favourable" within the meaning of Article III:4. In the light of the above, we do not agree with the European Union's reading of the Appellate Body's statement in EC–Asbestos. Specifically, we do not consider that the Appellate Body's statement that a Member may draw distinctions between imported and like domestic products without necessarily violating

> Article III:4 stands for the proposition that the detrimental impact of a measure on competitive opportunities for like imported products is not dispositive for the purposes of establishing a violation of Article III:4.

It follows that detrimental impact suffices in and of itself to meet the LFT-requirement. The relevant detrimental impact is the impact on "competitive opportunities". The impact is thus to be determined in the sense of the potential (as opposed to occurrence) for adverse trade effects. This suffices in and of itself to meet the LFT-requirement. In this respect, we recall also that Article III of GATT aims to protect competitive conditions, and not quantified or quantifiable trade targets. It, therefore, protects latent or potential competition as well as actual competition. Consequently, a ban on sales of imported ANDS (a like product to domestic TCs) and the consequential absence of sales ban for domestic TCs qualifies as LFT.

Furthermore, the GATT panel report on US – Superfund has dismissed the relevance of trade effects when it comes to demonstrating a violation of Article III.4 of GATT. In *Korea – Various Measures on Beef*, the Appellate Body confirmed this finding (§267). The consequence is quite straightforward. The complainant has to show differential treatment, without having to show how it has actually affected imported goods. In this vein, the absence of domestic production is irrelevant as well. A domestic ban violates Article III.4 even if there is no domestic production of either ANDS or TCs. What matters is that consumers view TCs and ANDS in a given market as like products and LFT is accorded to ANDS. And, of course, similar measures would violate Article I.1 as well, since this provision explicitly extends the coverage of the MFN clause to matters coming under the aegis of Article III of GATT.

Conclusion under GATT Article III

When the ban on ANDS is viewed as a domestic sales ban that is covered by the disciplines of Article III.4 of GATT, the conclusion is once again that it violates the relevant GATT/WTO commitment of the regulating Members since it imposes less favourable treatment on imported ANDS that are like domestic TCs. Neither the regulatory intent nor the lack of domestic production of TCs is relevant in this respect.

2.3 Preliminary Conclusion

Our analysis so far supports the conclusion that, no matter whether expressed as an import ban, or as a sales ban, a prohibition of ANDS to access a market, while allowing for the sale of TCs is inconsistent with the GATT.

In the first case, the measure will be in violation of Article XI of GATT, and in the second case, the measure will violate Article III of GATT.

The regulator, assuming no recourse to a request for waiver is made, can only defend its policies by invoking Article XX of GATT. We turn to this discussion in what now follows.

3. Responding to Invocation of Article XX of GATT

The party invoking Article XX of GATT (the WTO member imposing the import/sales ban) carries the associated burden of proof. In *US – Gasoline*, the Appellate Body explained that the party invoking this provision, will have to satisfy a two-tiered test (p. 22):

> first, provisional justification by reason of characterization of the measure under XX(g); second, further appraisal of the same measure under the introductory clauses of Article XX.[9]

Thus, as explained further below, the party adopting the measure would have the burden of proof of the following:

- That the measure falls within one of the subparagraphs of Article XX (e.g. public health or public morals);
- That the measure is "necessary" to achieve that aim;
- That the measure does not constitute arbitrary or unjustifiable discrimination between countries where the same conditions prevail; and
- That the measure is not a disguised restriction on international trade.

The party complaining about the import and sales ban will have, of course, the opportunity to rebut the arguments and evidence presented by the regulating party. Since the ball is on the

[9] In US-Shrimp (§§119-120) provided the rationale for this approach, which is now well embedded in case law.

other side, we will have to first explore the possible legal justifications that the original defendant might raise. As we will show in what now follows, the legal test for consistency stays the same, irrespective of the potential justification raised.[10]

3.1 Potential Justifications

A successful defense of measures under Article XX of GATT requires that the party invoking this provision meets cumulatively the requirements of the sub-paragraph invoked, as well as those embedded in the chapeau of the provision.

The sub-paragraphs of Article XX of GATT contain various possible justifications of an otherwise GATT-inconsistent measure. To justify the import/sales ban, the importing State could, in principle, raise one of the following two grounds:

- XX(b), the likeliest option, since it aims to protect human health, which is very much the rationale for a ban on ANDS;
- XX(a), a less likely, but possible option, if it raises the argument that ANDS violate public morals, since smoking and anything related to it such as the use of ANDS for example, is incompatible with the prevailing standards of right and wrong.

Both provisions include a necessity-test, hence it is irrelevant if the importing state invokes one or the other alternative. It will still have to meet the requirements of the same test. If it fails to do so, then complainant prevails. If it manages to meet the requirements of the necessity-test, then it will also have to meet the requirements of the chapeau-test.

3.2 Is an Import Embargo/Sales Ban Necessary?

To respond to the question whether an import/sales ban can be provisionally justified under Article XX(b), or XX(a) of GATT, we need to circumscribe briefly the case law understanding of the necessity-requirement. In doing that, we will be explaining whether the challenged measure meets the test, as developed in case law.

[10] In what follows, we present an exhaustive discussion of all potential justifications that the regulator might raise.

3.2.1 Means are Justiciable, not Ends

As long as the ends are among those set out in Article XX, the WTO will not question the legitimacy of the ends but will examine only whether the means are designed to address these ends and have the required relationship with the ends in question. This is the direct consequence of the negative integration character of the GATT contract. In *Korea – Various Measures on Beef*, the Appellate Body put it in eloquent terms (§176):

> It is not open to doubt that Members of the WTO have the right to determine for themselves the level of enforcement of their WTO-consistent laws and regulations.

This means that, in case of litigation, WTO courts cannot question, neither why the importer aims at promoting public health/morals, nor the level of protection/enforcement sought. They can only ask whether an import/sales ban serves the achievement of the intended regulatory objective.

By deciding on the level of enforcement, a WTO member ipso facto prejudges the means it can use to attain it: a very demanding level of enforcement would give little scope for measures other than an embargo. This is precisely the situation we are facing in this case. And yet, in *Brazil – Retreaded Tyres*, the Appellate Body put a dent in the right to use the most drastic measures, even if the requested level of enforcement is quite high. In light of the importance of this issue for the facts of this case, we will explain this point in sufficient detail.

In this report, the Appellate Body held that measures like an import/sales ban would be accepted, only if the party adopting them managed to prove that they have made a "material contribution" to the attainment of the objective (§150):

> As the Panel recognized, an import ban is "by design as trade-restrictive as can be." We agree with the Panel that there may be circumstances where such a measure can nevertheless be necessary, within the meaning of Article XX(b). We also recall that, in Korea–Various Measures on Beef, the Appellate Body indicated that "the word 'necessary' is not limited to that which is 'indispensable.'" Having said that, when a measure produces restrictive effects

> on international trade as severe as those resulting from an import ban, it appears to us that **it would be difficult for a panel to find that measure necessary unless** it is satisfied that the measure is apt to make a material contribution to the achievement of its objective. Thus, we disagree with Brazil's suggestion that, because it aims to reduce risk exposure to the maximum extent possible, an import ban that brings a marginal or insignificant contribution can nevertheless be considered necessary. (emphasis added)

It seems to us, that the Appellate Body wanted to convey that, for a very restrictive measure to be accepted as necessary, it must make a real (material, in its parlance) contribution to the attainment of the stated objective. In other words, unless that measure was used, the objective would either not have been attained, or its attainment would have been severely eviscerated. In this vein, the Appellate Body sees a trade-off between two competing propositions:

- On the one hand, it cannot prejudge the level of enforcement sought, but
- On the other, it does not allow the use of very restrictive measures, unless they are really really necessary to achieve the stated objective.

Consequently, the message that the Appellate Body wanted to convey here, is that it would not lightheartedly accept the most egregious cases of market segmentation. One would have intuitively thought that some sort of measurement of the contribution would be necessary. The Appellate Body took the view that this measurement can also take the form of a qualitative assessment that is supported by sufficient evidence.

In *EC – Seal Products* as well, the panel underscored that it would find it hard to reconcile total bans on sales with the necessity requirement, absent a finding to the effect that the challenged measure had made a material contribution to the attainment of the stated objective (§§7.633 *et seq.*). It then found that the challenged measure, for various reasons, "may have contributed to a certain extent" to the attainment of the objective, because it would reduce the overall demand for seal products (§§7.637–638).[11] The Appellate Body, in a lengthy passage (§§ 5.211 *et seq.*) found nothing wrong with the panel's conclusion that the measure may have contributed to the objective (§ 5.225).

[11] This panel ultimately concluded that the EU measure, although it was in its view necessary to protect public morals, it still violated the chapeau of Article XX of GATT.

This is the last contribution of case law to this discussion. There is of course, some distance between "material contribution", and "contribution to a certain extent". One possible explanation of the more relaxed attitude of the Appellate Body in *EC – Seal Products*, the more recent case, could be that the measure anyway was in manifest contradiction with the requirements of the chapeau of Article XX (which we discuss later). Furthermore, even though the Appellate Body did use different language to express the same concept, it did not signal deviation from the standard established in *Brazil – Retreaded Tyres*.[12]

As a result, the finding that recourse to drastic measures like embargoes, will be accepted only if the contribution to the attainment of the regulatory objective is substantial, is, in our view, still good law. Therefore, the regulating party must prove that the ban will make a "material" or close to indispensable contribution to the health objective. As discussed below, this is not likely to be proven given the reduced risk nature of ANDS compared to TCs.

3.2.2 The Importance of the Objective Pursued Matters

The Appellate Body asked this question about the relevance of the importance of the policy objective for the first time, in its report on *Korea – Various Measures on Beef*. We quote from §162:

> It seems to us that a treaty interpreter assessing a measure claimed to be necessary to secure compliance of a WTO-consistent law or regulation may, in appropriate cases, take into account the relative importance of the common interests or values that the law or regulation to be enforced is intended to protect. The more vital or important those common interests or values are, the easier it would be to accept as "necessary" a measure designed as an enforcement instrument.

This was confirmed in *EC – Asbestos* (§172).

This being said, the importance of the objective in terms of its impact on the review process should not be over-estimated. What the Appellate Body wanted to convey here, is simply

[12] In *EC – Seal Products*, the Appellate Body confirmed this understanding in §5.215, footnote 1300.

that, when going through its "weighing and balancing" process, it will control also for the importance of the objective sought. Thus, the importance of the objective sought, does not emerge as the decisive factor in deciding whether the necessity-requirement has been met or not. It will affect the standard of review, that much is clear, but it will complement and not substitute for the remaining analysis under Article XX of GATT.

3.2.3 Necessary Means Close To Indispensable

In an often-cited passage, the Appellate Body, in its report on *Korea – Various Measures on Beef* (§§161 *et seq.*), explained that the term "necessary" should be understood as closer to the term "indispensable" rather than to the term "making a contribution". The more a measure contributes to realizing an objective the easier it will be for an adjudicator to pronounce on its necessity.

In the same passage, the Appellate Body held that the less a measure has an impact on international trade, the closer it comes to its understanding of "necessity".

What do we make of this analysis for the case we discuss here? The import/sales ban must ideally contribute significantly to the objective (protection of human health/public order) while, at the same time not restrict international trade that much.[13] The measure definitely does not meet the second leg of the test, since a ban by definition has the maximum restrictive impact on international trade. As far as the first leg of the test is concerned, the lack of contribution of the ban to the protection of health renders the ban unnecessary, it seems. An assessment of the contribution of the measure that focuses only on the potential harm caused by the consumption of ANDS is one-sided and ignores the substitution effect that ANDS have for consumers who would otherwise smoke the potentially riskier TCs because of the unavailability of ANDS.

As noted by the seventy-two independent health experts in their letter to the WHO/FCTC, "[a] lost opportunity for a public health gain represents a real harm to public health, and

[13] This passage is reminiscent of the theory of first-best instruments to address distortions, but the agreement does not require the adoption of first-best instruments.

should be recognised as such".[14] Indeed, in a related letter to the WHO, a number of independent health experts explained that "[m]illions of smokers have moved from cigarettes to less harmful alternatives where the laws allow it. Where ANDS have been popular, we have seen rapid declines in adult smoking, for example in the United Kingdom, Sweden, the United States, and in Japan where cigarette consumption fell by 27 percent in the two years between first quarter 2016 and the same period in 2018 following the introduction of heated tobacco products".[15]

Therefore, ANDS play an important positive role in a harm reduction policy that offers what these experts believe to be a safer alternative for smokers. To ban ANDS while allowing ordinary TCs would undo the positive effect on smoking caused by the availability of ANDS. A measure can never be necessary to fulfil the objective or be justifiable if it goes against that objective.[16] In presence of a ban (import- or sale) of ANDS, the only reasonable consequence is that TC users do not have the opportunity to switch to a potentially less harmful alternative to smoking TCs.

3.2.4 Absolute As Opposed To Relative Necessity

In *China – Publications and Audio-visual Products*, the Appellate Body provided a comprehensive analysis of the understanding of the necessity-requirement in relative terms, and not in absolute terms (§327). In other words, if an alternative measure is reasonably available that provides an equivalent contribution to the fulfilment of the legitimate objective, the measure will not be necessary. This is how it would work in our case.

The defendant would have to make a prima facie case to the effect that its measure (import/sales ban) is necessary to protect human health, taking into consideration, however, that that the sales of TCs (the riskier product) is already taking place. This fact alone appears to make the prima facie requirement very difficult, if not impossible, to meet. If the

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[14] See, "Letter from seventy-two specialists in nicotine science, policy and practice - Innovation in tobacco control: developing the FCTC to embrace tobacco harm reduction", 1 October 2018, p. 2, Available at https://clivebates.com/documents/WHOCOP8LetterOctober2018.pdf.

[15] See, Letter from Professor Abrams and Professor Niaura of the NYU College of Global Public Health, "WHO should reject prohibition and embrace 'tobacco harm reduction' and risk-proportionate regulation of tobacco and nicotine products", 3 September 20187, p.2, Available at: https://clivebates.com/documents/WHOCOP8LetterSeptember2018.pdf.

[16] WTO Appellate Body Report, *Brazil – Retreaded Tyres*, para. 228.

complainant can point to another measure that could achieve the same objective without also creating a similarly restrictive effect on international trade (say, labelling requirements on the health externalities from use of any such products or related information campaigns), then the defendant will have one additional hurdle to overcome. It will have to explain why such alternatives are not reasonably available to it. To do this, it would have to, for example, show that financing a campaign to raise awareness of the risks, as suggested by the complainant, would entail as consequence a financial burden it could not possibly sustain (this is the "hardship"-test, that the Appellate Body has been referring to in this and related case law).[17] This is an argument that would be nearly impossible to sustain in light of the fact that governments run such campaigns all the time. In any case, the costs of such labelling requirements would be borne by the producers and importers of the products, and not the government. Therefore, the argument must fall. The availability of less restrictive alternatives to a ban such as labelling requirements or information campaigns on the health externalities are additional reasons why the ban must be unnecessary.

3.2.5 Preferring a GATT-Consistent rather than a GATT-Inconsistent Option

The *Thailand – Cigarettes* dispute, a GATT panel case of 1990, stands for the proposition that a measure is not necessary, if a GATT-consistent or less GATT-inconsistent alternative exists. There are strong similarities between this and the case under consideration in this Note. Thailand had imposed an import ban on cigarettes, while allowing for the sale of domestic cigarettes in its market. When challenged, it argued that its embargo on the importation of cigarettes, while restricting the overall quantity of cigarettes sold in its market, was justified by the fact that it aimed to ensure the quality of cigarettes imported. The panel (§75) felt that Thailand could have ensured its objective (good quality of cigarettes sold and restrictions on demand), through the use of non-discriminatory, and hence GATT-consistent, measures (non-discriminatory labeling, etc.). In so doing, the GATT panel even went against the suggestions of the World Health Organization, which had effectively advocated in favour of banning imported manufactured cigarettes.

[17] In *Dominican Republic – Import and Sale of Cigarettes*, the Appellate Body almost verbatim exported the allocation of the burden of proof as per *US – Gambling*, in the trade in goods-context as well (§70).

In our case, if the objective of the importer was to protect human health/public morals, then the most appropriate way to do it, would be to warn (potential) consumers of the alleged danger that consumption of ANDS represents to health. It could have chosen a GATT-consistent option, that is. By imposing an import/sales ban on ANDS only, it does not serve the regulatory objective unilaterally set.

3.3 Preliminary Conclusion

It is difficult to conclude in definitive manner whether the defendant will manage to successfully demonstrative substantive compliance with the relevant sub-paragraphs of Article XX, even though the better arguments lie with a negative response. This is so for two important reasons, namely, because:

- drastic measures only exceptionally will be allowed;
- a GATT-consistent option could probably help it reach its objective.

In our view, there are thus good reasons to believe that the regulating member will not meet the necessity requirement, as it has to do in order to mount a successful defence of its otherwise GATT-inconsistent measure. The lack of contribution of the ban to the protection of health and the availability of less restrictive alternatives to a ban such as information campaigns and labelling render the ban unnecessary.

But let us assume for the sake of argument that the defendant has managed to demonstrate that its measures pass the first leg and are necessary to achieve their objectives. This is not the end of the road, as we have already suggested. The defendant must also demonstrate that its measures meet the requirements of the chapeau. We turn to this discussion in what now immediately follows.

3.4 Does an Import Embargo/Sales Ban Meet the Requirements of the Chapeau?

For a WTO member to successfully discharge its burden of proof under the chapeau of Article XX, it must demonstrate that its measures do not constitute an arbitrary, or unjustifiable discrimination, or a disguised restriction of trade. The third requirement is of

course distinct from the first two, which concern degrees of discrimination. Case law though, is quite fuzzy as to whether these two requirements are distinct, or overlapping. In *US – Shrimp (Article 21.5–Malaysia)*, the Appellate Body held that these three requirements are distinct (§118). And yet, the same Appellate Body, in its report on *US – Shrimp*, held the opposite (§150).

We submit that this discussion is inconsequential. What matters is what the substantive content of the three terms amounts to.

3.4.1 Substantive Consistency and Application

We quote §625 of the Appellate Body report on *China – Rare Earths*, which is probably the best explanation of the standard of review adopted when examining claims of inconsistency with the chapeau:

> Although… the focus of the inquiry is on the manner in which the measure is applied, the Appellate Body has noted that whether a measure is applied in a particular manner "can most often be discerned from the design, the architecture, and the revealing structure of a measure." It is thus relevant to consider the design, architecture, and revealing structure of a measure in order to establish whether the measure, in its actual or expected application, constitutes a means of arbitrary or unjustifiable discrimination between countries where the same conditions prevail.

An enquiry into the design, architecture, and revealing structure of the challenged measure is thus warranted in order to decide on its consistency with the chapeau. For the purposes of our discussion, this would mean that a panel would look into the ban on ANDS of course, as well as into the rationale for the measure (public health/public morals).

3.4.2 The "Plat de Resistance": the Even-Handedness Requirement

On its face, the chapeau of Article XX of GATT imposes a requirement of even-handedness. We quote the relevant passage:

> ... the requirement that such measures are not applied in a manner which would constitute a means of arbitrary or unjustifiable discrimination between countries where the same conditions prevail, or a disguised restriction on international trade, ...[18]

The question that naturally arises, is whether the term "discrimination" should be co-extensive to the manner in which "so as to afford protection" has been understood in the case law regarding Article III of GATT.

In *US – Gasoline*, the Appellate Body addressed this issue directly, and found that the legal test for consistency is not identical across the two provisions (Articles III and XX). On p. 26 in the same report, the Appellate Body explained itself as to where it saw the difference in the legal test:

> We have above located two omissions on the part of the United States: to explore adequately means, including in particular cooperation with the governments of Venezuela and Brazil, of mitigating the administrative problems relied on as justification by the United States for rejecting individual baselines for foreign refiners; and to count the costs for foreign refiners that would result from the imposition of statutory baselines. In our view, these two omissions go well beyond what was necessary for the Panel to determine that a violation of Article III:4 had occurred in the first place.

Of interest to our discussion, is the Appellate Body's view that the two omissions, which go beyond what was necessary to find violation of Article III, should be taken into account in order to find violation of the chapeau. The requirement thus, for even-handedness under the chapeau, is quite elaborate. This in turn, entails an even higher burden for the party invoking the chapeau when drawing regulatory distinctions in treatment.

We now turn to the interpretation of the term "disguised restriction of trade". There are some banal interpretations that have seen the light of day, of no or marginal interest to our

[18] It is of course, debatable whether "disguised restriction of trade" should be treated as part and parcel of the even-handedness requirements. Arguably, it is a distinct requirement. In this Note, I will treat it as part of it though, since this is how case law has discussed it so far. In my view though, it is distinct requirement. The way I personally understand the legal discipline in the chapeau of Article XX, it contains two distinct elements: an element of even-handedness, which invites comparison of treatment of a particular good in countries (including the regulating country) where the same conditions prevail; and a separate requirement to avoid disguised restrictions of trade, which is akin to abuse of law. This requirement amounts to a legal imperative to use means for stated ends, and not in order to advance other, hidden objectives.

discussion. In *US – Gasoline*, the Appellate Body rejected the interpretation that the term "disguised restriction of trade" is limited to concealed or unannounced restrictions only. It upheld, in other words, the idea that the obligation to avoid disguised restrictions of trade is not a mere exercise in transparency.

What is then "disguised restriction of trade" all about? Case law has provided a framework to use when addressing claims that a measure falls short of this requirement. We turn once again to the Appellate Body report on *US – Gasoline* (p. 25):

> ... the kinds of considerations pertinent in deciding whether the application of a particular measure amounts to "arbitrary or unjustifiable discrimination," may also be taken into account in determining the presence of a "disguised restriction" on international trade. The fundamental theme is to be found in the purpose and object of avoiding abuse or illegitimate use of the exceptions to substantive rules available in Article.

This view is reminiscent of the French doctrine of "abus de droit".[19] In other words, in the name of protecting one of the values embedded in the body of Article XX, WTO members should not, in under-handed manner, promote the interests of local produce. "Abus de droit" falls squarely within the parameters of this statement: use an instrument not for the intended, and acceptable, function, but for a different one (un-intended, as well as un-acceptable).

How does all this relate to our discussion?

Article XX, unlike the provisions regarding obligations assumed under the GATT, does not prescribe instruments that must be disciplined in a specific way. It enlists grounds, which, if genuinely pursued, allow WTO members to deviate from the disciplining of instruments as per the obligations assumed (Articles I, II, III, XI of GATT).

We have established that ANDS and TCs are like goods. We have also established that banning the former, and allowing the sale of the latter amounts to LFT. Even if we assume that the defendant has met its burden under Article XX(a)/XX(b) of GATT, it cannot pass the hurdle of the chapeau. A measure, which allows the sale of TCs and ANDS is a disguised

[19] The Appellate Body, in its report on *Brazil – Retreaded Tyres*, endorsed this analysis in §§224 *et seq.*

restriction of trade, and/or an unjustifiable, and arbitrary discrimination that thus violates the GATT. This is why: if the purpose is to protect public health, it simply cannot be that between two like goods, only half of them are banned. If the purpose is protection of health, all like products (ANDS, and TCs alike) must be banned/disciplined, unless there are good reasons for a regulatory distinction that is necessitated by the health objective such as providing a less stringent regime for ANDS given their potential role in a harm reduction strategy.[20] If only ANDS are banned, consumption of TCs will increase because of the role in a harm reduction policy played by ANDS that substitute for TCs, as we have discussed earlier, and the regulatory purpose will be defeated, since overall consumption at best will remain unaffected. By failing to do as much, the defendant has ipso facto failed to meet the requirements of the chapeau.

There is an additional argument in favour of this conclusion under the chapeau. In *Brazil – Retreaded Tyres*, the Appellate Body held that if the adjudicator concludes that the basis for the measure bears no rational connection with the objective pursued, then it has to find that the chapeau has been violated (§227). Under the terms "arbitrary-", "unjustifiable discrimination", and "disguised restriction of trade", the Appellate Body saw a minimum requirement that must be satisfied as well: rational connection between end sought, and means in place.[21]

The "rational disconnect" standard appeared yet again in *EC – Seal Products*. There, Canada had argued that the European Union was not pursuing protection of animal welfare, when it allowed the killing of seals by the Inuit community of Greenland. The Appellate Body interpreted first the Canadian claim as a statement to the effect that, a rational disconnect between the means (imports of seal products from these brutally killed seals) and the objective (protection of animal welfare) existed, as a result of the only partial exclusion of seal products from the EU market, when the objective was to ban all goods produced following unacceptable methods of harvesting seals (§5.319).

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[20] Recall, that it is not the complainant who has to demonstrate that the defendant is operating a disguised restriction of trade, or operating an arbitrary and/or unjustifiable discrimination. It is the defendant, i.e. the member imposing the ANDS ban that must prove that it does not. Consequently, the complainant does not have to demonstrate, for example, that the defendants' producers of TCs will profit from limited competition.

[21] Irrespective whether we base ourselves on the "rational disconnect" thesis, or the substitution effect discussed earlier, the analysis is the same: there is no need to inquire into trade effects.

This case thus, is quite relevant for our discussion here. As in *EC – Seals Products*, the regulating state here is facing two types of products, both of which allegedly represent a health risk. And yet, it bans only one of them, the less risky one. The question of rational disconnect is posed in almost identical terms across the two cases.

Under this case law, consequently, the regulating state by not addressing the reasons why it bans ANDS but not TCs, is violating the rational-disconnect obligation.

In other words, under the chapeau, the regulating state will have to explain why there is one sauce for the goose so to speak, and one for the gander. What explains in other words, the ban on sales of ANDS and the permission to trade TCs? The regulating state cannot avoid this question. And we have difficulty seeing how it could ever explain this given that, in the opinion of the above quoted seventy-two health experts, the banned ANDS are less risky than the permitted TCs.

Consequently, a ban on ANDS would violate the requirements included in the chapeau of Article XX of GATT, even if the ban applied to all imports and domestic ANDS alike, since it would be excluding TCs from its scope.

Furthermore, the MFN (most favoured nation) requirement is explicitly embedded in the chapeau, which requests absence of discrimination across countries, where the same conditions prevail. This term has been consistently understood as prohibiting discriminatory behaviour.

In the WTO-era, the Appellate Body in *US – Gasoline* discussed the issue whether this requirement should be understood as referring exclusively to exporting countries or, conversely, whether it should encompass the regulating country as well. Although the Appellate Body did not formally rule on this issue on this occasion, it saw no reason to deviate from the prevailing practice, which privileged the latter interpretation (pp. 23–24):

> It was asked whether the words incorporated into the first two standards "between countries where the same conditions prevail" refer to conditions in importing and exporting countries, or only to conditions in exporting countries. The reply of the United States was to the effect that it interpreted that phrase as referring to both the exporting countries and importing

> countries and as between exporting countries. At no point in the appeal was that assumption challenged by Venezuela or Brazil. we see no need to decide the matter of the field of application of the standards set forth in the chapeau nor to make a ruling at variance with the common understanding of the participants.

Finally, there is once again no need to demonstrate actual trade effects or to measure their significance. What matters is that the even-handedness requirement has been violated, irrespective of the trade volumes that will be eventually reduced.

One final comment is warranted at this stage. One might not exclude that the regulating state invokes the precautionary principle, arguing that, since the risk from ANDS has not been precisely assessed, its measures are necessary to address, on precautionary grounds, the potential risk. This argument it seems to me, is easy to thwart. The precautionary principle has not been recognized in the GATT legal order in any of the reports issued so far and the Appellate Body found that the "precautionary principle" had not yet attained authoritative formulation outside the field of international environmental law "did not release Members from their WTO obligations".[22]

[22] Appellate Body Report, *EC – Hormones*, paras. 123-125. See also Appellate Body Report, *Japan – Apples*, para. 233.

4. Brief Concluding Remarks

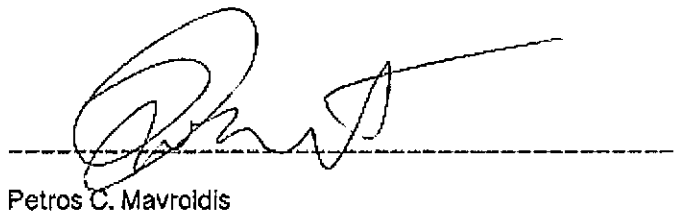
In this Note, we discussed the consistency of an import/sales ban on ANDS with the relevant WTO rules, when no similar prohibition on the same of TCs has been put into place.

Our conclusions are as follows:

- An import ban on ANDS, mandated by a formal law, violates Article XI of GATT, since
    - it constitutes a prohibition on importation, and thus a prohibited zero import quota;
    - it is attributable to the importing WTO member;
    - there is no need to show trade effects, and
    - the regulatory intent of the ban is irrelevant;
- A sales ban on ANDS, mandated by a formal law, violates Article III of GATT, since
    - ANDS and TCs are like products;
    - a ban on imported ANDS, while allowing the sale of TCs, amounts to LFT for imported like products;
    - there is no need to demonstrate trade effects and it is thus irrelevant if the banned products represent only a small volume of trade; and
    - the regulatory intent of the discriminatory ban on ANDS is not relevant under Article III of GATT, since any modification of the conditions of competition to the detriment of imported like products is prohibited even if there is no evidence of any protectionist intent;
- The regulating WTO member may seek to justify its measures by invoking Article XX(b) and/or Article XX(a). Both provisions include the same "necessity" test for consistency, and thus, it is simply irrelevant if the importing WTO member will invoke one or the other, or both of them. There are good reasons to believe that the defendant will not meet the necessity-requirement, as it has to do in order to mount a successful defence of its otherwise GATT-inconsistent measure. The lack of contribution of the ban to the protection of health, and the availability of less restrictive alternatives to a ban such as information campaigns and labelling support a finding that the ban is unnecessary;

- In any case, even if the regulating member were to be successful in demonstrating the "necessity" of the ban on ANDS, this will not suffice to justify the ban. We examined in particular the consistency of the measure under the chapeau of Article XX of GATT, and found that the ban on ANDS will fail to meet the chapeau requirements, since
    - the ban is a disguised restriction on trade for two, distinct reasons relating to the substantive basis for the difference in treatment as well as the procedural explanation for the different treatment:
        - because the regulating state, in the name of protecting human health (and/or public morals) is banning the sale of certain goods while not banning the sale of like goods that are, according to many scientists, much more harmful to health; and
        - because it has not explained its decision to ban some and not other, more harmful products, and is unlikely to be able to provide the required reasoned and reasonable explanation that is rationally connected with the health objective of the measure.
    - the ban is also an unjustified and/or arbitrary discrimination, since the importing WTO member has banned the sales of some imported products, as opposed to other like products that are more harmful to health, without any reasoned and reasonable explanation that is rationally connected with the health objective of the measure.

Dated:



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43. Would've or Should've? Impaired Benefits Due to Copyright Infringement, US–Section 110 (5), (co-authored with Gene M. Grossman), pp. 294–314 in Henrik Horn and Petros C. Mavroidis (eds.), The WTO Case Law, The American Law Institute Reporters' Studies, Cambridge University Press: Cambridge, UK, 2007.

44. The Sounds of Silence, US–Carbon Steel, (co-authored with Gene M. Grossman), pp. 367–380 in Henrik Horn and Petros C. Mavroidis (eds.), The WTO Case Law, The American Law Institute Reporters' Studies, Cambridge University Press: Cambridge, UK, 2007.

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46. Here Today, Gone Tomorrow? Privatization and the Injury Caused by Non-Recurring Subsidies, US–Lead and Bismouth II, (co-authored with Gene M. Grossman), pp. 183–213 in Henrik Horn and Petros C. Mavroidis (eds.), The WTO Case Law, The American Law Institute Reporters' Studies, Cambridge University Press: Cambridge, UK, 2007.

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49. What is a Subsidy? US–Softwood Lumber III, (co-authored with Henrik Horn), pp. 523–550 in Henrik Horn and Petros C. Mavroidis (eds.), The WTO Case Law, The American Law Institute Reporters' Studies, Cambridge University Press: Cambridge, UK, 2007.

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57. Bronner Kebab: Beyond Refusal to Deal and Duty to Cooperate, (co-authored with Damien J. Neven), pp. 355–370 in Claus-Dieter Ehlermann & Isabela Atansiu, European Competition Law Annual: What is an Abuse of Dominant Position? Hart Publishing, Oxford, UK, 2006.

58. Is the Use of the WTO Dispute Settlement System Biased? (co-authored with Henrik Horn and Håkan Nordstrøm), pp. 454-486 in Petros C. Mavroidis and Alan O. Sykes (eds.), The WTO and International Trade Law Dispute Settlement, Elgar Publishing, Aldershot, UK, 2005.

59. The Case for Tradable Remedies in WTO Dispute Settlement System (co-authored with Kyle Bagwell and Robert W. Staiger), pp. 395 – 414 in Simon J. Evenett and Bernard Hoekman (eds.), Economic Development & Multilateral Trade Cooperation, Palgrave McMillan & The World Bank : Washington DC, 2005.

60. Le Recours à des Experts et ses Mesaventures en Droit de l'OMC (co-authored with Pauline Lièvre) pp. 201 – 220 in Marie Anne Frison Roche and Alexandra Abello, Droit et Economie de la Propriété Intellectuelle, LGDJ : Paris, 2005.

61. Come together? Producer Welfare, Consumer Welfare and WTO Rules, pp. 277-290 in Ernst-Ulrich Petersmann (ed.), Reforming the World Trading System: Legitimacy, Efficiency and Democratic Governance, Oxford University Press: Oxford, UK, 2005.

62. Do Not Ask Too Many Questions: the Institutional Arrangements for Accommodating Regional Integration Within the WTO, pp. 239-278 in E. Kwan Choi and James C. Hartigan (eds.), Handbook of International Trade, volume II, Economic and Legal Analysis of Trade Policy Institutions, Blackwell Publishing: Malden, MA, 2005.

63. Human Rights, Developing Countries and the WTO Constraint: the Very Thing that Makes you Rich Makes me Poor?, pp. 244-260 in Eyal Benvenisti and Moshe Hirsch (eds.), The Impact of International Law on International Cooperation, Cambridge University Press: Cambridge, UK, 2004.

64. Proposals for Reform of Article 22 of the DSU: Reconsidering the 'Sequencing' Issue and Suspension of Concessions, pp. 61–74 in Federico Ortino and Ernst-Ulrich Petersmann (eds.), The WTO Dispute Settlement System 1995-2003, vol. 18 Studies In Transnational Economic Law, Kluwer: London, UK, 2004.

65. Developments of WTO Dispute Settlement Procedures Through Case-Law, pp. 153–176 in Federico Ortino and Ernst-Ulrich Petersmann (eds.), The WTO Dispute Settlement System 1995-2003, vol. 18 Studies in Trans-national Economic Law, Kluwer: London, UK, 2004.

66. The Trade Disputes Concerning Health Policy Between the EC and the US, pp.233-245 in Ernst-Ulrich Petersmann and Mark A. Pollack (eds.), Trans-national Economic Disputes, The EU, the US and the WTO, Oxford University Press: Oxford, UK. 2003.

67. National Health Regulation and the SPS Agreement: the WTO Case-Law of the Early Years (co-authored with Henrik Horn), pp. 255–284 in Thomas Cottier and Petros C. Mavroidis (eds.),The Role of the Judge in International Trade Regulation, Experience and Lessons for the WTO, The World Trade Forum Series, vol. IV, The University Of Michigan Press: Ann Arbor, Michigan, 2003.

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70. Judicial Supremacy, Judicial Restraint and the Issue of Consistency of Preferential Trade Agreements with the WTO: the Apple in the Picture, pp. 583-601 in Dan Kennedy and James Southwick (eds.), The Political Economy of the International

Trade Law, Essays in Honor of Robert E. Hudec, Cambridge University Press: Cambridge, UK, 2002.

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75. The WTO Agreement on Telecommunications: It's Never Too Late (co-authored with Damien J. Neven), pp. 307-318 in Damien Geradin (ed.), The Liberalization of State Monopolies in the European Union and Beyond, Kluwer: London, 2000.

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Low), pp. 115-139 in Einar Hope (ed.), Competition and Trade Policies, Routledge, 1998.

81. The Treatment of Dumping, Subsidies and Restrictive Business Practices in Regional Arrangements: A comment, pp. 389-396 in Paul Demaret, Jean-François Bellis, Gonzalo Garcia Jimenez (eds.), Regionalsim and Multilateralism after the Uruguay Round, Convergence, Divergence and Interaction, European Interuniversity Press, Series European Policy No 12, Brussels 1997.

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84. Enforcing the Uruguay Round Agreements (in Greek). pp. 167-190 in A.A. Fatouros, K. Stephanou (eds.), The WTO Agreements on World Trade of Goods and Services, Sakkoulas Publications: Athens, 1996.

85. The EC Trade, Competition and Industrial Policies; Complementarities and Conflicts: A comment, pp. 115–121 in A. Jacquemin, P. Buigues (eds), The EEC Policies on Competition, Trade and Industry, Complementarities and Conflicts, Elgar: Aldershot, UK, August 1995.

86. Linking Competition and Trade Policies in the Central and Eastern European Countries (co-authored with Bernard Hoekman), pp. 111–154 in Alan Winters (ed.), Foundations of an Open Economy, Trade Laws for Eastern Europe, CEPR Publications: London, UK, 1995.

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2. Law and Competition in Twentieth Century Europe: Protecting Prometheus, by David Gerber, Columbia Journal of European Law, 6: 259-264, 2000.

3. Lexcalibur: The House that Joe Built, A review of "The Constitution of Europe: Do the New Clothes Have an Emperor?", by Joseph H.H Weiler, Columbia Journal of Transnational Law, 38: 669-677, 2000.

4. International Trade Regulation, by Michael J. Trebilcok and Robert Howse, Journal of World Trade, 34: 171-172, 2000.

5. International Trade Regulation, by Edmond McGovern, Journal of World Trade, 33: 205-206, 1999.

6. The World Trading System, 2nd edition, by John H. Jackson, Journal of World Trade, 32: 185-188, 1998.

7. Antidumping Industrial Policy; Legalized Protectionism in the WTO and What to do About it, by Brian Hindley and Patrick Messerlin, Journal of World Trade, 31: 167-168, 1997.

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10. GATT Uruguay Round, edited by Thomas Cottier, Aussenwirtschaft, 50: 515–518, 1995.

11. Enforcing International Trade Law, by Robert E. Hudec, Aussenwirtschaft, 49: 625–628, 1994.

12. Der Agäis-Konflikt, by Heintschell von Heinegg, Révue Hellènique de Droit International, 42: 461–464, 1990.

SHORTER NOTES

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Sultans of Swing, The Emerging WTO Case Law on TBT (with Carlo M. Cantore), European Journal of Risk Regulation, 258-260, 2013.

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The European Union as an International Actor, Columbia Journal of European Law, 6: 271-274, 2000.

OTHER PUBLICATIONS

2019: China and the WTO: Towards a Better Fit, with André Sapir, Bruegel, Brussels

2018: All Quiet in the Western (European Football) Front: Regulation of Football in the European Continent, EUI Working Papers, RSCAS, EUI: Fiesole, Italy, 2018/26
Summary reprinted in Oxford University Business Law Blog
https://www.law.ox.ac.uk/business-law-blog/blog/2018/07/all-quiet-western-european-football-front-regulation-football

CUTS-international.org

2012: Briefing Paper, On Compliance in the WTO, Enforcement Among Unequal Disputants (2012/4)

EUI

Data set on WTO dispute settlement
http://globalgovernanceprogramme.eui.eu/wto-case-law-project/

Dissenting Opinions in the WTO Appellate Body: Drivers of their Issuance and Implications for the Institutional Jurisprudence (with Evan Y. Kim), RSCAS 2018/51: EUI, Florence.

ICTSD (International Centre for Trade and Sustainable Development)

Opposites Attract: Bringing the Trade and Regulatory Communities Together
http://e15initiative.org/blogs/opposites-attract-bringing-the-trade-and-regulatory-communities-together/

VoxEU.org

2008: The WTO's Difficulties in Light of the GATT's History, VoxColumn, VoxEU.org, 29 July 2008

2013: Race for the WTO Director-General Job: Seven Candidates Speak, VoxEU.org, E-book (co-edited with Bernard M. Hoekman), April, http://www.voxeu.org/sites/default/files/file/WTO%20book(1).pdf

2013: Pay Attention to the WTO Leadership Contest: It Matters!, (co-authored with Bernard M. Hoekman), VoxEU, April 4, http://www.voxeu.org/article/pay-attention-wto-leadership-contest-it-matters

2013: Developing Countries and DSU Reform (co-authored with Marc L. Busch), pp. 99-104 in Simon Evenett and Alejandro Jara (eds.), Building on Bali, a Work Programme for the WTO, VoxEU.org E-book http://www.voxeu.org/article/building-bali-new-voxeu-ebook

2014: Members Only: Embracing Diversity in the WTO (co-authored with Bernard M. Hoekman), VoxEU.org http://www.voxeu.org/article/members-only-embracing-diversity-wto

2016: Clubs and the WTO post-Nairobi: What is Feasible? What is Desirable? (co-authored with Bernard M. Hoekman) http://www.voxeu.org/article/clubs-and-wto-post-nairobi

Social Science Research Network

My papers are available on SSRN at: http://ssrn.com/author=202909

RESEARCH GRANTS

1. American Law Institute (1991-2012): Principles of International Trade: the Law of the World Trade Organization (WTO). The study was conducted and co-authored with Henrik Horn (chief co-editor) and Kyle W. Bagwell, Gene M. Grossman, Robert W. Staiger, and Alan O. Sykes.

2. Bruegel (2009-2010): Preferential Trade Agreements. The study was co-authored with Henrik Horn, and André Sapir and published by Bruegel. A shorter version appeared in the World Economy, 2010 (cited supra).

3. MISTRA (2007-2013): I participated in a research consortium (www.entwined.se) working on various issues regarding the intersection of trade (WTO) law and environmental policies with special focus on policies relating to climate change. The outcome of this research has appeared in academic journals as cited supra.

4. ASEAN (2011-2013): I participate in a research consortium aiming at improving the current dispute settlement system of the ASEAN.

5. World Bank (2000-2010): Research grant for the WTO data set (www.worldbank.org/trade/wtodisputes)

6. EUI (2011-PRESENT):Research grant for the WTO data set http://globalgovernanceprogramme.eui.eu/wto-case-law-project/

7. EUI (2010-PRESENT): Research grant for the WTO case law-project http://globalgovernanceprogramme.eui.eu/wto-case-law-project/

HONOURS

Doctor Honoris Causa

Honorary Doctor of Laws: University of Antwerpen (Anvers), Belgium, 2013.

Honorary Doctor of Laws: Gothenburg University, Sweden, 2010.

Awards

American Society of International Law (ASIL) 'Certificate of Merit for a Work in a Specialized Area of Law' for the monograph 'The Regulation of International Trade', vols. 1 and 2, MIT Press: Cambridge, Massachusetts, 2017.

American Society of International Law (ASIL) 'Certificate of Merit for a Work in a Specialized Area of Law' for the monograph 'Trade in Goods', 2nd Edition, Oxford University Press: Oxford, UK, 2013.

International Franqui Medal (and Chair): University of Leuven, Belgium, 2009.

American Society of International Law (ASIL) 'Award of Highest Technical Craftsmanship' for The WTO Law, Practice and Policy (co-authored with Mitsuo Matsushita, and Thomas J. Schonbaum), Oxford University Press: Oxford, UK, 2005.

MEMBERSHIP IN BOARDS

1. **International Academic Advisory Council, University of Gothenburg, School of Business, Economics, and Law:** Member of the Council.

2. **Council of the World Trade Law Association**: Member of the Board.

3. **Columbia Journal of Trans-National Law**: Member of the Board of Advisors.

4. **Columbia Journal of European Law**: Member of the Board of Advisors.

5. **Global Trade and Finance Series, Kluwer Publishing**: Member of the Advisory Board.

6. **Journal of World Investment and Trade**: Associate Editor (2002-2013); Editorial Advisory Board (2013-).

7. **Journal of World Trade**: Associate Editor.

8. **The World Trade Review**: Editorial Board.

9. **The Geneva Post Quarterly**: Editorial Board.

10. **Yearbook on International Investment Law and Policy**: Advisory Board.

11. **Journal of International Trade,** Board of Advisors.

REPORTER FOR ACADEMIC ASSOCIATIONS

1. **American Law Institute (ALI):** Chief Co-Rapporteur in December 2001 to the project "Principles of Trade Law: The World Trade Organization" which was published in 2013.

2. **International Law Association (ILA), International Trade Law Committee (ITLC):** Rapporteur.

MEMBER OF ACADEMIC ASSOCIATIONS

1. **American Law Institute (ALI)**: Member (as of 2007).

2. **Centre for Economic Policy Research (CEPR)** Fellow (2003-2011).

3. **The Swiss Institute of Comparative Law**, Lausanne: Member of the Scientific Board (as of 2012).

MISCELLANEOUS

1. **Court of Arbitration for Sport (CAS)**: Arbitrator (2007-).

2. **Commission on Financial Fair Play**, UEFA, Member (2008-).

THE QUESTION OF THE APPLICATION OF THE FRAMEWORK CONVENTION ON TOBACCO CONTROL TO ALTERNATIVE NICOTINE DELIVERY SYSTEMS

Expert Opinion by Prof. Dr. Jan Wouters

Credentials

Professor Jan Wouters (°1964) is Full Professor of International Law and International Organizations, Jean Monnet Chair *ad personam* EU and Global Governance and founding Director of the Leuven Centre for Global Governance Studies and of the Institute for International Law at the University of Leuven (KU Leuven). As Visiting Professor at Sciences Po (Paris), Luiss University (Rome) and the College of Europe (Bruges) he teaches EU external relations law. As Adjunct Professor at Columbia University he teaches comparative EU-US perspectives on international human rights law. As Visiting Professor to the Universities of Ottawa and Trento in 2019, he teaches global and regional perspectives on international law. He has been working for more than 20 years as *Of Counsel* at Linklaters, Brussels.

Professor Wouters offers 30 years of academic scholarship and more than 25 years of practical experience in most areas of international law, from general international law to international criminal law, international economic law, international humanitarian law, international human rights law, international investment law, the law of international organizations (in particular the United Nations, UN specialized agencies and the World Trade Organization) and the law of outer space, as well as in the law of the European Union, corporate law and banking and financial law and global governance. He brings a strong insight in the multifaceted interactions between legal norms at international, European and national levels.

Professor Wouters is Member of the Royal Academy of Belgium for Sciences and Arts. He taught at the Universities of Antwerp and Maastricht, was Visiting Professor at Liège University, Kyushu University, the Pontificia Universidad Católica de Chile, the Hebrew University, the University of Ottawa and Trento University, and *Référendaire* at the European Court of Justice (1991-1994). He is Editor of the *International Encyclopedia of Intergovernmental Organizations*, Deputy Director of the *Revue belge de droit international*, Editor-in-Chief of the International Law book series with Intersentia Publishers and of the Leuven Global Governance book series with Edward Elgar Publishers, and editorial board member in eleven international journals. He has published widely on international and EU law, international organizations, global governance, and corporate and financial law, including more than 70 books, 130 journal articles and 200 chapters in international books. His most recent books include *Informal International Lawmaking* (2012), *Private Standards and Global Governance* (2012), *China, the European Union and Global Governance* (2012), *The EU's Role in Global Governance* (2013), *National Human Rights Institutions in Europe* (2013), *The Law of EU External Relations* (2nd ed. 2015), *China, the EU and the Developing World* (2015), *Global Governance of Labour Rights* (2015), *Global Governance Through Trade* (2015), *The Contribution of International and Supranational Courts to the Rule of Law* (2015), *Global Governance and Democracy* (2015), *Armed Conflicts and the Law* (2016), *Judicial Decisions on the Law of International Organizations* (2016), *Internationaal Recht in Kort Bestek* (2nd ed. 2017), *Research Handbook on EU Energy Law and Policy* (2017), *Commercial Uses of Space and Space Tourism* (2017), *The Commons and a New Global Governance* (2018), *EU Human Rights and Democratization Policies* (2018), *International Law: a European Perspective* (2018), and *The G7, Anti-Globalism and the Governance of Globalization* (2018). Apart from his participation in international scientific networks, he advises various international organizations and governments, trains international officials and is often asked to comment international events in the media.

Educational Qualifications

- PhD in Law, KU Leuven (1996)
- Visiting Researcher, Harvard Law School (1990-91)
- Master of Laws, Yale University (1990)
- Lic. Juris, Antwerp University (1987)
- Bachelor of Philosophy, Antwerp University (1984)

Positions Currently Held

- Jean Monnet Chair *ad personam* EU and Global Governance, KU Leuven
- Full Professor of International Law and the Law of International Organizations, KU Leuven; courses on European and International Law, Public International Law, Law of International Organizations, Law of the World Trade Organization, Humanitarian and Security Law from a European Perspective, Space Law and Policy, Seminar/Master Thesis/Practical Exercises International Law and International Organizations
- Director of the Leuven Centre for Global Governance Studies and Institute for International Law, KU Leuven
- Visiting Professor, Faculty of Law (Common Law), University of Ottawa; Sciences Po (Paris), Luiss University (Rome), College of Europe (Bruges), Faculty of Law, Pontificia Universidad Católica de Chile, University of Ottawa, Trento University; Adjunct Professor, Columbia University (SIPA): courses on EU External Relations, International Law, Comparative Human Rights Law
- *Of Counsel*, Linklaters, Brussels
- Expert, Indicative List for Panels of the World Trade Organization
- Member, Roster of Panelists, Free Trade Agreement between the EU, Colombia and Peru

Former Positions

1994-2006	Professor of Corporate Law (mergers and acquisitions), Catholic University of Brussels (postgraduate programme KU Leuven-KUB in corporate law)
1997-2003	Professor of European Banking and Securities Law, Maastricht University
1997-1998	Senior Lecturer on European, Economic and Financial Law, Antwerp University
1993-1998	Lecturer and Senior Lecturer in European and International Law, Maastricht University
1991-1994	Law Clerk (*référendaire*), European Court of Justice, Luxembourg
1989	Legal Adviser to the Belgian Minister of Finance, Brussels
1987-1989	Assistant in Financial, Economic and Commercial Law, Antwerp University

Academic Honours

- Member, Advisory Council, Queen Mary Global Policy Institute (since 2018)
- Visiting Professor, the Hebrew University of Jerusalem, 2016-2017
- Herbert Smith Freehills Visiting Professor, Lauterpacht Centre for International Law, Cambridge University, 2016-2017
- Member, Advisory Board, Centre for Multilevel Federalism, Delhi, India (since 2015)

- Senior Visiting Fellow, the Graduate Institute, Geneva, Spring 2014
- International Chair, Luiss University, Rome, Spring 2014
- Visiting Professor, Université Nice Sophia Antipolis, Spring 2014
- Senior Visiting Fellow, Institute of Advanced Studies, University of Bologna, 2013
- Course Holder of the course « *Le statut juridique des standards publics et privés dans les relations économiques internationales* », Hague Academy of International Law, 29 July - 2 August 2013, The Hague
- Visiting Scholar, Centre d'Etudes européennes, SciencesPo, Paris, 2012
- Senior Visiting Fellow, European Union Institute for Security Studies, Paris, 2012
- Fellow, Netherlands Institute for Advanced Study in the Humanities and Social Sciences (NIAS), 2010
- Honorary President, United Nations Association Flanders – Belgium (*Vereniging voor de Verenigde Naties)* (since 2009; President 2003-2009, 2013-2018)
- Jean Monnet Chair *ad personam* European Union and Global Governance granted by European Commission (2009)
- Member of the Royal Flemish Academy of Belgium for Sciences and Arts (since 2008)
- Fernand Braudel Fellow, European University Institute, 2008
- Honorary Member, Association of International Relations ("Kring Internationale Betrekkingen", Leuven), since 2002
- Stibbe Prize, 1997
- Walter Leën Prize for Social Law, 1996
- Rotary Foundation Fellow, 1990-91
- Francqui Fellow, Belgian American Educational Foundation, 1989-90

Other Professional Activities

- Visiting professorships: Master of Laws in International Economic Law and Policy (LL.M. IELPO), University of Barcelona (2010-2017); European Master's Degree in Human Rights and Democratisation (EMA), Venice (2009-2016); Executive Master of European and International Business Law M.B.L.-HSG, University of Sankt-Gallen (2001-2008); Leiden University (International Tax Programme, since 2003); University of Kyushu (Master of Laws Programme, 2007); Ghent University (Master of Laws Programme, 2003-2009); Liège University (D.E.A./D.E.S., 1996-1998); Université Libre de Bruxelles (European Programme in International Economic Law, EPIEL, 2005-2006)
- Membership of international and national expert bodies: Expert, Indicative List for Panels of the World Trade Organization; Member, roster of panelists, Free Trade Agreement between the EU, Colombia and Peru; Member, Group of Independent Experts on the European Charter of Local Self-Government, Council of Europe; Panel Member, European Research Council (ERC) 2013 and 2015 Consolidator Grants; Chair of the Panel 'Law and Criminology', Research Foundation Flanders (FWO), Belgium (2017; panel member 2012-2017); Member, Belgian Expert Group on National Minorities
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- Membership of professional organizations : Academic Council on the United Nations System (ACUNS); American Society of International Law; Belgian Society of International Law; European Society of International Law; Harvard Club Belgium; International Law Association and Belgian Branch of International Law Association; International Society for Military Law and Law of War; Royal Dutch Society of International Law.
- Membership of jury of scientific prizes: Fernand Collin Prize (most prestigious scientific prize for Dutch-speaking legal scholarship in Belgium); Prize of the *Revue belge de droit international*; Prix de thèse René Cassin.

Research

- General interest for public international law, the law of international organizations, European Union law and global governance
- Present research priorities include: law of treaties and other sources of public international law, including informal lawmaking; the International Criminal Court and fight against impunity, including corporate accountability ; legitimacy and accountability of international organizations; the international and European security architecture ; the law of the World Trade Organization ; international humanitarian law ; the EU in international relations and global governance

I. Introduction

This expert opinion (opinion) examines questions of public international law relating to the scope of application of the World Health Organization's Framework Convention on Tobacco Control (FCTC or Convention). In particular, the opinion aims at responding to the question whether the FCTC applies to what health experts call Alternative Nicotine Delivery Systems (ANDS). The opinion focuses in particular on (i) electronic nicotine delivery systems (ENDS, also known as e-cigarettes or vapour products), that generally do not contain tobacco, (ii) heated tobacco products (also known as Heat Not Burn or tobacco heating products), which do contain tobacco but do not burn it, and (iii) nicotine pouches.

The opinion will address three main questions:

1. Based on the text of the FCTC, as interpreted in accordance with the general rules of treaty interpretation of the Vienna Convention on the Law of Treaties[1] (VCLT), do ANDS fall within the scope of application of the FCTC?
2. Based on the principles relating to the temporal application of treaties under public international law, should the FCTC be interpreted to apply to ANDS despite the FCTC's textual limitation to tobacco products?
3. What, if any, is the legal relevance of the discussions of the Conference of the Parties (COP) of the FCTC on ANDS for purposes of determining the scope of application of the FCTC?

To put it in a non-technical manner: the main question addressed in this opinion is whether under the FCTC the Parties have committed themselves to adopting measures restricting or prohibiting the marketing, promotion and sale of certain products that – as will be seen further in this opinion - did not exist at the time of adoption of the Convention, and that do not present the same risk profile as the products that are covered by the Convention.

The opinion starts with recapturing some of the basics about the rationale for, and nature of, the FCTC, as well as the features of ANDS and the chronology of events relating to the Convention and ANDS. It will then look at the text of the FCTC and examine in particular the definition of the term "tobacco products", which determines the scope of application of the FCTC. Applying the VCLT, the opinion will look at the ordinary meaning of the terms used in this definition, in their context and in the light of the object and purpose of the Convention. Finally, the opinion will examine if there is any subsequent agreement or subsequent practice of the Parties that needs to be taken into consideration together with the context.

II. The FCTC and ANDS: nature, rationale, chronology

This section recaptures some of the basics about the rationale for, and nature of, the FCTC as well as the features of ANDS, and the chronology of events relating to the Convention and ANDS. Given the novel nature of these "next generation" products, it is important to start the analysis at the time of the adoption of the FCTC to see in respect of which products and for what reasons States agreed to a joint approach to tobacco control.

[1] Vienna Convention on the Law of Treaties (adopted 23 May 1969, entered into force 27 January 1980) 1155 UNTS 331.

a. The FCTC

The FCTC is an international treaty on *tobacco control.*[2] This is reflected throughout the FCTC, for example (i) in its title (the Framework Convention on *Tobacco Control*); (ii) in its preamble (e.g. "[r]ecognizing that the spread of the *tobacco* epidemic is a global problem…; [r]eflecting the concern of the international community about the devastating worldwide health, social, economic and environmental consequences of *tobacco* consumption and exposure to *tobacco* smoke"); (iii) in Article 1(d), which defines "tobacco control" as "a range of supply, demand and harm reduction strategies that aim to improve the health of a population by eliminating or reducing their consumption of *tobacco* products and exposure to *tobacco* smoke"; and (iv) in Article 3, which states the "Objective" of the FCTC as follows: "The objective of this Convention and its protocols is to protect present and future generations from the devastating health, social, environmental and economic consequences of *tobacco* consumption and exposure to *tobacco* smoke…". More ample considerations on the Convention's scope of application will be developed *infra,* III.

It is important to recall that the FCTC constitutes a *framework treaty.* It is characteristic for a framework treaty that it formulates certain objectives and principles and sometimes also an institutional framework on the basis of which later more detailed treaties (possibly in the form of protocols) are meant to come out. Such a framework treaty is legally binding under international law, although its framework nature implies that it outlines objectives and principles rather than laying down specific obligations, even though typically it contains a number of minimum obligations.[3] In that sense, the FCTC constitutes a treaty that sets forth a number of minimum obligations, the general objectives of the Parties and the institutional mechanisms (including legal instruments, i.e. protocols) by which such aims will subsequently be negotiated, developed and implemented. The "framework" nature of the Convention implies that it is an agreement that sets forth certain broad objectives rather than specific legal obligations, with the exception of a limited set of obligations that are expressly included "as a minimum." Needless to say, to interpret the broadly worded principles of a framework convention as comprehensive and specific legal obligations would fail to give due account to the intent of the drafters and render redundant the need to develop specific obligations through the institutions and mechanisms created by the framework convention.

In addition, the FCTC's generally worded obligations and frequent instances of deference to national law and constitutional principles highlight the fact that the FCTC's objectives and obligations are subject to limitations imposed by each Party's national law. They signify an element of "subsidiarity", taking into account the great diversity of national legal systems, and thereby leaving flexibility to the Parties to determine the manner in which they intend to meet their obligations.

b. ANDS

ANDS are not conventional tobacco products (such as cigarettes), but represent alternative tobacco and nicotine products that do not burn tobacco to deliver nicotine to the user. ANDS may be used to support smoking cessation attempts and are generally considered as being

[2] Emphasis added here and in the further quotes in this paragraph.
[3] See J. Wouters, C. Ryngaert, T. Ruys and G. De Baere, *International Law: a European Perspective* (Hart Publishing, 2018), 71.

significantly less risky than cigarettes and are part of harm reduction strategies in several countries.[4]

Thus, it has been stated about e-cigarettes that there is a "growing consensus that they are significantly less harmful than tobacco use",[5] and that "[t]he most widely cited estimate of relative risk is from PHE's 2015 e-cigarette evidence review – which concluded that it would be reasonable to estimate that e-cigarette use is likely to be around 95% safer than smoking".[6] Similar considerations relating to the contribution of novel tobacco products to harm reduction strategies also apply to non-combustible, heated tobacco products.[7] The need to distinguish between combustible and non-combustible products was recently highlighted by a group of 72 well-known, independent health experts. In their letters to the WHO and the FCTC COP8, they considered both ENDS and heated tobacco products as ANDS.[8] Indeed, whereas conventional tobacco products are burnt through combustion – creating a complex mixture of gases and smoke particles, which leaves ash behind – heated tobacco products apply heat to the tobacco material, but there is no combustion, no smoke like a cigarette, and no ash.

The lack of combustion greatly reduces exposure to numerous toxicants and carcinogens present in combustible tobacco cigarettes.[9] For example, the 2018 United States Annual Review of Public Health states: "Most reviews of toxicological, clinical, and epidemiological evidence indicate that the chemicals found in e-cigarettes, when used as intended, are far fewer and well below levels seen in cigarette smoke. According to the Royal College of Physicians in the United Kingdom, 'the available data suggest that they are unlikely to exceed 5% of those associated with combusted tobacco products'".[10] Therefore, there are important differences in the physical characteristics of combustible and non-combustible products, including the chemical properties of the resulting combustible smoke and the aerosol produced by ENDS and heated tobacco products.

The opinion evaluates whether the FCTC applies to the following ANDS categories:

1) *ENDS*. These are rechargeable, battery-powered devices, commonly known as e-cigarettes, that heat liquid formulations – e-liquids – to create a vapour that is inhaled. Most e-liquids contain water, propylene glycol and glycerol, flavourings and nicotine, although some e-liquids do not contain any nicotine. These products do not contain tobacco. In addition, the vapour contains far fewer of the toxicants found in the smoke produced when tobacco is burned and those it does contain are emitted at substantially lower levels.

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[4] See e.g. British Medical Association, E-cigarettes: Balancing risks and opportunities (2017); A. McNeill, L. S. Brose, R. Calder, L. Bauld and D. Robson, Evidence review of e-cigarettes and heated tobacco products (Public Health England, 2018).

[5] British Medical Association, E-cigarettes: Balancing risks and opportunities, at 1.

[6] British Medical Association, E-cigarettes: Balancing risks and opportunities, at 6.

[7] Simonavicius E, et al., Heat-not-burn tobacco products: a systematic literature review. Tobacco Control Published Online First: 04 September 2018. doi: 10.1136/tobaccocontrol-2018-054419 ("Peer-reviewed evidence on heated tobacco products indicates that HnB are effective nicotine delivery devices that expose users and bystanders to substantially fewer harmful and potentially harmful compounds than smoking cigarettes.").

[8] Available at: https://clivebates.com/documents/WHOCOP8LetterSeptember2018.pdf

[9] NASEM (2018), Public Health Consequences of E-Cigarettes ("There is conclusive evidence that completely substituting e-cigarettes for combustible tobacco cigarettes reduces users' exposure to numerous toxicants and carcinogens present in combustible tobacco cigarettes").

[10] Abrams et al (2018) Harm Minimization and Tobacco Control: Reframing Societal Views of Nicotine Use to Rapidly Save Lives, Annu. Rev. Public Health 2018. 39:193–213.

2) *Heated tobacco products*. These are rechargeable, battery-powered devices that heat tobacco to generate a nicotine-containing aerosol with a tobacco taste that the user inhales. The heated tobacco vapour includes nicotine, water, humectants, and some natural and familiar tobacco flavours. Because the tobacco has not been burned or excessively heated, the aerosol produced by heated tobacco products contains far fewer and lower levels of odorous, irritant, or toxic chemicals than conventional cigarette smoke. As the U.S. FDA has recognized, "the products produce fewer or lower levels of some toxins than combustible cigarettes".[11]
3) *Nicotine pouches*: These are oral nicotine pouches which consumers place under their lip and the nicotine is then absorbed through their gum. They are available in a range of flavours and nicotine strengths. They are not for chewing or sucking and do not contain tobacco.

c. Chronology

The FCTC was signed in 2003 and entered into force on 27 February 2005. This is well before the globalization of ENDS and heated tobacco products. It seems indeed beyond doubt that the first e-cigarettes entered the European and US markets in 2006 and 2007, respectively,[12] and that their use doubled between 2008 and 2012 in North America and the EU.[13] While electronic heated tobacco products have come on the market even more recently,[14] especially nicotine pouches are among the most recent developments.[15]

As a matter of fact, it must therefore be clear from the outset that the drafters of the FCTC did not – and could not - discuss ANDS, i.e. products that differ from any of the existing tobacco products and that do not present the same risk profile as the tobacco products which gave rise to the Convention's provisions.

This point has been recognized in an important letter to the WHO about the role of ANDS in a harm reduction strategy for tobacco control. The October 2018 letter from a group of 72 independent health experts mentioned above called on the WHO to embrace technology innovation in the fight against diseases caused by smoking, stating:

> "In the field of tobacco control and public health, the world has changed significantly since the Framework Convention on Tobacco Control was signed in 2003. It is impossible to ignore or dismiss the rise of Alternative Nicotine Delivery Systems (ANDS). These are established and new technologies that deliver nicotine to the user without combustion of tobacco leaf and inhalation of tobacco smoke. These technologies offer the prospect of significant and rapid public health gains through

[11] See FDA, "FDA News Release: FDA permits sale of IQOS Tobacco Heating System through premarket tobacco product application pathway" (30 April 2019), available at https://www.fda.gov/news-events/press-announcements/fda-permits-sale-iqos-tobacco-heating-system-through-premarket-tobacco-product-application-pathway ("[T]he agency determined that authorizing these products for the U.S. market is appropriate for the protection of the public health because, among several key considerations, the products produce fewer or lower levels of some toxins than combustible cigarettes.").").

[12] See the timeline on http://www.casaa.org/historical-timeline-of-electronic-cigarettes/

[13] See R. Grana, N. Benowitz and S.A. Glantz, 'E-cigarettes: a scientific review', *Circulation* 219 (2014), e490-e492.

[14] See A. McNeill, L.S. Brose, R. Calder, L. Bauld and D. Robson, Evidence review of e-cigarettes and heated tobacco products, at 25.

[15] See S. Poynton, J. Sutton, S. Goodall, J. Margham, M. Forster, K. Scott, K. McAdam, J. Murphy and C. Proctor, 'Novel hybrid tobacco product that delivers a tobacco flavor note with vapour aerosol' (Part 1), *Food and Chemical Toxicology* 106 (2017), 522-532.

'tobacco harm reduction'. Users who cannot or choose not to quit using nicotine have the option to switch from the highest risk products (primarily cigarettes) to products that are, beyond reasonable doubt, much lower risk than smoking products (e.g. pure nicotine products, low-toxicity smokeless tobacco products, vaping or heated tobacco products). We believe this strategy could make a substantial contribution to the Sustainable Development Goal to reduce premature deaths through non-communicable diseases (SDG Target 3.4)."[16]

Admittedly, the Parties to the FCTC began to analyse one type of ANDS, namely ENDS or vapour products, in 2010 when the COP requested the FCTC Convention Secretariat to prepare a report based on the experience of Parties on the matter of ENDS for consideration at the fifth session of the COP in 2012.[17] Thereafter, the FCTC has continued to evaluate scientific, regulatory and market developments in relation to ENDS as well as heated tobacco products – most recently in COP8 in 2018.[18] For further considerations on the COP's work in this matter, see *infra,* V. Importantly, the fact that the COP discusses these matters does not turn these products into tobacco products covered by the Convention. Whether a product is covered by the FCTC depends on the definition of covered tobacco products. That is what the following section looks into.

III. The definition of "tobacco products" in the FCTC in their context and in the light of the object and purpose of the FCTC

a. Introduction

The FCTC defines "tobacco products" in its Article 1(f) as follows: "products entirely or partly made of the leaf tobacco as raw material which are manufactured to be used for smoking, sucking, chewing or snuffing".

The Convention deals with tobacco control writ large and in that context imposes specific minimum obligations with respect to covered "tobacco products" such as in Articles 11 and 13 of the FCTC. The objective of the Convention, formulated in its Article 3, uses terminology that focuses on the devastating consequences of tobacco use and exposure to tobacco smoke:

> "The objective of this Convention and its protocols is to protect present and future generations from the devastating health, social, environmental and economic consequences of *tobacco consumption* and exposure to *tobacco smoke* by providing a framework for *tobacco control measures* to be implemented by the Parties at the national, regional and international levels in order to reduce continually and substantially the prevalence of *tobacco use* and exposure to *tobacco smoke*" (emphasis added)

One therefore has to consider the text and object and purpose of the FCTC more widely. For this purpose it is important to rely on the general rules on treaty interpretation in international law. These rules are laid down in Articles 31-33 of the VCLT, which are considered to reflect

[16] See https://clivebates.com/documents/WHOCOP8LetterOctober2018.pdf at p1.
[17] See Decision FCTC/COP7(9) at https://www.who.int/fctc/cop/cop7/FCTC_COP7_9_EN.pdf
[18] See e.g. FCTC/COP/8/1/, https://www.who.int/fctc/cop/sessions/cop8/FCTC_COP_8_1_Provisional_agenda-en.pdf

customary international law.[19] They do not need to be described in detail here. As is known, the basic rule for treaty interpretation is laid down in Article 31(1) VCLT, pursuant to which "[a] treaty shall be interpreted in good faith in accordance with the ordinary meaning to be given to the terms of the treaty in their context and in light of its object and purpose."

Last but not least, it is important to emphasize that it is unnecessary to apply the principles of treaty interpretation when the text is clear. In this respect, the Permanent Court of International Justice has stated that '[h]aving before it a clause which leaves little to be desired in the nature of clearness, [the Court] is bound to apply this clause as it stands'.[20] In the words of Vattel, the first general maxim concerning interpretation is that it is not permitted to interpret what does not require interpretation.[21]

b. Ordinary meaning of the terms used in the definition of covered "tobacco products"

As indicated above, the FCTC is a treaty on tobacco control. A core notion is clearly the one of *"tobacco products"*, as defined in its Article 1(f), cited above: it is referred to in the fourth, fifth, 11th and 12th recitals of the preamble, as well as in Articles 1(d), (e) and (f), 4(2)(b) and (4), 6(2)(a) and (b) and (3), 13(1) and (4)(c), 19(2)(a). Moreover, it is the central concept used in Articles 9, 10, 11, 15 and 16, as the title of these articles (except Article 16) indicates, and it is used repeatedly therein.

The FCTC aims at regulating and controlling not just the demand and supply of tobacco products but at "the widest possible international cooperation" on "the spread of the tobacco epidemic" (second recital of the preamble), which also includes scientific and technical cooperation and communication of information (Part VII of the Convention).

The term "cigarettes" is used only sparingly in the FCTC (fourth, sixth, 12th recital of the preamble, Articles 15(4)(b) and (c), 16(3)), and it is clear that the Convention also aims to apply to "other tobacco products" (fourth and 12th recitals of the preamble). It is thus clear that "tobacco products" is a term that concerns not just cigarettes but also any other product covered by the definition of "tobacco products" in Article 1 (f) – i.e. a product that (1) is made of tobacco leaf and that (2) is manufactured to be used for smoking, sucking, chewing or snuffing.

Determining the scope of application of the Convention is therefore first and foremost dependent on the interpretation of the notion of "tobacco products".

As stated, Article 1(f) of the Convention defines this notion as "products entirely or partly made of the leaf tobacco as raw material which are manufactured to be used for smoking, sucking, chewing or snuffing".

The text of this definition is rather clear. It is surely a very broad definition: not just because it applies to any product that is entirely *or partly* made of the leaf tobacco as raw material, but

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[19] See *inter alia* International Court of Justice (ICJ), *Arbitral Award of 31 July 1989* ICJ Rep [1991] 69–70 para. 48; *Kasikili/Sedudu Island* (Botswana v Namibia) [1999] II p. 1074, para. 18; *Certain Questions of Mutual Assistance in Criminal Matters* (Djibouti v France) ICJ Rep [2008] p. 219, para. 112.

[20] *Question Concerning the Acquisition of Polish Nationality* [1923] PCIJ Series B, No 7, 20.

[21] Cited by C Rousseau, *Droit international public* (Paris, Sirey, 1970) 269, own translation from French: '[l]a première maxime générale sur l'interprétation est qu'il n'est pas permis d'interpréter ce qui n'a pas besoin d'interprétation'.

also because the product can be used for multiple purposes: smoking, sucking, chewing or snuffing.

On the other hand, the text of the definition makes clear that it only applies to products that use *"the leaf tobacco as raw material"*. It also makes clear that not every use of tobacco is covered but only the "smoking, sucking, chewing or snuffing" thereof. If the drafters had intended to include any and all products made at least in part of the leaf tobacco as raw material, there would have been no need to add the second element of the definition, which limits the group of tobacco products to those "manufactured to be used" for these four specific actions.

As *ENDS products* and *nicotine pouches* do not contain tobacco, a textual interpretation of the FCTC would immediately exclude them from the Convention's scope of application.

This is different for *heated tobacco products*: they involve tobacco as a raw material, even though the tobacco is not being burned or excessively heated. They would thus seem to meet the first part of the definition relating to the raw material, i.e. "entirely or partly made of the leaf of tobacco".

However, the relevant question for these products is whether the heating of tobacco amounts to "smoking, sucking, chewing or snuffing" so as to meet also the second part of the definition. Clearly, the consumer of a heated tobacco product is not sucking, chewing or snuffing the tobacco. The question remains whether heating tobacco without burning it is to be equated with "smoking" the tobacco.

The ordinary meaning of the term "smoking" – which as such is not defined in the FCTC - appears to refer to the "visible suspension of carbon and other particles in air, given off by a burning or smouldering substance."[22] The burning or smouldering substance in this case would be tobacco. In the context of ENDS, there is no tobacco to be burned and thus no combustion (i.e. "an act or instance of burning"[23]). In the context of heated tobacco products, the tobacco is heated but not burned. There is therefore no "burning or smouldering" of the substance. The verb "to smoke" is defined as to "inhale and exhale the smoke of tobacco or other substance from a pipe, cigar or cigarette."[24] The focus in these definitions is thus on the combustion or burning of the tobacco and the inhaling of the resulting smoke. That definition does not seem to fit with the way heated tobacco products are consumed. In a heated tobacco product, the consumable in the device is not combusted or burned but merely heated to the point that it creates an aerosol that is then inhaled. The product is a vaping product and not a smoking product because it is a "non-combustible" product, as has been recognized by numerous public health authorities.[25]

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[22] *Shorter Oxford Dictionary*, sixth edition, definition of the noun "smoke" p. 2886.

[23] *Merriam-Webster Dictionary*, "combustion" (2019), available from: https://www.merriam-webster.com/dictionary/combustion.

[24] *Shorter Oxford Dictionary*, sixth edition, definition of the verb "to smoke" p. 2887.

[25] FDA, "FDA News Release: FDA permits sale of IQOS Tobacco Heating System through premarket tobacco product application pathway" (30 April 2019), available at https://www.fda.gov/news-events/press-announcements/fda-permits-sale-iqos-tobacco-heating-system-through-premarket-tobacco-product-application-pathway (noting that these heated tobacco products are "non-combusted"); Public Health England, Evidence review of e-cigarettes and heated tobacco products (January 2018) (referring to heated tobacco products as "non-combustible" products and distinguishing ENDS from "combustible tobacco products").

In other words, because it is not combusted or burned, the heated tobacco product is a product that is partly made of the leaf of tobacco which is manufactured to be used for vaping, and not smoking.

Based on a textual analysis of the concept of "tobacco products" as defined in the FCTC it is therefore held that heated tobacco products are made of the leaf tobacco and thus potentially fall within this concept, but ENDS products, which are not made of the leaf tobacco, certainly do not. For heated tobacco products, the relevant question is whether the tobacco is used for "smoking". The preliminary conclusion based on the ordinary meaning of the term "smoking" is that this does not apply to these novel products.

The question may arise, however, whether, despite these clear textual conclusions, ENDS products could be held to fall within the scope of application of the FCTC on the basis of other principles of treaty interpretation, notably an interpretation "in the light of its object and purpose", or on the basis of principles of effectiveness and/or evolutive treaty interpretation (on the latter two, see *infra,* IV). These principles may also shed further light on the question whether heated tobacco products should be covered by the definition of "tobacco products" despite the clear textual limitations resulting from the use of the term "smoking".

The objective of the FCTC, as laid down in the aforementioned Article 3 of the Convention, is to "protect present and future generations from the devastating health, social, environmental and economic consequences of tobacco consumption and exposure to tobacco smoke". However, as seen above, scientifically there is a "growing consensus" that e-cigarettes "are significantly less harmful than tobacco use"[26] and that "it would be reasonable to estimate that e-cigarette use is likely to be around 95% safer than smoking".[27] In other words, with respect to ENDS products, one cannot really speak of "devastating health, social, environmental and economic consequences" and of a "spread of the tobacco epidemic" in the sense of "a global problem with serious consequences for public health", as stated in the second recital of the FCTC's preamble. It is important to note in this respect that there is also no scientific consensus that ANDS would be a "gateway" to ordinary smoking: a 2016 WHO report confirmed that the debate on this issue "is unresolved".[28]

In light of the foregoing, it has to be concluded that ENDS products do not only fall outside the scope of application of the FCTC based on the ordinary meaning of the terms of the Convention, but also, in the current state of scientific knowledge, in light of the Convention's object and purpose.

A similar conclusion seems to impose itself for heated tobacco products, which are grouped by health experts together with e-cigarettes as ANDS, and which may play an important role in a harm reduction strategy. It was concluded above that the ordinary meaning of the terms "used for smoking" does not apply to these products, in which the tobacco is used for vaping the aerosol that is produced by heating the tobacco.

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[26] British Medical Association, E-cigarettes: Balancing risks and opportunities, at 1.

[27] British Medical Association, E-cigarettes: Balancing risks and opportunities, at 6.

[28] Report by WHO, Electronic Nicotine Delivery Systems and Electronic Non-Nicotine Delivery Systems (ENDS/ENNDS), FCTC/COP/7/11, 6. Nevertheless, and despite the lack of legal force of these additional comments, the report adds that "preventing this eventuality requires making the initiation and persistence of smoking as difficult as possible" and recommends Parties that have not banned the importation, sale, and distribution of these products to consider a number of options.

The context and object and purpose of the FCTC confirms that there is no reason for reading the term "smoking" more broadly. Looking at the tobacco control-related context as well as the above described object and purpose of the FCTC of protecting consumers from the devastating health effects of tobacco consumption and exposure to tobacco "smoke" while stimulating harm reduction strategies, leads to the conclusion that the term "smoking" in this context must be equated with the "combustion" of the tobacco, since that is what causes the harm to health.

Indeed, as noted earlier, science establishes a need to distinguish between combustible and non-combustible products, as the lack of burning tobacco greatly reduces exposure to toxicants and carcinogens present in combustible tobacco cigarettes.[29] There are therefore important differences in the physical characteristics of combustible and non-combustible products, including the chemical properties of the resulting combustible smoke and the aerosol produced by ENDS and heated tobacco products.

The important role that ANDS (including heated tobacco products) can play in a strategy of tobacco harm reduction was recently emphasized in a letter by independent experts. The public health experts noted that: "[m]illions of smokers have moved from cigarettes to less harmful alternatives where the laws allow it. Where ANDS have been popular, we have seen rapid declines in adult smoking, for example in the United Kingdom, Sweden, the United States, and in Japan where cigarette consumption fell by 27 percent in the two years between first quarter 2016 and the same period in 2018 following the introduction of heated tobacco products."[30] Therefore, the context of the need to fight the tobacco epidemic and the references in for example the Convention's Preamble to the fact that scientific evidence has unequivocally established that tobacco consumption and exposure to tobacco smoke cause death, disease and disability, do not necessarily apply to heated tobacco products, which are not used for "smoking".

The object and purpose of the FCTC, as reflected in Article 3 of "protect[ing] present and future generations from the devastating health, social, environmental and economic consequences of tobacco consumption and exposure to tobacco smoke", referred to above (*supra,* III.a), appears to confirm the interpretation advanced above of the term "smoking." ANDS such as heated tobacco products, would not only not be covered in light of the ordinary meaning to be given to the term "smoking" but also there is no generally agreed scientific evidence that their "consumption" has the aforementioned devastating effects. Such products rather seem to play an important positive role as part of a harm reduction policy, which is a key aspect of tobacco control. Applying the same obligations and restrictions to heated tobacco products as to tobacco products under the Convention would result in removing the less harmful alternative from the market and, in that sense, go against the need to pursue a harm reduction strategy.

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[29] NASEM (2018), *Public Health Consequences of E-Cigarettes*; Abrams et al (2018), 'Harm Minimization and Tobacco Control: Reframing Societal Views of Nicotine Use to Rapidly Save Lives', Annu. Rev. Public Health 2018. 39:193–213; and Letter to WHO, 'WHO should reject prohibition and embrace 'tobacco harm reduction' and risk-proportionate regulation of tobacco and nicotine products', available at: https://clivebates.com/documents/WHOCOP8LetterSeptember2018.pdf.

[30] Available at: https://clivebates.com/documents/WHOCOP8LetterSeptember2018.pdf

IV. Impact of principles of temporal application of treaties on the scope of application of the FCTC

This section evaluates whether the application of international law principles on the temporal interpretation of treaties calls for ANDS to be covered by the terms of the FCTC.

a. Principles of effective and evolutive treaty interpretation

The principle of *effectiveness*, *principe de l'effet utile* or *ut res magis valeat quam pereat* (it may rather have effect than be destroyed) entails that where there are two possible interpretations of a treaty, the interpretation that gives meaning and effect is to be preferred.[31]

Apart from this, the principle of *evolutive interpretation* implies that a treaty is to be interpreted in light of the contemporary legal order rather than in light of the law as it stood at the time of its adoption. This approach allows treaties to inform social life as it evolves.[32] In Europe, especially the European Court of Human Rights has developed an approach of evolutive interpretation as an interpretative method of its own.[33]

However, neither an *effective* nor *evolutive* treaty interpretation calls for an undue extensive interpretation of treaties in the sense of going beyond what is expressed in the terms of the treaty. The International Law Commission has specifically commented on this tension between an *effective* and *evolving* interpretation so as not too statically read a treaty, on the one hand, and the risk of extending the meaning of treaties illegitimately beyond their text, on the other. It has pronounced that there "are definite limits" to the use which may be made of such principles to illegitimately go beyond the text of treaties, and that "to adopt an interpretation which ran counter to the clear meaning of the terms would not be to interpret but to revise the treaty".[34]

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[31] See International Law Commission, 'Draft Articles on the Law of Treaties with commentaries' (1966) *Yearbook of the International Law Commission*, Vol. II, at 219. See further H. Gutièrrez Posse, 'La maxime ut res magis valeat quam pereat (interprétation en fonction de l'"effet utile"): les interprétations "extensives" et "restrictives"' (1972) 23 *Österreichische Zeitschrift für öffentliches Recht* 229.

[32] See R. Kolb, *The Law of Treaties: An Introduction* (Chelthenham, Edward Elgar, 2016),158; G. Distefano, 'L'interprétation évolutive de la norme internationale' (2011) 2 *Revue générale de droit international public* 373; C. Djeffal, *Static and Evolutive Treaty Interpretation: A Functional Reconstruction* (Cambridge, CUP, 2015); S.T. Helmersen, 'Evolutive Treaty Interpretation: Legality, Semantics and Distinctions' (2013) 6 *European Journal of Legal Studies* 127.

[33] The Court first mentioned this approach in the *Tyrer v United Kingdom* case, where it had to decide whether judicial corporal punishment of juveniles amounted to degrading punishment within the meaning of Article 3 of the European Convention on Human Rights. The Court held that it did. For this purpose, it held that 'the Convention is a living instrument which [...] must be interpreted in the light of present day conditions', and that, '[i]n the case now before it the Court cannot but be influenced by the developments and commonly accepted standards in the penal policy of the Member States of the Council of Europe in this field': *Tyrer v The United Kingdom* App no 5856/72, 25 April 1978, para. 31. This passage inaugurated the Court's pervasive use of evolutive interpretation in later years, see e.g. *Marckx v Belgium* App no 6833/74, 13 June 1979. See further J.E. Helgesen, 'What are the Limits to the Evolutive Interpretation of the European Convention on Human Rights?' (2011) 31 *Human Rights Law Journal* 275; T. Thienel, 'The "Living Instrument" Approach in the ECHR and Elsewhere: Some Remarks on the Evolutive Interpretation of International Treaties', in J. Delbrück, U.E. Heinz, K. Odendahl, N. Matz-Lück and A. von Arnauld (eds.), *Aus Kiel in die Welt: Kiel's contribution to international law: Festschrift zum 100-jährigen Bestehen des Walther-Schücking-Instituts für Internationales Recht* (Berlin, Duncker & Humblot, 2014), 165–200.

[34] International Law Commission, 'Draft Articles on the Law of Treaties with commentaries' (1966) *Yearbook of the International Law Commission*, Vol II, at 219.

b. Application of these principles to ANDS and the FCTC

The question arises whether, despite not being named in the Convention or even conceived of at the time of its negotiation, the FCTC can be held to apply to ANDS based on an application of the international law principles of *effective* and *evolutive* treaty interpretation.

As noted above (*supra,* II.c), ANDS were not part of the negotiations for the FCTC. This is true for both e-cigarettes and other ENDS products, nicotine pouches as well as tobacco-containing ANDS such as heated tobacco products. Non-tobacco based ANDS such as ENDS products and non-combustible tobacco products were definitely not part of the FCTC at the time of its adoption. That is also what is reflected in the text of the FCTC, in particular in the definition of the two-pronged test for "tobacco products" (*supra,* III.b). As indicated by the International Law Commission, there are clear limits under international law for extending the meaning of the FCTC beyond its text as interpreted through the tools of *effective* and *evolutionary* interpretation. To utilize these tools in order to bring non-covered products within the scope of application of the FCTC, would be problematic. It would unduly extend the text of the FCTC beyond its ordinary meaning and beyond its general objectives, as stated above.

Moreover, as will be indicated below, there is no evidence that the FCTC Parties have entered into a subsequent practice that would call for these products to fall within the remit of the Convention. In fact, very few Parties to the FCTC regulate ENDS and heated tobacco products in the same way as covered "tobacco products". For example, the UK Government is actively supporting the use of non-combustible products as part of its tobacco harm reduction activities. It imposes different marketing and excise regulations, and generally allows public place vaping and retail display. Even regulators in jurisdictions that have historically prohibited alternatives to conventional tobacco products, such as Canada and New Zealand, are stepping away from such regulatory regimes. For example, with respect to ENDS , Canada in 2018 enacted a new legislative framework for ENDS products with the aim "to protect youth from nicotine addiction and inducements to tobacco use, while allowing adults to legally access vaping products as a less harmful alternative to tobacco".[35]

The International Law Commission has confirmed that "subsequent agreements and subsequent practice, like other means of interpretation, 'may assist in determining whether or not the presumed intention of the parties upon the conclusion of the treaty was to give a term used a meaning which is capable of evolving over time'".[36]

The work done to date in relation to ANDS has focused mainly on evaluating the situation in terms of their impact on tobacco control and their potential as smoking cessation tools. There therefore does not seem to be a subsequent practice to suggest that Parties consider that the same treatment should be given to covered tobacco products and ANDS.

With respect to ANDS, including tobacco containing ANDS such as heated tobacco products, an evolutive interpretation would not likely suffice to apply the FCTC to non-combustible tobacco products. Given their different characteristics and risk profile, to do so would not appear to be necessary to ensure an effective application of the FCTC either. As indicated

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[35] Health Canada, https://www.legco.gov.hk/general/english/library/stay_informed_overseas_policy_updates/new-tobacco-and-vaping-products-legislation.pdf

[36] See Second Report on Subsequent Agreements and Subsequent Practice in Relation to Treaties, http://legal.un.org/docs/?symbol=A/CN.4/671, p. 50, para. 115. See also International Law Commission, Subsequent agreements and subsequent practice in relation to the interpretation of treaties. Text of the draft conclusions adopted by the Drafting Committee on second reading, 11 May 2018, A/CN.4/L.907, Conclusion 8.

above, the text and context of the term "tobacco products" and the object and purpose of the FCTC appear to militate against an expansive reading of the FCTC to a novel product that is less harmful to health and may play an important positive role in a harm reduction strategy.

Independent research by the UK Department of Health in 2017 found that consumers using heated tobacco devices are exposed to between 50-90% less "harmful and potentially harmful" compounds compared with conventional cigarettes.[37] Similarly, a report by Public Health England in 2018 found 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", and added that "[t]he available evidence suggests that heated tobacco products may be considerably less harmful than tobacco cigarettes and more harmful than e-cigarettes".[38]

V. Legal relevance of COP discussions for the scope of application of the FCTC

The analysis in this section aims at verifying whether one can find in the discussions of the COP with regard to ANDS possible indications of "any subsequent agreement between the parties regarding the interpretation of the treaty or the application of its provisions" or "any subsequent practice in the application of the treaty which establishes the agreement of the parties regarding its interpretation", which would have to be taken into account for the interpretation of the FCTC, together with the context, as prescribed by Article 31(3) VCLT.

In the first place some terminological clarifications are due. A "subsequent agreement" is an agreement between the parties, reached after the conclusion of a treaty, regarding the interpretation of the treaty or the application of its provisions, while a "subsequent practice" consists of conduct in the application of a treaty, after its conclusion, which establishes the agreement of the parties regarding the interpretation of the treaty.[39]

For example, in the case-law of the World Trade Organization ("WTO"), the term "subsequent agreement" has been interpreted to refer to "substance rather than to form". Thus, so as long as an agreement "clearly expresses a common understanding, and an acceptance of that understanding among Members with regard to the meaning of the term in question" it would be considered to meet the definition of a 'subsequent agreement'.[40] The Appellate Body has explained that the extent to which a subsequent agreement will inform the interpretation and application of a treaty term or provision depends on "the degree to which it 'bears specifically' on the interpretation and application of the respective term or provision".[41] This means that the subsequent agreement must represent an "authentic interpretation" of the treaty parties of the specific term or provision in question in order for it to be taken into account.[42]

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[37] Department of Health UK, Statement on the toxicological evaluation of novel heat-not-burn tobacco products (December 2017).

[38] Public Health England, Evidence review of e-cigarettes and heated tobacco products (January 2018).

[39] International Law Commission, Subsequent agreements and subsequent practice in relation to the interpretation of treaties (Text of the draft conclusions adopted by the Drafting Committee on second reading), 11 May 2018, A/CN.4/L.907, Conclusion 4.

[40] See, e.g. Appellate Body Report, *US – Clove Cigarettes*, para. 267.

[41] See, e.g. Appellate Body Report, *US – Tuna II (Mexico)*, para. 372 (referring to Appellate Body Report, *US – Clove Cigarettes*, para. 265).

[42] See, e.g. Appellate Body Reports, *EC – Bananas III (Article 21.5 – Ecuador II) / EC – Bananas III (Article 21.5 – US)*, paras. 389-390 (referring to "Report of the International Law Commission on the Work of its 18th Session, Geneva, 4 May-19 July 1966" (1966) II Yearbook of the International Law Commission 172, at 221, para. 14).

In the second place, in relation to "subsequent practice", the WTO has established that this requires a "concordant, common and consistent" sequence of acts or pronouncements, which are sufficient to establish a discernable pattern implying the agreement of the parties regarding a particular interpretation of a treaty term or provision.[43] In one instance, the International Court of Justice has even held that a subsequent practice of the parties to a treaty "can result in a departure from the original intent on the basis of a tacit agreement".[44] This is, however, not the case in the WTO where the Appellate Body has made it clear that it would not accept an interpretation that would result in a modification of a treaty obligation, as this would not anymore be an "application" of an existing treaty provision.[45] On the basis of this apparent divergence, Professor Georg Nolte, Special Rapporteur for the International Law Commission, recently noted that "a treaty may preclude the subsequent practice of the parties from having a modifying effect. Thus, the treaty itself governs the question in the first place"[46] and that "[t]he possibility of amending or modifying a treaty by subsequent practice of the parties has not been generally recognized" in international law.[47]

In the third place, the obligation under Article 31(3)(c) of the VCLT to take account of any relevant rules of international law applicable in the relations between the parties requires a systemic interpretation of all relevant international law rules. Specifically, an interpretation may have to take account of material sources external to a treaty, such as other treaties, customary rules, or general principles of law, which are relevant to the interpretation of the treaty term or provision in question to arrive at a consistent meaning.[48] The International Court of Justice endorses this position, stating for example that "an international instrument has to be interpreted and applied within the framework of the entire legal system prevailing at the time of the interpretation".[49] In the WTO, the Appellate Body has referred with approval to the above-quoted statement by the International Court of Justice.[50] It has also explained that in order for another rule of international law to be "relevant" it needs to "concern the same subject matter as the treaty terms being interpreted",[51] and that it is likely insufficient for the rule to apply only between *some* of the WTO Members for it to be relevant.[52]

In light of the foregoing considerations it needs to be considered whether the FCTC Parties have entered into a subsequent agreement or practice since the inception of the FCTC, or whether there exists an applicable rule of international law, that would call for the treaty to apply to ANDS.

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[43] See, e.g. Appellate Body Report, *Japan – Alcoholic Beverages II*, para. 26.
[44] *Dispute regarding Navigational and Related Rights (Costa Rica v. Nicaragua)*, Judgment, I.C.J. Reports 2009, para. 64; see also *Legal Consequences for States of the Continued Presence of South Africa in Namibia (South West Africa) notwithstanding Security Council Resolution 276 (1970)*, Advisory Opinion, I.C.J. Reports 1971, para. 22.
[45] See, e.g. Appellate Body Reports, *EC – Bananas III (Article 21.5 – Ecuador II) / EC – Bananas III (Article 21.5 – US)*, para. 391.
[46] G. Nolte, Second report on subsequent agreements and subsequent practice in relation to the interpretation of treaties (26 March 2014), A/CN.4/671, para. 139.
[47] International Law Commission, Subsequent agreements and subsequent practice in relation to the interpretation of treaties (Text of the draft conclusions adopted by the Drafting Committee on second reading), 11 May 2018, A/CN.4/L.907, Conclusion 7, para. 3.
[48] Report of the Study Group of the International Law Commission, "Fragmentation of International Law: Difficulties Arising From the Diversification and Expansion of International Law", 2006, p. 180.
[49] *Namibia (Legal Consequences)*, Advisory Opinion I.C.J. Reports 1971, p. 31.
[50] Appellate Body Report, *US – Shrimp*, fn. 109.
[51] Appellate Body Report, *US – Anti-Dumping and Countervailing Duties (China)*, para. 308.
[52] Appellate Body Report, *EC and certain member States – Large Civil Aircraft*, para. 845.

The FCTC was adopted by the World Health Assembly on 21 May 2003 and entered into force on 27 February 2005. As indicated above, this is before the globalization of ENDS and heated tobacco products, which first entered the European and US markets in 2006 and 2007 respectively, whereas heated tobacco products have come on the market more recently (see *supra,* II.c).

It was only years after the inception of the FCTC that the Parties started to analyze ANDS:

- In 2008, the FCTC Working Group on Articles 9 and 10 made a recommendation in its report to the Third session of the COP (COP3) to request the WHO to identify best practices in reporting to regulators on the contents, emissions and the characteristics of products, including electronic systems (see Decision FCTC/COP3(6));
- In 2010, the FCTC Secretariat presented a report to the Fourth session of the COP (COP4) on the Control and Prevention of Smokeless Tobacco Products and Electronic Cigarettes (see Report FCTC/COP/4/12). The report noted that there was a growing global concern about the quality, safety and "regulatory gap" of these emerging products, broadly called ENDS;
- Also in 2010, the FCTC Working Group on Articles 9 and 10 requested the COP to indicate whether it agreed that ENDS are to be considered "tobacco products" and should be part of future work of the working group (FCTC/COP/4/6 Rev.1). There was, however, no decision made on whether ENDS should be considered tobacco products;
- In 2012, the COP5 requested the Convention Secretariat to identify options for the prevention and control of ENDS and to examine emerging evidence on the health impacts of ENDS use (see Decision FCTC/COP/5/13);
- In 2014, the COP6 requested the Convention Secretariat to invite the WHO to prepare a report on ENDS and electronic non-nicotine delivery systems (ENNDS) for the Seventh session of the COP (COP7) (See Decision FCTC/COP6(9)). The WHO also presented a report to COP6 on the evolution of novel tobacco products (see Report FCTC/COP/6/14);
- In 2016, the WHO presented the report to COP7 updating the evidence of the health impact of ENDS/ENNDS, their potential role in tobacco cessation and their impact on tobacco control efforts, as well as an assessment on regulatory options (see Report FCTC/COP/7/11);
- Also at COP7, a decision was taken inviting the Parties to consider applying some regulatory measures suggested in the report prepared by the WHO, such as prohibition or restriction of the manufacture, importation, distribution, presentation, sale and use of ENDS/ENNDS (see Decision FCTC/COP7(9));
- In 2018, the FCTC Secretariat presented a report to the Eight session of the COP (COP8) on regulatory and market developments on electronic nicotine delivery systems (ENDS) and electronic non-nicotine delivery systems (ENNDS) (see Report FCTC/COP/8/10); and
- The COP8 stated in its decision on novel and emerging tobacco products that "heated tobacco products are tobacco products and are therefore subject to the provisions of the WHO FCTC" (see Decision FCTC/COP8/(22)).

Based on the foregoing synopsis of the work of the FCTC in the area of ANDS, there is support for concluding (i) that the FCTC has not adopted a subsequent agreement or practice on

applying the FCTC to non-tobacco ANDS such as ENDS products; and (ii) that it should be examined further whether there is a subsequent agreement or subsequent practice that the FCTC applies to other ANDS tobacco products developed after the inception of the Convention.

First, in relation to non-tobacco ANDS such as ENDS products, there is no evidence that the FCTC Parties have reached a subsequent agreement or entered into a subsequent practice that would call for these products to fall within the remit of the treaty. The work done to date has focused mainly on evaluating the situation in terms of the impact of these products on tobacco control and their potential as smoking cessation tools, as well as to identify best practices among the Parties. Importantly, in 2010, at the direct request from the FCTC Working Group on Articles 9 and 10, the Parties considered but did not take a decision recognizing that ENDS are to be considered "tobacco products". Accordingly, there appears to be no evidence that the FCTC Parties "clearly expresse[d] a common understanding" that non-tobacco ANDS shall be covered by the Convention.[53] In particular, there is no subsequent agreement that "bears specifically"[54] on the interpretation and application of a specific FCTC term or provision that would call for such ANDS to be covered by the Convention, as the work done to date has focused on evaluating the impact of these products on tobacco control and their potential as smoking cessation tools. Nor does it seem that there has been a "concordant, common and consistent" sequence of acts or pronouncements, sufficient to establish a discernable pattern, implying the agreement of the FCTC Parties that non-tobacco ANDS shall be covered by the Convention.[55] Moreover, to our knowledge there are no other relevant rules of international law that would seem to bear upon the interpretation of the FCTC so as to include non-tobacco ANDS within its remit.

Second, in relation to heated tobacco products, the above referenced COP8 Decision FCTC/COP8/(22) "recognizes" in its preamble that such products are "tobacco products and are therefore subject to the provisions of the WHO FCTC".[56] Moreover, in its para. 5, the Decision

> "REMINDS Parties about their commitments under the WHO FCTC when addressing the challenges posed by novel and emerging tobacco products such as heated tobacco products and devices designed for consuming such products, and consider prioritizing the following measures in accordance with the WHO FCTC and national law:
> (a) to prevent the initiation of novel and emerging tobacco products;
> (b) to protect people from exposure to their emissions and to explicitly extend the scope of smoke-free legislation to these products in accordance with Article 8 of the WHO FCTC;
> (c) to prevent health claims from being made about novel and emerging tobacco products;
> (d) to apply measures regarding advertising, promotion and sponsorship of novel and emerging tobacco products in accordance with Article 13 of the WHO FCTC;
> (e) to regulate the contents and the disclosure of the contents of novel and emerging tobacco products in accordance with Articles 9 and 10 of the WHO FCTC;
> (f) to protect tobacco-control policies and activities from all commercial and other vested interests related to novel and emerging tobacco products, including interests of the tobacco industry, in accordance with Article 5.3 of the WHO FCTC;

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[53] See, e.g. Appellate Body Report, *US – Clove Cigarettes*, para. 267.
[54] See, e.g. Appellate Body Report, *US – Tuna II (Mexico)*, para. 372 (referring to Appellate Body Report, *US – Clove Cigarettes*, para. 265).
[55] See, e.g. Appellate Body Report, *Japan – Alcoholic Beverages II*, para. 26.
[56] Sixth recital to the preamble of Decision FCTC/COP8/(22).

(g) to regulate, including restrict, or prohibit, as appropriate, the manufacture, importation, distribution, presentation, sale and use of novel and emerging tobacco products, as appropriate to their national laws, taking into account a high level of protection for human health;
(h) to apply, where appropriate, the above measures to the devices designed for consuming such products;"

At first glance, the explicit language in the preamble and in the operational part of Decision FCTC/COP8/(22) appears to express the view of the COP that heated tobacco products fall within the scope of application of the FCTC as "tobacco products". However, the question arises whether the "recognition" in the Preamble of this non-legally binding Decision of the COP and the "reminder" of existing commitments in the FCTC which apply to "tobacco products" suffice to constitute a subsequent agreement or a subsequent practice. In this respect, it should first of all be noted that the Decision does not "bear specifically" on the question whether novel tobacco products are covered by the definition of "tobacco products". In fact, it simply asserts as much in the Preamble. Importantly, in the Preamble, the Decision also "recognizes" that "some Parties have adopted various regulatory strategies with respect to heated tobacco products, in particular concerning their inclusion in smoke-free legislation,"[57] thereby indicating that the Parties do not share the common understanding that novel tobacco products should be treated the same way as covered tobacco products. This casts doubt on the extent to which there is a shared understanding of whether heated tobacco products actually are covered or should be covered by the definition of tobacco products under the CFTC such that all rules and restrictions apply.

Nor does it appear that this "recognition" in the preamble of this Decision or the general reminder of existing FCTC commitments amounts to a "concordant, common and consistent" sequence of acts or pronouncements, which are sufficient to establish a discernable pattern implying the agreement of the parties regarding a particular interpretation of a treaty term or provision. In fact, the reason why attention is given to ENDS and novel tobacco products seems to be because there is no common practice of treating these products in the same way as covered tobacco products. If it remains isolated to a single occurrence, the Decision's "recognition" can hardly be seen as a common and consistent sequence of acts and pronouncements. Had there been a common understanding among the Parties that heated tobacco products are covered tobacco products to which the same commitments apply, there would have been no need for the discussion that was had in the most recent COP meetings.

Therefore, with regard to heated tobacco products the COP8 Decision does not appear to be sufficient evidence for a subsequent practice, in the sense that it would amount to "conduct in the application of the treaty, after its conclusion, which establishes the agreement of the parties regarding the interpretation of the treaty". As seen above, in practice a number of Parties to the FCTC do not treat ANDS the same way as covered tobacco products. If the Parties wanted to amend the FCTC, there is a mechanism for this which requires consensus. Given the very divergent approaches to ANDS, including heated tobacco products, there is not likely to be such a consensus.

[57] Eighth recital to the preamble of Decision FCTC/COP8/(22).

VI. A Final Word on the Relevance of the FCTC to ANDS

This legal opinion considers that the FCTC does not apply to ANDS, for the reasons set out above. There is one aspect of the FCTC that does seem worth highlighting as it further supports the above conclusion that it would not be approriate to apply the same strict tobacco-related regulation to ANDS.

In defining tobacco control, Article 1(d) of the FCTC refers to the adoption of "harm reduction strategies that aim to improve the health of a population by eliminating or reducing their consumption of tobacco products and exposure to tobacco smoke" (emphasis added).

The WHO has also recognized the role of tobacco harm reduction, stating that "[i]f the great majority of tobacco smokers who are unable or unwilling to quit would switch without delay to using an alternative source of nicotine with lower health risks, and eventually stop using it, this would represent a significant contemporary public health achievement."[58]

In sum, the FCTC recognizes harm reduction as a part of the strategy for improving public health by reducing tobacco consumption and exposure to tobacco smoke. Tobacco control and public health are furthered through reducing exposure to tobacco and smoke, which is equally recognized in Article 3 on the "Objective" of the treaty. The question therefore arises whether a proper application of the FCTC should not require a more favourable treatment of ANDS.

The harm reduction approach to tobacco control in the context of ANDS has much support from a range of stakeholders. The letter of 72 health experts to the WHO referred to earlier in this opinion emphasizes that authorities should "adopt a more positive approach to new technologies and innovations that have the potential to bring the epidemic of smoking-caused disease to a more rapid conclusion".[59] Noting that the "the major distinction between nicotine products is whether they are combustible or non-combustible",[60] these experts recommend that the "FCTC and its implementation should embrace 'risk-proportionate regulation'", which "means that the stringency of regulation or taxation applied to product categories should reflect risk to health".[61] They continue:

> "WHO and Parties to the FCTC should be aware of and careful to avoid the harmful unintended consequences of prohibitions or excessive regulation. If WHO-endorsed policies make noncombustible alternatives to smoking less easily accessible, less palatable or acceptable, more expensive, less consumer friendly or pharmacologically less effective, or inhibit innovation and development of new and improved products, then these policies can cause harm by perpetuating smoking".[62]

Additionally, the impact of excessive regulation on the ANDS sector was underscored in a recent independent, peer-reviewed research publication which found that:

> "[w]ith a few exceptions, awareness and use of nicotine vaping products varied by the strength of national regulations governing nicotine vaping product sales/marketing, and

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[58] WHO FCTC (2016), *Report on Electronic Nicotine Delivery Systems ("ENDS") and Electronic Non-Nicotine Delivery Systems ("ENNDS") to the seventh session of the Conference of the Parties*, available at http://www.who.int/fctc/cop/cop7/FCTC_COP_7_11_EN.pdf at paragraph 5.

[59] See https://clivebates.com/documents/WHOCOP8LetterSeptember2018.pdf, at p. 1.

[60] Ibid.

[61] Ibid, at p. 2

[62] Ibid. (underlining added)

by country income" and "[i]n contrast to many of the [less restrictive policies] and [restrictive policies] countries, rates of use were quite low in the [most restrictive policies] countries (Australia, Uruguay and Brazil), indicating that strict regulation and enforcement of [nicotine vaping products] laws in these countries may have limited smokers' access to these products and/or discouraged smokers from using them".[63]

In sum, by prohibiting or severely restricting the sales of these new categories of products and/or by extending to them combustible regulations as would be the consequence of applying the strict requirements of the FCTC to ANDS, countries could unwillingly contribute to perpetuating smoking. The question arises whether such policies would be fully consistent with the harm reduction considerations of the FCTC.

VII. Conclusion

The analysis in the opinion leads to the following conclusions:

1. The chronology of events confirms that ANDS were not part of the covered products of the FCTC at the time of its adoption, since they did not exist as such.

2. In accordance with the general rules of treaty interpretation of the Vienna Convention on the Law of Treaties, ENDS products and nicotine pouches do not only fall outside the scope of application of the Framework Convention on Tobacco Control based on the ordinary meaning of the terms of the Convention, but also, in the current state of scientific knowledge, in light of the Convention's object and purpose.

3. Heated tobacco products, by contrast, meet the first part of the definition of covered tobacco products for the purpose of the application of the FCTC since they contain tobacco. However, they do not appear to meet the second part of the definition, which requires that the tobacco products "are manufactured to be used for smoking, sucking, chewing or snuffing". Heated tobacco products do not involve burning the tobacco and inhaling the smoke of the burnt tobacco. They merely imply the vaping of the aerosol created by heating the tobacco. The context as well as the object and purpose of the FCTC seem to confirm that novel tobacco products do not fall within the scope of application of the Framework Convention on Tobacco Control.

4. There is no evidence that the Parties to the Framework Convention on Tobacco Control have entered into a subsequent agreement or subsequent practice that brings non-tobacco products such as ENDS products and nicotine pouches within the remit of the Convention.

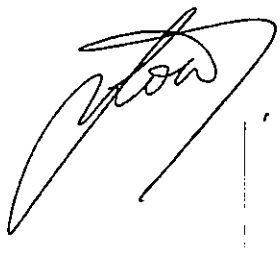
5. The Preamble to Decision FCTC/COP8/(22) of the Conference of the Parties to the Framework Convention on Tobacco Control appears to reflect the view of the Conference of the Parties that heated tobacco products fall within the scope of application of the FCTC as "tobacco products". However, for various reasons, this single reference in the Preamble to this Decision is insufficient to amount to a

[63] Gravely, et al (2019) "Prevalence of awareness, ever-use and current use of nicotine vaping products (NVPs) among adult current smokers and ex-smokers in 14 countries with differing regulations on sales and marketing of NVPs: cross-sectional findings from the ITC Project", *Addiction*. Available at https://doi.org/10.1111/add.14558.

subsequent agreement or subsequent practice within the meaning of Article 31(3)(b) of the Vienna Convention on the Law of Treaties, in the sense that it amounts to "conduct in the application of the treaty, after its conclusion, which establishes the agreement of the parties regarding the interpretation of the treaty". In fact, the Parties' application of the FCTC with respect to novel tobacco products confirms a widely divergent practice, as some parties promote the use of novel tobacco products as part of a harm reduction strategy, while others treat them as ordinary tobacco products. A statement in the Preamble of this single Decision does not change that reality, and cannot amend the text of the definition of covered products by expanding it to apply to products made of tobacco that is not intended for smoking, sucking, chewing or snuffing.

Date: 9 July 2019

Signature:



Prof. Dr. Jan Wouters

HERBERT SMITH FREEHILLS

Secretary for Food and Health
Food and Health Bureau
18/F, East Wing
Central Government Offices
2 Tim Mei Avenue, Tamar
Hong Kong

For the attention of Professor Sophia Chan, JP

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www.herbertsmithfreehills.com

Our ref
6461/12474/31022546
Your ref
FH CR 1/3231/19
Date
28 November 2019

By email and by hand

Dear Madam / Sir

Smoking (Public Health) (Amendment) Bill 2019 (the "Bill")

We act for British-American Tobacco Company (Hong Kong) Limited.

We refer to the Bill and our previous submissions to the Bills Committee on the Bill dated 8 April and 21 June 2019.

As mentioned in paragraph 5.6.4 of our submission dated 8 April 2019, our client previously provided samples of its tobacco heating products ("**THPs**") (i.e. *glo* and Neostiks) to the Commissioner of Customs and Excise for laboratory testing on 27 April 2018. However, in November 2018, these samples were returned to our client untested without any explanation, before the Government later decided to introduce the Bill.

The Government's approach in relying on the test result of only one product from a particular manufacturer, as justification to impose a blanket ban on all other products from a range of different manufacturers (including our client) which affects a number of industries, is plainly unfair and irrational. Each product could be very different and carry different risk levels. For example, whilst we understand that iQOS (the only product tested by the Government) heats the tobacco stick up to

350°C,[1] we are instructed that our client's *glo* would heat Neostiks at a significantly lower temperature of approximately 240°C and consequently would be likely to produce fewer toxicants and lower levels of those toxicants. The substance and composition of Neostiks may also be different with that of iQOS. There are also other THPs in the international market which the Government has ignored and failed to consider. It is entirely inappropriate for the Government to have failed to properly consider the health effects of all types of products before introducing the Bill.

As a matter of fact, similar testing has been conducted on THPs, including those of our client which the Government has failed to consider to date. For example, according to the articles published by the Regulatory Toxicology and Pharmacology,[2] the test results of THPs demonstrated, *inter alia*, that:

(a) in comparison to the University of Kentucky 3R4F Reference Cigarette (3R4F) (as referred to in paragraph 2.5 of our client's previous submissions to the Bills Committee dated 8 April 2019)[3] the toxicant levels in emissions from our client's THPs were significantly reduced across all chemical classes. For the nine toxicants proposed by the World Health Organization Study Group on Tobacco Product Regulation for mandatory reduction in cigarette emissions, the mean reductions in our client's THPs' aerosol were 90.6-99.9% per consumable, with an overall average reduction of 97.1%;[4]

(b) significant emissions reductions in comparison to conventional cigarettes were measured for our client's THPs, with levels of nicotine, acetaldehyde, formaldehyde and particulate matter being more than 90% reduced relative to cigarette smoke emissions within the laboratory conditions. The data shows that using our client's THPs has the potential to result in considerably reduced environmental emissions that affect indoor air quality relative to conventional cigarettes;[5] and

(c) mouth level exposure to nicotine free dry particulate matter and nicotine levels were significantly lower when using THPs than conventional cigarettes.[6]

We therefore respectfully urge the Government to conduct laboratory testing on our client's products, and take the testing results into account if the Government continues to pursue the Bill in the Legislative Council. Please find enclosed sample device and consumables from our client for this purpose.

To assist with the Government's testing, we further enclose our letter to the Commissioner of Customs dated 27 April 2018 which contained a detailed explanation of our client's products. The

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1 https://www.pmi.com/smoke-free-products/iqos-our-tobacco-heating-system

2 https://www.sciencedirect.com/journal/regulatory-toxicology-and-pharmacology/vol/93/suppl/C

3 LC Paper No. CB(2)1175/18-19(11).

4 Forster et al. (2018), 'Assessment of novel tobacco heating product THP 1.0. Part 3: Comprehensive chemical characterisation of harmful and potentially harmful aerosol emissions' *Regulatory Toxicology and Pharmacology* 93 (2018) 14-33.

5 Forster et al. (2018), Assessment of tobacco heating product THP1.0. Part 4: Characterisation of indoor air quality and odour' *Regulatory Toxicology and Pharmacology* 93 (2018) 34-51.

6 Gee et al. (2018), Assessment of tobacco heating product THP1.0. Part 8: Study to determine puffing topography, mouth level exposure and consumption among Japanese users' *Regulatory Toxicology and Pharmacology* 93 (2018) 84-91.

composition of our client's products and related scientific research can be found in the enclosures therewith.

As mentioned above, our client has in fact at a very early stage offered to assist the Government to understand its THPs by sending the relevant products for testing. The Government has, however, made a conscious decision not to test the same, and instead relied on the test results of a single particular product of its choice in introducing the Bill. The Government's decision not to test our client's THPs is disingenuous in the circumstances.

We look forward to receiving your response. If you have any queries in testing our client's products, please feel free to contact Mr Dominic Geiser or Mr Truman Mak of our office.

In the meantime, all our client's rights are reserved, including its right to produce a copy of this correspondence to the Bills Committee and/or the Court at the appropriate time.

Yours faithfully,

Herbert Smith Freehills

Encls.

cc: Clerk to Bills Committee on Smoking (Public Health) (Amendment) Bill 2019
Legislative Council Secretariat
Legislative Council Complex
1 Legislative Council Road
Central, Hong Kong
By email and by hand (excluding sample products)

HERBERT
SMITH
FREEHILLS

Commissioner of Customs and Excise
Customs and Excise Department
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www.herbertsmithfreehills.com

Our ref
6461/12474/31012325
Your ref

Date
27 April 2018

By hand

Dear Sirs

Information on British American Tobacco's newly developed electronically heated tobacco product ("EHTP") – Neostiks™ ("Neostiks")

We act for British-American Tobacco Company (Hong Kong) Limited ("**BATHK**").

Further to the conversation of Ms Jenny Lam of BATHK with Mr. Jonathan Fung of your office on 15 February 2018, we are writing on behalf of BATHK to provide you with further information on Neostiks, British American Tobacco's newly developed EHTP and with the enclosed sample devices and consumables for your review and testing.

1. INTRODUCTION TO NEOSTIKS

1.1 Neostiks are part of a new EHTP developed by British American Tobacco, intended to be used exclusively in conjunction with an electronic tobacco heating device called glo™ ("**glo**").

1.2 Neostiks are made predominantly of reconstituted tobacco and contain various tobacco grades as well as binders and humectants. They are intended to be used by inserting into the glo heating device for an electronically-controlled heating process to produce a tobacco aerosol consisting mainly of water, glycerine, flavours and nicotine which is different to tobacco smoke. The electronically-controlled heating in glo prevents combustion from occurring. The glo heating mechanism ensures that the tobacco is not heated above 245°C; much lower temperatures than at which traditional smoking tobacco is combusted, usually in the range of 600-900°C.

1.3 Please refer to the product description paper enclosed herewith (the "**Description Paper**") for a detailed description of Neostiks with graphical illustration for your reference. We also enclose a paper entitled 'Tobacco Heating Products glo: measurement of mainstream emissions' and a paper entitled 'Tobacco heating products overview of the scientific assessment of glo' both prepared by British American Tobacco for a summary of the ingredients and emissions of Neostiks.

2. DIFFERENCES BETWEEN NEOSTIKS AND CIGARETTES

2.1 Neostiks are fundamentally different to traditional cigarettes. As stated in a Customs Classification Paper prepared by British American Tobacco dated August 2017 enclosed herewith (the "**BAT Customs Paper**"), Neostiks are different to cigarettes in a number of material aspects, including that:

2.1.1 Neostiks are made predominantly from reconstituted tobacco whereas factory made cigarettes contain, on average, no more than 10% of reconstituted tobacco in cut form;

2.1.2 Neostiks contain significantly less tobacco compared to cigarettes. The weight of the reconstituted tobacco in each Neostik is about 260 milligrams, whereas the weight of the tobacco in a standard cigarette ranges from 600 to 700 milligrams;

2.1.3 cigarettes generate tobacco smoke from a process of self-sustaining combustion composed mainly of a complex mixture of chemical compounds to be inhaled by the smoker. In contrast, Neostiks are to be heated with glo and when used with glo, the tobacco in Neostiks does not combust and does not produce smoke as in a cigarette. Instead, it generates a tobacco aerosol that is fundamentally different from the tobacco smoke emitted from a cigarette; and

2.1.4 the smoke generated from cigarettes lingers in the air for a substantially longer period than the tobacco aerosol generated from Neostiks, which disappears quickly from the surrounding air.

2.2 Scientific evidence demonstrates that using only EHTPs, such as Neostiks, could potentially reduce the risk to health for conventional smokers who smoke traditional cigarettes. For example:

2.2.1 Public Health England, an executive agency of the UK Department of Health and Social Care, noted that "[t]*he available evidence suggests that heated tobacco products may be considerably less harmful than tobacco cigarettes*";[1]

2.2.2 the Committees on Toxicity, Carcinogenicity and Mutagenicity of Chemicals in Food, Consumer Products and the Environment in the United Kingdom has assessed and concluded that:

(A) users of heat-not-burn tobacco products would be exposed to 50%-90% fewer harmful and potentially harmful compounds compared with conventional cigarettes;[2]

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[1] Public Health England, 'Evidence review of e-cigarettes and heated tobacco products 2018' https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/680964/Evidence_review_of_e-cigarettes_and_heated_tobacco_products_2018.pdf (accessed 25 February 2018) (the "**Public Health England Report**").

(B) "*It is likely that there is a reduction in overall risk to health for conventional smokers who switch to heat-not-burn tobacco products*";[3] and

(C) "*A reduction in risk would be expected to be experienced by bystanders where smokers switch to heat-not-burn tobacco products*";[4] and

2.2.3 a report published by Dr Marina Murphy of British American Tobacco (the "**Murphy Report**") dated November 2017 noted that:

(A) there are around 90-95% less of certain toxicants[5] in aerosol generated through the use of Neostiks with glo as compared to cigarette smoke;[6]

(B) test results show that glo aerosol has a much-reduced or no notable biological impact on cells in the lab compared to conventional cigarette smoke using a system that was developed to mimic the way human lung cells are exposed to aerosols in real-life;[7] and

(C) test results indicate substantial reductions in numbers and levels of environmental toxicants for glo use compared to cigarette smoking.[8]

2.3 In view of the matters in paragraphs 2.1 and 2.2, it is in BATHK's respectful view that Neostiks should be treated differently to cigarettes, including for the purposes of customs classification (see section 3) and product testing.

3. APPROPRIATE CLASSIFICATION OF NEOSTIKS FOR CUSTOMS PURPOSES

3.1 In view of the differences between Neostiks and cigarettes explained in section 2, it is in BATHK's respectful view that for duty assessment purposes under the Dutiable Commodities Ordinance (Cap. 109) (the "**Ordinance**"), Neostiks should be classified as "*all other manufactured tobacco except tobacco intended for the manufacture of cigarettes*" (the "**Other Tobacco Category**") under paragraph 1(d) of Part II of Schedule 1 to the Ordinance.

3.2 Such a classification would:

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2 Paragraph 7 of a statement summary entitled 'Toxicological evaluation of novel heat-not-burn tobacco products – non-technical summary' published by the Committees on Toxicity, Carcinogenicity and Mutagenicity of Chemicals in Food, Consumer Products and the Environment in December 2017 (the "**TOC Statement Summary**").

3 Paragraph 27 of the TOC Statement Summary.

4 Paragraph 29 of the TOC Statement Summary.

5 This is a comparison between the smoke from combusted tobacco in a standard 3R4F reference cigarette (approximately 9 mg tar), and the vapour from heated tobacco in glo, in terms of the 9 types of harmful components which the World Health Organisation recommends to reduce in cigarette smoke.

6 Science Codex, ' Toxicant levels are around 90 percent less in glo emissions compared to cigarette smoke', 24 October 2017: http://sciencecodex.com/toxicant-levels-are-around-90-percent-less-glo-emissions-compared-cigarette-smoke-616330 (accessed 11 January 2018) and a report entitled 'British American Tobacco publishes a series of studies supporting the reduced-risk potential of glo' published by Dr Marina Murphy of British American Tobacco in November 2017.

7 The Murphy Report at page 2.

8 The Murphy Report at page 3.

3.2.1 comply with the Ordinance given that Neostiks do not fall under the definitions of "cigarette", "cigar" or "Chinese prepared tobacco";

3.2.2 be consistent with the Hong Kong Government's established policy to use taxation as a means to protect public health from the harmful effects of tobacco; and

3.2.3 be consistent with the approach adopted by the Word Customs Organisation ("**WCO**").

a) Existing provisions of the Ordinance (i.e. the Dutiable Commodities Ordinance (Cap. 109))

3.3 Under Part II of Schedule 1 to the Ordinance, tobacco is classified under the following four different categories, each defined in the Ordinance and having a different rate of duty to be paid:

3.3.1 cigarettes;

3.3.2 cigars;

3.3.3 Chinese prepared tobacco; and

3.3.4 the Other Tobacco Category.

3.4 "Cigarette" is defined as "*any roll of tobacco capable of being smoked by itself not being a cigar*" (emphasis added). Hence, to constitute a cigarette, it must be a roll of tobacco that is capable of being smoked.

3.5 The verb "smoke" is not defined under the Ordinance. It is, however, defined under the Smoking (Public Health) Ordinance (Cap. 371), an ordinance which regulates tobacco products including cigarettes, as "*inhaling and expelling the smoke of tobacco or other substance*". Hence, to constitute smoking, there must be an inhaling or expelling of tobacco "smoke".

3.6 As explained in paragraph 2.1.3 above, unlike cigarettes which produce smoke via a process of self-sustained combustion, when used as intended with glo the tobacco in Neostiks does not combust and produces an aerosol very different to cigarette smoke. Hence, Neostiks do not fall under the definition of "cigarette" under the Ordinance. Accordingly, they should not be assessed as such for duty purposes.

3.7 Similarly, Neostiks also do not fall under the definition of "cigar", which also requires it to be "*capable of being smoked by itself*", or the definition of "Chinese prepared tobacco" as they are not "*prepared in the traditional Chinese manner from tobacco leaf grown in China*".

3.8 In view of the above, the only appropriate classification of Neostiks for the purposes of Part II of Schedule 1 to the Ordinance would be the Other Tobacco Category.

b) The Hong Kong Government's established policy

3.9 According to the Legislative Council brief LC Paper No. CB(1)1198/13-14(02) dated 7 April 2014, a brief prepared in support of the Dutiable Commodities (Amendment) Bill 2014 for increasing duties for tobacco products, taxation is a means adopted by the Government to promote its established policy in protecting public health from the harmful effects of

tobacco.[9] The Government recognised that "*it was well established internationally and empirically that tobacco price had a strong inverse correlation with tobacco consumption*" and thus used taxation in an attempt to influence tobacco consumption behaviour of smokers.[10]

3.10 Hence, classifying Neostiks under the Other Tobacco Category for duty purposes would beneficially alter existing smoker's tobacco consumption behaviour by encouraging them to cease or lower their consumption of smoking products with a higher toxicants level (such as cigarettes) to using products such as Neostiks with much lower toxicants levels and potentially less harmful products.

3.11 In addition, Dr Scott Gottlieb, Commissioner of the US Food and Drug Administration, has noted that "*the nicotine in cigarettes is not directly responsible for the cancer, lung disease, and heart disease that kill hundreds of thousands of Americans each year…it's the other chemical compounds in tobacco, and in the smoke created by setting tobacco on fire, that directly and primarily cause the illness and death, not the nicotine*".[11]

3.12 Scientists also widely acknowledge that smoking related diseases are caused largely by the toxicants found in cigarette smoke – not the nicotine itself.[12] Hence, the Food and Drug Administration hopes that "*we can all see the potential benefits to addicted cigarette smokers, in a properly regulated marketplace, of products capable of delivering nicotine without having to set tobacco on fire*". A report by the UK Royal College of Physicians also states that the health and life expectancy of existing smokers could be radically improved by encouraging as many as possible to switch to a smoke-free source of nicotine (which would include nicotine from ETHPs).[13]

3.13 In view of the comments and suggestions of the US Food and Drug Administration and the UK Royal College of Physicians mentioned above, there is a clear public policy benefit in encouraging existing traditional cigarette smokers to switch to EHTPs like Neostiks. This approach is also consistent with Public Health England's suggestion to apply taxation to favour least harmful options,[14] such as Neostiks.

3.14 In view of the above, classifying Neostiks under the Other Tobacco Category for duty assessment purposes is consistent with the Government's established policy in using taxation to protect public health by encouraging existing smokers to switch from smoking traditional cigarettes to using products that are capable of delivering nicotine with much lower tobacco levels, and potentially reduced health risk.

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9 https://www.legco.gov.hk/yr13-14/english/bc/bc05/papers/bc050408cb1-1198-2-e.pdf (accessed 26 February 2018) at paragraphs 3-4 (the "**2014 LC Paper**").

10 Paragraph 11 of the 2014 LC Paper.

11 Commissioner of Food and Drug Administration, 'Protecting American Families: Comprehensive Approach to Nicotine and Tobacco', 28 July 2017: https://www.fda.gov/NewsEvents/Speeches/ucm569024.htm (accessed 25 February 2018).

12 British American Tobacco, 'ANDS role in supporting public health strategies', September 2017 (the "**ANDS Paper**") section A.

13 Section A of the ANDS Paper.

14 Page 220 of the Public Health England Report.

c) Approach in the WCO

3.15 In October 2017, the WCO Harmonized System Committee ("**HSC**") considered the appropriate classification of EHTP consumables in the 2017 Harmonized System Nomenclature.

3.16 In advance of that meeting, the WCO Secretariat recommended to its members that EHTPs should be treated, for customs classification purposes, under a category that is different to both cigarettes and all other forms of combustible tobacco. This is because:

3.16.1 *EHTPs are not intended to be combusted or smoked.*

The Secretariat commented that "*... the use of "EHTP" products does not involve combustion, so they are not designed to be smoked in the traditional manner ...*" and "*... if it is decided that heading 24.02 covers only products intended to be smoked by combustion, the Secretariat considers that the "EHTP" product cannot be regarded as "smoking tobacco" within the meaning of subheading 2403.1 ...*";

and

3.16.2 *The tobacco in ETHPs is different from that in smoking tobacco products (including cigarettes).*

Consequently, for classification purposes they should be treated differently than cigarettes and other forms of smoking tobacco. In particular, the tobacco used in EHTPs is reconstituted whereas combustible tobacco products contain much smaller amounts of reconstituted tobacco.

3.17 Two tobacco heating products were considered by the HSC in its October 2017 meeting. One called a "EHTP", a tube of reconstituted tobacco intended to be heated, but not combusted, by an electronic heating device (similar in nature to BAT's glo Neostiks consumables).[15] The other, called a "tobacco capsule", a tobacco pod designed to be used with a different type of heating device to the "EHTP".[16] It was confirmed in the November 2017 meeting of the European Commission's Customs Code Committee that "*... a large majority of contracting parties voted for classification of these products in subheading 2403.99 ...*" which covers "Other manufactured tobacco and manufactured tobacco substitutes; "homogenised" or "reconstituted" tobacco; tobacco extracts and essence – Other" (see section 8.3 of the enclosed Summary Report of the 182nd meeting of the Customs Code Committee of the European Commission dated 7 November 2017 for your reference).

3.18 In December 2017, one contracting party submitted a reservation to the HSC (i.e. a request to re-discuss the issue) and, by consequence, the classification decision for "EHTPs" will be i) considered at the WCO Council meeting in June 2018; and ii) will be re-argued during the agenda of the HSC in September 2018. Whilst until then, the recommendation of the WCO HSC is not binding on the WCO contracting parties, it is evident that, in order to ensure consistency and predictability in customs classification among WCO contracting parties, an alignment with the generally accepted WCO recommendation before its official implementation is nevertheless advisable. Further, it should be considered that this product

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15 See note NC2406E1a from the WCO Harmonized System Committee dated 7 August 2017.
16 See note NC2429E1a from the WCO Harmonized System Committee dated 23 August 2017.

is, as a matter of fact, classified under subheading 2403.99 of the HS in the clear majority of countries in which they are currently sold (including EU, Japan, USA).[17]

3.19 No reservation was submitted against the "tobacco capsule" tobacco heating product following the October 2017 HSC meeting. It was confirmed in the January 2018 document from the WCO entitled "*Decisiones de la sesion 60 del OMA*" that this product should be classified under 2403.99 – a binding decision for the WCO contracting parties (i.e. including Hong Kong) that should now be adopted globally.

3.20 Given this position – and the way in which almost all countries classify tobacco heating products that are currently on the market outside the category of "cigarettes" – it would appear to be an anomaly should any contracting party to the WCO choose to classify EHTPs in anything other than subheading 2403.99 of the 2017 HS.

3.21 Please also refer to the BAT Customs Paper for a detailed explanation as to why Neostiks should be classified under the code 2403.99 but not under other codes such as codes under the heading 2402 ("Cigars, cheroots, cigarillos and cigarettes, of tobacco or of tobacco substitutes").

3.22 In view of the above, classifying Neostiks under the Other Tobacco Category is consistent with the approach agreed by a large majority of the contracting states in the WCO.

3.23 Therefore, we respectfully urge the Government to study the evidence available and classify Neostiks that are intended to be used with the glo device under the Other Tobacco Category under the Ordinance.

4. REFERENCE DOCUMENTS

4.1 The following documents are enclosed herewith to assist your further understanding of Neostiks:

- 4.1.1 the Description Paper;
- 4.1.2 the BAT Customs Paper;
- 4.1.3 a statement on the toxicological evaluation of novel heat-not-burn tobacco products published by the Committees on Toxicity, Carcinogenicity and Mutagenicity of Chemicals in Food, Consumer Products and the Environment in December 2017;
- 4.1.4 the TOC Statement Summary;
- 4.1.5 the Murphy Report;
- 4.1.6 the ANDS Report;
- 4.1.7 a summary of the Public Health England Report prepared by British American Tobacco in February 2018;
- 4.1.8 *Decisiones de la sesion 60 del OMA*;
- 4.1.9 Summary Report of the 182nd meeting of the Customs Code Committee of the European Commission dated 7 November 2017;

[17] The notable exceptions are Australia and South Africa which have classified EHTPs under subheading 2403.91 (i.e. an alternative subheading, which also covers non-combustible tobacco products).

4.1.10 'Tobacco heating products overview of the scientific assessment of glo' prepared by British American Tobacco;

4.1.11 'Tobacco Heating Products glo: measurement of mainstream emissions' prepared by British American Tobacco; and

4.1.12 a paper prepared by British American Tobacco on why the aerosol produced by glo should not be described as "tar".

Yours faithfully,

Herbert Smith Freehills

Encls

Novel Details Description File

Novel Tobacco Product

Table of Contents

1. Narrative Summary

1.1 Name and address of the Submitter

Nicoventures Trading Limited (NvT)
1 Water Street
London
WC2R 3LA

Email address: trade@nicoventures.co.uk

1.2 Basis of Determination of a "Novel Tobacco Product"

According to the Tobacco Products Directive, a "Novel Tobacco Product" is defined as a tobacco product which:

(a) does not fall into any of the following categories: cigarettes, roll-your-own tobacco, pipe tobacco, water pipe tobacco, cigars, cigarillos, chewing tobacco, nasal tobacco for oral use and

(b) is placed on the market after 19 May 2014

On this basis, it is NvT determination that the **Neostik** is a Novel Tobacco Product.

1.3 Product Information

The subject of this submission is a "Novel Tobacco Product". The **Neostiks** are currently being developed by "Nicoventures Trading Limited", a wholly-owned subsidiary within the "British American Tobacco" group of companies.

The **Neostik** is used with a device, called '**glo**'.

Table 1: Product category and intended use

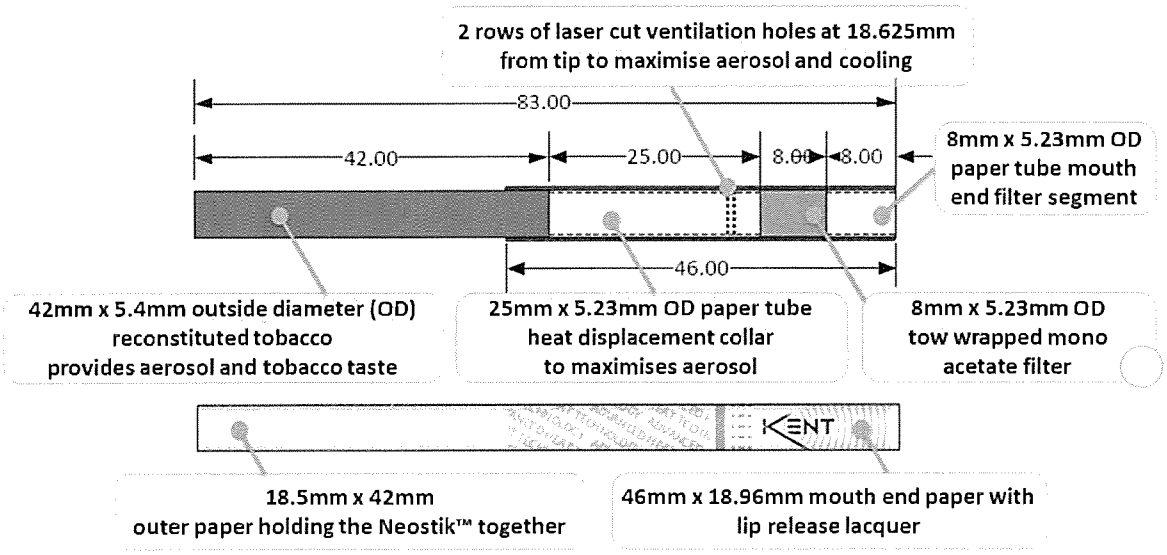
	Category	Intended Use	Product Descriptor
☒	Novel Tobacco Product	Disposable **Neostik** / consumable with separate tobacco and filter sections. Heated under ordinary conditions of use.	**Neostik** (Section 2.0)
☒	Device	Heat source. Used as directed by the manufacturer or distributor.	**Glo** Device (Section 3.0)

2.0 Design features of the Neostik:

There is no tobacco cut-filler (tobacco leaf cut into small pieces found in cigarettes). Neostiks are made of 100% reconstituted tobacco containing various tobacco grades as well as binders and humectants.

When used as directed and intended Neostiks neither ignite nor burn. The electronically-controlled heating, in combination with the processed, reconstituted tobacco, prevents combustion from occurring. When used, glo heating mechanism ensures that the tobacco is not heated above 240 °C. Neostiks content of water and glycerin facilitates the unique low-temperature heating use which results in the emission of an aerosol fundamentally different from the smoke emitted from a cigar or cigarette when it is used. The Neostik is heated not burned; it does not combust and this produces heated tobacco vapour, but no smoke or ash. The physical and thermal properties of the tobacco material in the Neostik, the composition and components of the Neostik and the use of the glo device is very different from a cigarette.

Figure 1: Cross-section diagram of a Neostik™



The reconstituted tobacco is made by a process widely used in the tobacco industry, where selected tobacco types are ground into a fine powder, mixed with humectants and binders, and then laid down to be dried into sheets with a specified thickness and weight. These reconstituted tobacco sheets are then cut into small pieces suitable for Neostiks manufacturing.

There is a much smaller amount of tobacco in a Neostik compared to a cigarette. The weight of the reconstituted tobacco in the Neostik is about 260 milligrams. In comparison, the weight of the cut filler in a standard cigarette rod ranges from 600 to 700 milligrams.

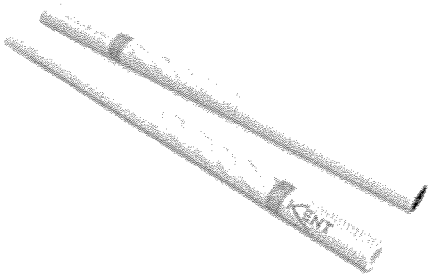


*Figure 2: Picture of **Neostik***

Table 2.0: Specification of the Neostik

Specification	Nominal Dimension
Neostik length	83.0 mm
Neostik diameter	5.23 mm
Neostik weight	491- 505.08mg

The **Neostik** is made from a filter portion, containing two paper tubes fixed either side of a cellulose acetate segment, and a tobacco rod, containing reconstituted tobacco sheet.

The **Neostik** is available in a variety of tobacco blends and flavourings.

The names **glo** and **Neostik** are all resitered trademarks, regsitered to British American Tobacco (Brands) Ltd within the "British American Tobacco" group of companies.

2.1 Subject of submission:

The Neostik contains 100% reconstituted tobacco containing various tobacco grades as well as binders and humectants.

Table 3.0: Composition of the Neostik:

Section 2.0 Neostik

Information on additives and ingredients is submitted under "Tobacco Ingredients" and "Additives and other substances/elements" as per the data dictionary requirement.

Emissions data is submitted under "Other emission".

SUPPLEMENTARY INFORMATION

3.0 glo Device

The glo device has been designed in the UK, engineered in the USA and is assembled in China by a leading Swedish manufacturer. The glo device is shown in Figure 3.

Figure 3: The glo™ device

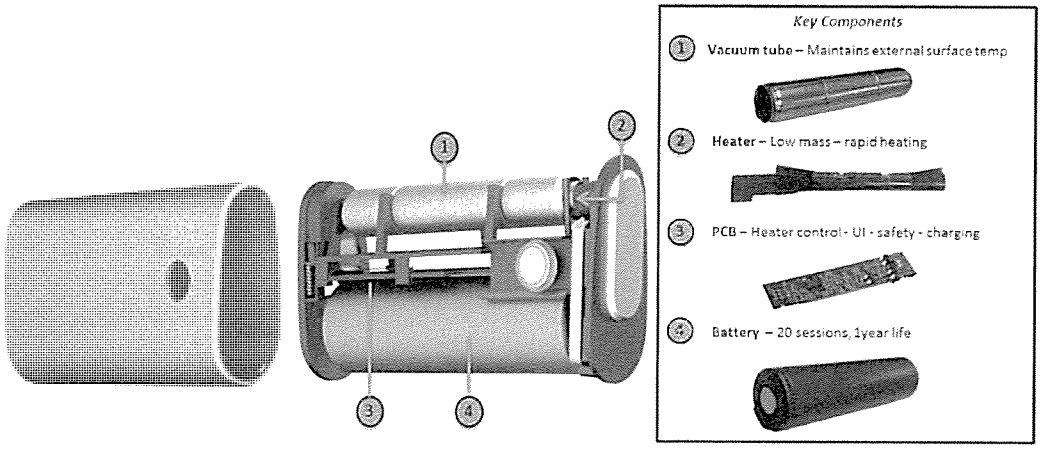
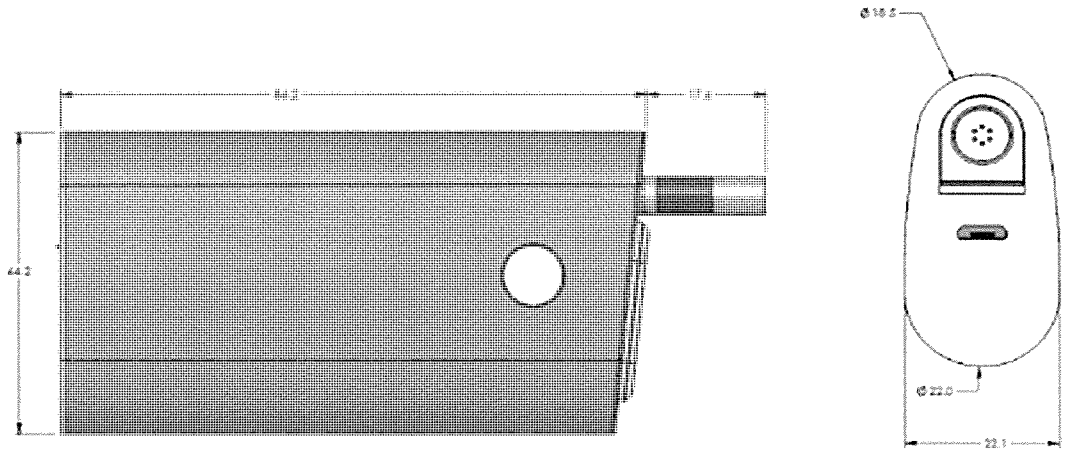


Figure 4 shows the external dimensions of the glo device: base width 44.2mm, base depth 22.1mm, and height 86.2mm (plus the 17.6mm tip of one of the Neostiks when inserted). glo weighs around 100g.

Figure 4: The external dimensions of the Glo™ device



glo consists of a vacuum tube (for a comfortable external temperature & efficiency), heater, PCB (printed circuit board) to control the heater, a lithium ion battery, a single button with 4 white LEDs (light emitting diodes) to inform the user, and a vibration motor to provide additional cues.

The outer casing of glo is made from anodized aluminium with laser etched engravings. The top and base of the device are made from high quality plastics, as shown in Figure 5.

Figure 5: The high-quality material and finish of the Glo™ device

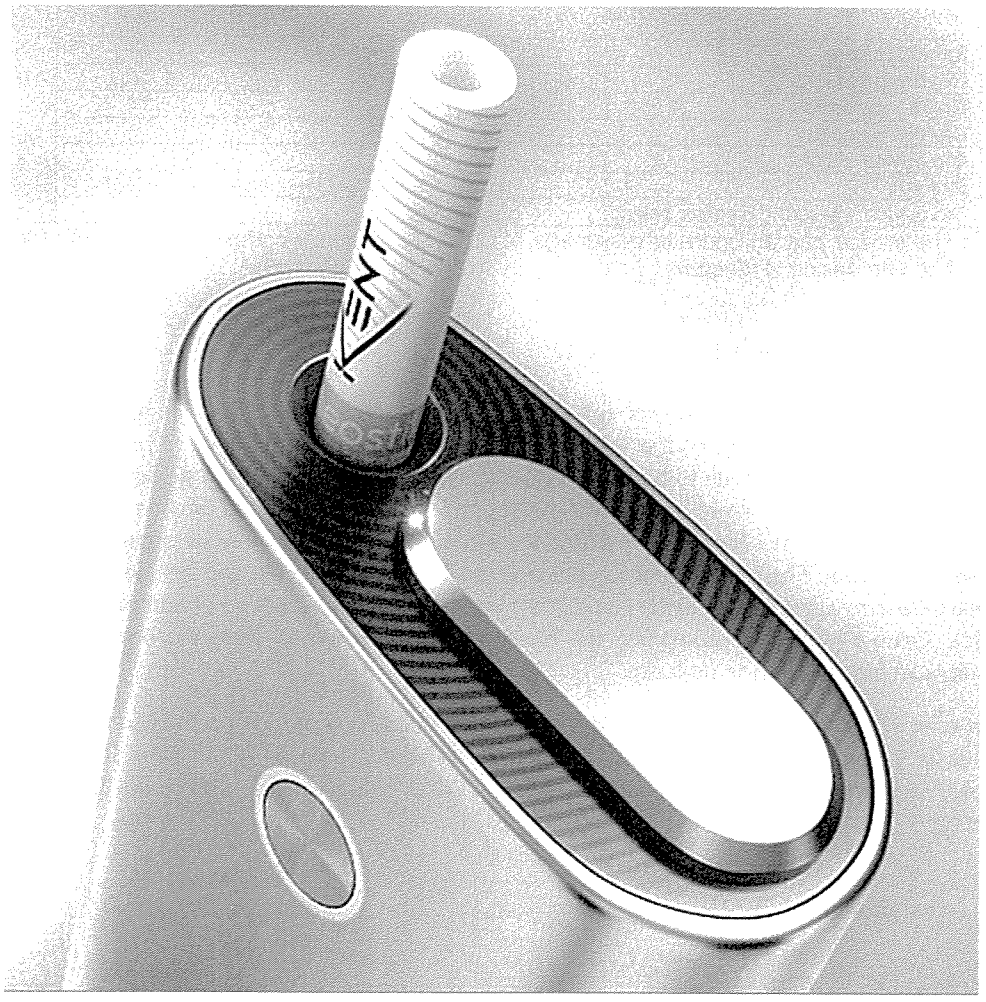

KENT

Table 5.0: Specification of the Glo device

Specification	Nominal Dimension
Glo device height	86.2 mm
Glo device width	44.2 mm
Glo device depth	22.1 mm
Glo device weight	100.0 g
Battery	Lithium ion battery re-chargeable via USB
Glo device + inserted Neostik height	103.8 mm

The device has an operational voltage of 3.7V and is solely compatible with **Neostiks**. The **Glo** device is reusable.

3.1 Features and operational overview

The Neostik is inserted into the device (glo) and the user turns on the electronics by means of a *button* to initiate the heating of the tobacco. Once the initial heating phase is complete (40 seconds), the Neostik is ready to be used. The Neostik is retained within the device throughout the session. The device follows an in-use heating profile that is designed to provide a consistent sensory experience. The Neostik generates an aerosol composed mainly of water, glycerine, nicotine and flavour. The product thereby enables the adult user to inhale and exhale the aerosol (heated tobacco vapour). glo and the Neostik can deliver puffs over a period of approximately 3.5 minutes. Once this cycle is complete, the Neostik must be removed from the device. A new Neostik must be used for the next use.

There is an initial pre-heating ramp up time of 40 of seconds, followed by the session time of 3 minutes 30 seconds. Each charge can provide up to 30 back to back sessions. When using the wall plug supplied, the charge time is about 2 hours. When charged via a USB, it may take up to 4 hours.

3.2 Declaration of Conformance

glo has a number of active patents and patent applications in place.

The glo device has also been thoroughly safety tested by an independent UKAS accredited testing laboratory to ISO/IEC 17025:2005; and ISO/IEC 17065:2012 to provide product certification, in line with the General Product Safety Directive 2001/95/EC. The following standards have been applied therein.

- General Product Safety Directive (GPSD): 2001/95/EC - EN60335-1:2012+A11:2014 [Non-CE Marking Directive]
- The restriction of the use of certain hazardous substances in electrical and electronic equipment (RoHS): 2011/65/EU – EN 50581:2012 [CE Marking Directive]

- Regulation on Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH): EC1907/2006 [Non-CE Marking Directive]
- Electromagnetic Compatibility Directive (EMC): 2014/30/EU- EN 55014-
- 1:2006+A2:2011 & EN 55014-2:2015 [CE Marking Directive]
- Battery (Transportation of Dangerous Goods): UNECE Recommendations on the Transport of Dangerous Goods Manual of Tests and Criteria 6th Revised Edition Amendment 2 Section 38.3 Lithium Metal and Lithium –Ion Batteries ST/SG/AC.10/11/Rev.6/Amend.2
- Batteries and accumulators and waste batteries and accumulators Directive: 2006/66/EC and Amendment 2013/56/EU. (Battery Directive)
- Battery (Safety): EN 62133:2013

The Technical File for this device is controlled by the Nicoventures division of British American Tobacco.

4.0 Available scientific studies

The available toxicity studies indicated in the Commission Implementing Decision (EU) 2015/2186 have been provided as a bibliography of published papers. The studies were obtained by BAT for toxicological assessments, to ensure that additives do not increase the inherent risk associated with the use of our products.

The risk assessment starts with a comprehensive search for relevant papers, using the additive's name, major synonyms and CAS Registry Number. The main sources searched are: TRACE[1], Toxnet[2], RTECS[3], TSCATS[4], INCHEM[5], Europa Food Flavouring[6], ECHA[7], EAFUS[8], ChemIDplus[9] and eChemportal[10].

4.1 Risk Assessment

Toxicological assessments are carried out by our scientists (including a number of European Registered Toxicologists (ERT)) at our Research and Development facilities in the UK. Our approach excludes the use of formally classified genotoxicants, non-threshold carcinogens, and reproductive and developmental toxicants, as additives. Based on Levels of Concern and weight-of evidence, our approach ensures that additives are used at levels lower than the relevant toxicological reference value.

Following a comprehensive search for all available toxicological information, our toxicologists select the most appropriate studies for evaluation for the intended route of exposure. To do this, our toxicologists evaluate the quality of all pertinent studies identified and the data used. The evaluation of data quality includes an assessment of its relevance and reliability as well as the adequacy of the information for hazard/risk assessment purposes, following the principles described by Klimisch *et al*[11].

BAT makes a range of tobacco products, in the smokeless, heated and combustible categories. The effects of heating or combustion on additive toxicity, have been addressed by extensive testing. For example, for additives added to cigarette tobacco, the results of pyrolysis, smoke chemistry, *in vitro* cytotoxicity, *in vitro* genotoxicity, inhalation toxicity and tumourigenicity studies have been widely published in peer-reviewed journals. Test results are included in our risk assessments, where applicable by product class.

Descriptions of our assessment processes can be found in published literature, for example:

An overview of the effects of tobacco ingredients on smoke chemistry and toxicity[12]

- An approach to ingredient screening and toxicological risk assessment of flavours in e-liquids[13]
- Contact sensitisation risk assessment approach for pouched snus ingredients[14]

- Assessment of the irritation potential of Swedish snus ingredients using the Epioral™ tissue model[15]

Further examples of our scientific publications are available at www.bat-science.com.

Health risks of tobacco use have primarily been determined in long term human epidemiological studies. For example, the smoking population in countries such as Canada, Australia and the UK has historically smoked Virginia style cigarettes, which contain few additives. In other countries such as the US and Germany smokers prefer American-blended style cigarettes, which contain significantly more additives. Notwithstanding the distinction in historical use of additives in these countries, there appears to be no obvious difference in the relative risks of cigarette smoking for these types of cigarette, or on the incidence of diseases such as lung cancer and chronic obstructive pulmonary disease[16], suggesting that the addition of additives to cigarettes may not increase the incidence of diseases associated with smoking.

4.2 Addictiveness

In its 2010 opinion on Addictiveness and Attractiveness of additives[17], SCENIHR came to the clear conclusion that no additive could be identified which has an "addictive" effect in isolation, and that there are no indications that additives increase the "addictive" effect of nicotine itself.

In a more recent final opinion[18], SCENIHR reviewed 1260 additives and selected only 14 substances for further study because they were suspected of facilitating inhalation or increasing nicotine uptake (mechanism possibly contributing to addictiveness to smoking).

4.3 Conclusion

Based on the available scientific evidence, BAT's scientists have concluded that the additives used in BAT's tobacco products, do not add to the toxicological risks of using those products.

1. Available at: http://www.bibra-information.co.uk/supported access to our chemical toxicology database TRACE.html
2. Available at: http://toxnet.nlm.nih.gov/index.html
3. Available at: http://ccinfoweb.ccohs.ca/rtecs/search.html
4. Available at: http://www.srcinc.com/what-we-do/databaseforms.aspx?id=384
5. Available at: http://www.inchem.org/
6. Available at: http://ec.europa.eu/food/food/chemicalsafety/flavouring/database/dsp_search.cfm
7. Available at: http://echa.europa.eu/information-on-chemicals
8. Available at: http://www.accessdata.fda.gov/scripts/fcn/fcnNavigation.cfm?rpt=eafusListing
9. Available at: http://chem.sis.nlm.nih.gov/chemidplus/chemidheavy.jsp
10. Available at: http://www.echemportal.org/echemportal/index?pageID=0&request_locale=en
11. Klimisch, H.J., Andreae, E., Tillmann, U., (1997). A systematic approach for evaluating the quality of experimental and ecotoxicological data. *Regul. Toxicol. Pharmacol.* 25, 1–5.
12. R. R. Baker, E. D. Massey and G. Smith. An overview of the effects of tobacco ingredients on smoke chemistry and toxicity. Food Chem. Toxicol. 42 Suppl: S53-S83, 2004.
13. S. Costigan and C. Meredith. An approach to ingredient screening and toxicological risk assessment of flavours in e-liquids. Regul. Toxicol. Pharmacol. 72 (2):361-369, 2015.
14. B. Lang, S. Costigan, S. Goodall and C. Meredith. Contact sensitisation risk assessment approach for pouched snus ingredients. Toxicology Letters 229S:S109, 2014. (Abstract)

15. L. Neilson, S. Faux, S., Hinchcliffe, T. Jai and C. Meredith. Assessment of the irritation potential of swedish snus ingredients using the Epioral™ tissue model. Society of Toxicology, Baltimore, USA, March 15-19th. The Toxicologist, Volume 108, no 1, pg 307-308 (March 2009) (Conference Poster)
16. World Health Organisation, 2004. Monographs on the Evaluation of the Carcinogenic Risk of Chemicals to Humans. Volume 83. Tobacco smoke and involuntary smoking. p 171. International Agency for Research on Cancer (IARC), Lyon, 2004
17. SCENIHR, 2010. Addictiveness and Attractiveness of Tobacco Additives. The Scientific Committee on Emerging and Newly Identified Health Risks. ISBN 978-92-79-12788-5. European Union. Available at: http://ec.europa.eu/health/scientific_committees/emerging/docs/scenihr_o_029.pdf.
18. SCENIHR, 2015. Final Opinion on Additives used in Tobacco Products (Opinion 1). The Scientific Committee on Emerging and Newly Identified Health Risks. European Union. Available at: http://ec.europa.eu/health/scientific_committees/emerging/docs/scenihr_o_051.pdf.
19. Pete Davis, Stuart Martin, Christopher Wright, and Sandra Costigan. Identifying thermal breakdown and reaction products in e-cigarette flavours. Philadelphia, USA: SRNT conference :189-POS2-44, 2015. Full poster available via www.bat-science.com.

Description of the Neostik™ consumables for British American Tobacco's Electrically Heated Tobacco Product and why they should be classified under heading 2403.99 of the World Customs Organization's Harmonized System Nomenclature

I. Introduction:

British American Tobacco (BAT) has developed an electronic tobacco heating product (ETHP) consisting of a heating device termed glo™ and accompanying re-constituted tobacco consumables called Neostiks™. The latter is a new generation tobacco product meant to be used with a heating device, and is profoundly different from conventional combustible tobacco products.

This document provides an explanation for the appropriate classification of the Neostik™ tobacco consumables under Subheading 2403.99 of the World Customs Organization's Harmonized System (HS) Nomenclature, established under the International Convention on the Harmonized Commodity Description and Coding System and effective from 1 January 2017.

Based on the intended purpose and material properties of the product, Neostiks™ are fundamentally different from 'cigarettes' as defined for customs and excise purposes. The tobacco in Neostiks™ is heated, not combusted, using the glo™ device as its heat source.

The heating of the reconstituted tobacco in Neostiks™ generates a tobacco aerosol of mainly water, glycerine and nicotine for the user to inhale via the filtered mouth-end. This aerosol is fundamentally different from the tobacco smoke emitted from the tobacco in a cigar or cigarette when it is used. The tobacco inside the Neostiks™ does not combust and produces no tobacco smoke or ash as in cigarettes or other forms of combustible tobacco.

Neostiks™, when used as intended, are very different in their fundamental characteristics to cigarettes and other smoking tobacco. They **cannot** be considered tobacco products for smoking. They should, consequently, be classified under Subheading 2403.99 of the HS.

II. Product Description:

BAT's ETHP is an innovative and patented next generation tobacco product that, when used as intended, heats but does not combust the tobacco in it. The ETHP consists of two main components which can function only in combination with each other:

1. glo™: The 'one unit' and 'one button' device is simple and intuitive to use. A single charge lasts more than 30 sessions based on back-to-back usage. glo™ consists of a vacuum tube, heater, PCB (printed circuit board), a lithium ion battery, a single button with 4 white LEDs (light emitting diodes) to inform the user, and a vibration motor.

2. **Neostiks™:** Neostiks™, wholly made of reconstituted tobacco, must be inserted into the glo™ heating device for it to be functional. Having been inserted into the glo™, the heating of the tobacco is initiated when the user presses a button on the device. Once the initial heating phase is complete, the Neostik™ is ready to be used.

   Neostiks™ generate a tobacco aerosol composed mainly of water, glycerine, nicotine and flavour. glo™ in combination with the Neostik™ can deliver puffs over a period of around 3.5 minutes. Once this cycle is complete, the Neostik™ must be removed from the device. A new Neostik™ must be used for the next use.

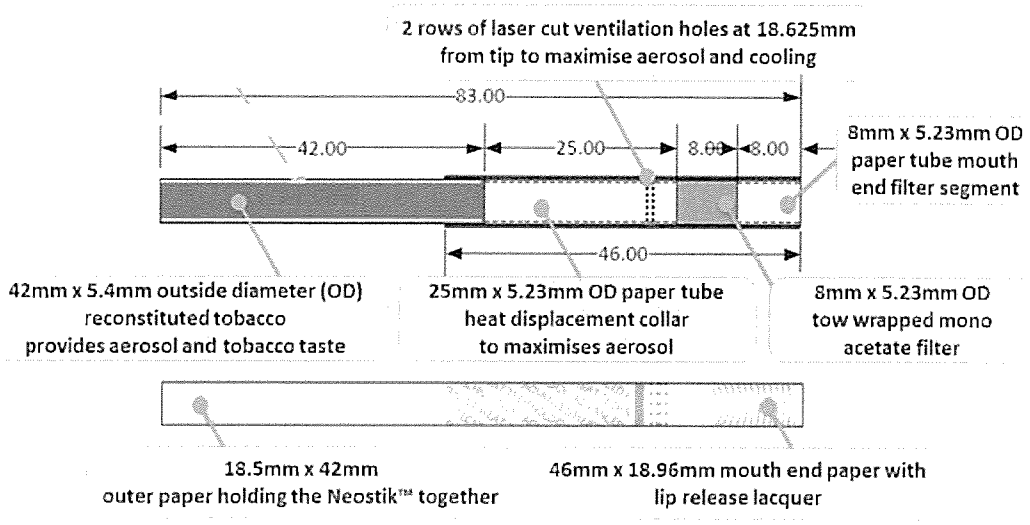
III. Composition of Neostiks™

Neostiks™ are made of 100% reconstituted tobacco and contain various tobacco grades as well as binders and humectants.

The reconstituted tobacco in Neostiks™ is produced through a pulping process – which is widely used in the tobacco industry – wherein the tobacco materials are mixed with humectants and binders and then laid down and dried into sheets of a specified thickness and weight. These reconstituted tobacco sheets are then cut into small pieces suitable for Neostiks™ manufacturing.

in contrast, factory made cigarettes contain, on average, no more than 10% of reconstituted tobacco in cut form.

Not only is the tobacco contained in a Neostik™ different to that in combustible tobacco products, also the physical and thermal properties of the reconstituted tobacco in the Neostik™, the composition of the Neostik™ and the use of the glo™ device is completely different from a traditional cigarette. The key differences are depicted in the diagram below.



Moreover, compared to a conventional cigarette, there is significantly less tobacco in Neostiks™. The weight of the reconstituted tobacco in the Neostik™ is about 260 milligrams. In comparison, the weight of the cut filler in a standard cigarette rod ranges from 600 to 700 milligrams.

IV. Functioning of Neostiks™

When used as intended, the tobacco in Neostiks™ does not combust and produces no tobacco smoke or ash as in a cigarette or other forms of combustible tobacco.

Cigarettes and other smoking tobacco is lit by the adult consumer and, through a process of self-sustained combustion, generates tobacco smoke composed mainly of a complex mixture of chemical compounds which is inhaled by the consumer. The tobacco in a lit cigarette smoulders between puffs at temperatures between 600-800°C. During a puff, the temperature increases to more than 900°C at the periphery of the burning zone. The self-sustaining combustion process is constant until the tobacco has been fully combusted and turned to ash or the consumer extinguishes the cigarette.

In contrast, Neostiks™ are designed to work exclusively with the glo™ electronic tobacco heating device. The electronically-controlled heating in glo™, coupled with the uniquely processed reconstituted tobacco, prevents combustion from occurring. The glo™ heating mechanism ensures that the tobacco is not heated above 240°C; much lower temperatures than at which smoking tobacco is combusted.

This heating of the tobacco in Neostiks™ generates a tobacco aerosol of mainly water, glycerine, flavours and nicotine for the user to inhale that is fundamentally different from the tobacco smoke emitted from a cigar or cigarette. The water content and glycerine in Neostiks™ facilitates the unique low-temperature heating use

which results in the emission of an aerosol as the glycerine evaporates and re-condenses into small droplets. This is fundamentally different from the smoke emitted from a cigar or cigarette when it is lit. Moreover, as there is no combustion, the heating of Neostiks™ does not result in any ash.

After the inhalation and exhalation of the aerosols, the vapour disappears quickly from the surrounding air. This is different from the smoke cigarettes generate which lingers in the air for a substantially longer period than the tobacco aerosols from Neostiks™.

V. Why British American Tobacco's Neostiks™ should be classified under subheading 2403.99 of the HS

Tobacco products are classified on a global basis for customs purposes under Chapter 24 of the WCO's Harmonized System Nomenclature ('Tobacco and manufactured tobacco substitutes') under three headings:

i ***2401: Unmanufactured tobacco; tobacco refuse***
ii ***2402: Cigars, cheroots, cigarillos, and cigarettes, of tobacco or of tobacco substitutes***
iii ***2403: Other manufactured tobacco and manufactured tobacco substitutes; "homogenised" or "reconstituted" tobacco; tobacco extracts and essences.***

Based on the headings within Chapter 24 of the HS together with the Explanatory Notes to the Harmonized System (the 'HSEN'), we consider that the HS code 2403.99 is appropriate for the classification of Neostiks™.

For the purposes of customs classification in the Harmonized System, it is generally recognised that two principles must be considered:

- first, the essential physical characteristics of the product in question; and
- second, to some extent (depending on the terms of relevant headings), their intended use.

This means that there must be sufficient commonality in the objective physical characteristics and properties between two different products for them to be treated in the same HS Chapter and under the same subheadings.

Neostiks™ display neither similarities in their intended use nor in their similar essential physical characteristics to the other products classified in the HS heading 24.01 or the HS heading 24.02.

HS subheading 24.01 covers unmanufactured tobacco and tobacco refuse. Neostiks™ do not fall under this subheading because they are a manufactured and finished tobacco product.

HS subheading 24.02 covers cigars, cheroots, cigarillos, and cigarettes (either containing tobacco or tobacco substitutes). All products covered under this subheading that are manufactured to be smoked. Indeed, the HSEN explains that:

- *"This heading is restricted to cigars (wrapped or not), cheroots, cigarillos and cigarettes, made of tobacco or of tobacco substitutes. Other smoking tobacco, whether or not containing tobacco substitutes in any proportion, is excluded (heading 24.03)."* It is clear from this explanation, and the reference to **other smoking tobacco**, that the tobacco products listed in this subheading are also intended to be smoked.
- In the third explanatory note to subheading 24.02, it is stated that *"Cigars, cheroots, cigarillos and cigarettes of tobacco substitutes, for example, "cigarettes" ("smokes") made from specially processed leaves of a variety of lettuce, containing neither tobacco nor nicotine."* Referring to cigarettes using the colloquial term 'smokes'

reinforces the common-sense interpretation that all of the products under HS subheading 24.02 are intended to be smoked by the consumer.

Cigarettes (and other smoking tobacco products) are lit by the adult consumer and, through a process of self-sustained combustion, generate tobacco smoke composed mainly of a complex mixture of chemical compounds which is inhaled by the consumer. In contrast, the tobacco in our Neostiks™ is heated at much lower temperatures than at which smoking tobacco is combusted. The heating of Neostiks™ tobacco generates an aerosol of mainly water, glycerine, flavours and nicotine for the user to inhale that is fundamentally different from the tobacco smoke emitted from a cigar or cigarette.

Neostiks™ do not fall under HS subheading 24.02 because they are, unlike all products classified under this subheading, not intended for smoking. Users of CTHPs do not inhale tobacco smoke – they inhale an aerosol that is not tobacco smoke.

Furthermore, Neostiks™ have no stand-alone usage. They are designed to be used with BAT's patented electronic tobacco heating device glo™, which prevents combustion from occurring and ensures that the tobacco is not heated above 240°C.

This means that Neostiks™ are classifiable in the remaining HS subheading 24.03. This includes the following subheadings[1]:

- Smoking tobacco, whether or not containing tobacco substitutes in any proportion:
  2403.11 -- Water pipe tobacco specified in Subheading Note 1 to this Chapter
  2403.19 -- Other

- Other:
  2403.91 -- "Homogenised" or "reconstituted" tobacco
  2403.99 -- Other

Because, for the reasons explained above, **Neostiks™ are not smoked**, they cannot be classified under the two subheadings 2403.11 and 2403.19 which cover different forms of **smoking** tobacco.

Logically, Neostiks™ can, therefore, be classified only under either subheading 2403.91 or 2403.99.

Neostiks™ do not fall under the HS subheading 2403.91 for "Homogenised" or "reconstituted" tobacco which is defined, in the HSEN as follows:

""Homogenized" or "reconstituted" tobacco mode by agglomerating finely divided tobacco from tobacco leaves, tobacco refuse or dust, whether or not on a backing (e.g., sheet of cellulose from tobacco stems), generally put up in the form of rectangular sheets or strip. It can be either used in the sheet form (as a wrapper) or shredded/chopped (as a filler)."

Although Neostiks™ are manufactured using reconstituted tobacco, the products classified under the HS subheading 2403.91 are, as the explanation makes clear, intermediate goods that are intended to be processed

[1] http://www.wcoomd.org/-/media/wco/public/global/pdf/topics/nomenclature/instruments-and-tools/hs-nomeclature-2017/2017/0424_2017e.pdf?la=en

further as ingredients into a finished manufactured product. In contrast, the composition and physical properties of Neostiks™ are of finished manufactured products intended to be consumed by the end user at the time it is cleared for customs.

This means the only reasonable HS subheading under which Neostiks™ can be classified for customs purposes is 2403.99, a subheading that covers tobacco products that are finished for final consumption (unlike the products under 24.01 and 2403.91) and whose intended use is not to be combusted and smoked (unlike the products under 24.02, 2403.11 and 2403.19).

Committee on TOXICITY

COMMITTEES ON TOXICITY, CARCINOGENICITY AND MUTAGENICITY OF CHEMICALS IN FOOD, CONSUMER PRODUCTS AND THE ENVIRONMENT (COT, COC and COM)

Statement on the toxicological evaluation of novel heat-not-burn tobacco products

Introduction

1. The COT, with support from the COC and the COM, was requested to assess the toxicological risks from novel heat-not-burn tobacco products, and compare these risks to those from conventional cigarettes. This assessment will provide the Department of Health (DH) and Public Health England (PHE) with a general opinion on the toxicological risks of such products. It will not fulfil any regulatory function of PHE.

2. To date, two novel heat-not-burn tobacco products have been notified to PHE in accordance with the Tobacco and Related Products Regulations 2016.

What are novel heat-not-burn tobacco products?

3. Novel tobacco products are defined in The Tobacco and Related Products Regulations 2016 as a tobacco product which –

a. Is not a cigarette, hand rolling tobacco, pipe tobacco, waterpipe tobacco, a cigar, a cigarillo, chewing tobacco, nasal tobacco or tobacco for oral use; and
b. Is first supplied by the producer after 19th May 2014.

4. In heat-not-burn tobacco products, processed tobacco is heated instead of being burnt as is the case for conventional tobacco products. Under the definition in the Tobacco and Related Products Regulations 2016, these are therefore novel tobacco products, and hence are required to be notified to PHE. In this evaluation, the Committees have considered the two heat-not-burn tobacco products which had been notified to PHE by November 2016, and which are available on the UK market.

5. A recent consultation by HM Treasury[1], noted there is a range of heat-not-burn tobacco products, where:

a. processed tobacco is heated directly to produce vapour
b. processed tobacco is designed to be heated in a vaporiser
c. devices produce vapour from non-tobacco sources, where the vapour is then passed over processed tobacco in order to flavour the vapour

6. The two products assessed by the Committees fall into the first and last of these groups, and as a result the temperature to which the tobacco is heated varies considerably between them. This may result in differences in the potential health outcomes. For one product, where the tobacco is heated directly, a maximum heating temperature of up to 350 °C was reported, while for the other product, in which the tobacco is heated by a vapour, the maximum temperature of the tobacco was reported to be less than 50 °C. For comparison, when tobacco in cigarettes is burnt it reaches temperatures of at least 800 °C.

Information obtained

7. The Committees reviewed data submitted to the EU Common Entry Gateway, the EU portal through which manufacturers submit information to the competent authorities of each Member State as per the requirements of the Tobacco & Related Products Regulations 2016, which transposes the EU Tobacco Products Directive (2014/40/EU).

8. To facilitate the discussion, a consolidated list of the types of information needed by the Committees to undertake their assessment was produced. The two manufacturers of products notified in the UK before November 2016 were asked to present the data they hold addressing these information needs to a joint discussion session of the COT, COC and COM held on 16th May 2017. The list of Committees' information needs is appended to this statement at Appendix 1.

9. In addition to the manufacturers' data, a literature search was undertaken to identify any available independent data on these products.

Available data

10. Of the two products considered, there was a marked difference in the amount of data available from the manufacturers on which the Committees could base their assessment. Only limited information on these products is available from independent sources.

[1] Tax treatment of heated tobacco products, published 20 March 2017: https://www.gov.uk/government/consultations/tax-treatment-of-heated-tobacco-products/tax-treatment-of-heated-tobacco-products (accessed 19/06/2017)

Exposure

11. Investigations on both products showed a decrease in the harmful and potentially harmful compounds (HPHCs) in the aerosol generated by the device to which the user would be exposed, compared to the HPHCs in the mainstream smoke from a conventional cigarette[2]. For both products, there were some HPHCs where the reduction was approximately 50%, but the reduction in a number of other HPHCs was greater than 90%, with many of the compounds being below the limits of detection or quantification for the assays used.

12. The Committees also requested data on additional contaminants from the devices themselves, as this had been identified as a possible area of concern for e-cigarettes. The available data presented and discussed with the manufacturers provided no evidence for exposures other than from compounds also present in conventional cigarette smoke.

13. The design of the devices means that any potential sidestream emissions from them will be very different to those from the burning tip of conventional cigarettes. In terms of environmental exposure to bystanders, indoor air following use of the heat-not-burn tobacco products has been assessed by both manufacturers, and compared with background and environments where conventional cigarettes (market brands) have been used. These assessments showed that while some of the measured components increased above background with the use of the heat-not-burn tobacco products, much greater increases occurred across all the measured components (volatile organic compounds, combustion related markers and tobacco smoke related markers including nicotine) following use of conventional cigarettes.

Toxicity data

14. In compiling the list of information requested by the Committees for this evaluation, there was a focus on cancer, mutagenicity, respiratory-related health effects, cardiovascular and liver effects.

15. The greatest contrast in the available data for the two products provided by the manufacturers was with respect to the type of toxicity data available. For both products however, two genotoxicity tests had been undertaken. For one product where tobacco is directly heated, *in vivo* study data were available for some endpoints with further work planned as well as some *in vitro* data, while for the other product where the tobacco is heated by a vapour, information was available from *in vitro* studies only.

[2] Throughout the statement, unless otherwise stated, comparison was between the product and the Kentucky 3R4F reference cigarette.

Epidemiological data

16. Both products are already available on the market in the UK and other countries around the world. Post-market surveillance is being undertaken by both manufacturers in these countries.

17. In addition, for the product where tobacco is directly heated epidemiology studies have been undertaken, mostly relating to the pattern of use rather than on health. Studies are continuing and the manufacturer's aim is to assess the impact on human health, directly or indirectly, compared to people who continue to use their preferred market brand of conventional cigarettes.

Committees' discussion

18. The Committees have considered only the two products notified in the UK, which therefore does not cover all three of the types of product outlined in the HM Treasury consultation on taxation of heated tobacco products.

19. A number of differences were identified between the two products, including the temperature to which the tobacco is heated, which will potentially have an impact on the number and amount of compounds that become volatilised and can be inhaled by the user. There is also a difference in the source of the nicotine in the aerosol. In the product where the tobacco is heated directly, the nicotine is derived from the tobacco in the device, while for the other product the nicotine is (mainly) within the liquid, which is aerosolised and passed through the tobacco.

20. The Committees noted the difference in the amount of toxicological and related data available for the two products, influencing the certainty of conclusions across the range of heat-not-burn tobacco products.

21. The request for the Committees to assess the absolute risk of heat-not-burn tobacco products was not possible to address. While there are data available on risks associated with cigarette smoking, it is not possible to extrapolate from these studies as the relative concentrations of the HPHCs in tobacco smoke are different to those in the aerosol from heat-not-burn tobacco products. Further, information on the quantitative contribution of specific compounds to the risk from exposure to conventional cigarettes and their emissions is not available.

22. The data, both from manufacturers and the limited independent sources, indicated that the aerosol generated from these novel products contains HPHCs, some of which are mutagenic and carcinogenic. The normal recommendation of the Committees is that exposure to such chemicals is kept as low as reasonably practicable, but there would be a likely reduction in risk for smokers deciding to use heat-not-burn tobacco products compared with continuing to smoke cigarettes as the exposure to HPHCs is reduced. Nevertheless using heat-not-burn tobacco products would involve a greater risk compared to stopping smoking completely.

23. A reduction in risk would be expected to be experienced by bystanders where smokers switch to heat-not-burn tobacco products.

24. The Committees were concerned over the potential for non-smokers including children and young people, who would not otherwise start to smoke cigarettes, to take up using these products as they are not without risk. There was also concern over whether use of these products would lead people to take up smoking cigarettes. Though outside the Committees' remit, monitoring of the number of non-smokers who take up use of heat-not-burn tobacco products, and their age profile, would be useful, and also if it could be determined whether in the absence of heat-not-burn tobacco products they would have taken up smoking.

25. The data considered by the Committees was not sufficient to comment on the relative risks of heat-not-burn tobacco products and e-cigarettes. This is of interest in case people switch from e-cigarettes to heat-not-burn tobacco products, and the Committees noted the potential that if people perceive e-cigarettes as safe this perception could transfer to heat-not-burn tobacco products, despite a lack of data on which to establish this. It was noted that for the product where a heated vapour is drawn over the tobacco for flavour, there are similarities with e-cigarettes, so some of the potential concerns that the COT has scoped out for e-cigarettes may also apply to this product (see TOX/2016/25). Consideration of these two aspects could be made when the COT e-cigarette work is taken forward.

26. The Committees considered the potential risks from use of these products during pregnancy. The current UK advice to pregnant women is to stop smoking entirely. However, the advice states: "If using an e-cigarette helps you to stop smoking, it is much safer for you and your baby than continuing to smoke" (NHS, 2017). There is no toxicity data for heat-not-burn tobacco products on the risk to the unborn child following use by the mother. Based on exposure to compounds of concern being reduced with heat-not-burn tobacco products compared to conventional cigarettes, the Committees considered that, though the aim should be for pregnant women to stop smoking entirely, the risk to the unborn baby is likely to be reduced if using these products during pregnancy instead of smoking. The Committees cannot presently comment on the relative risks of use of heat-not-burn tobacco products compared to e-cigarettes during pregnancy.

27. It was emphasised that nicotine itself is addictive, and can have harmful effects on health. In addition, users of any nicotine product would use the product in such a way, and in such quantity, as to achieve a similar effect to that they were used to from their previous smoking products. Depending on the concentrations of nicotine in different products, relative exposure to other compounds of concern could be increased or decreased in the process of achieving the desired nicotine effect. For example, a user might take a fewer or greater number of puffs, or use these products more often or for longer than they did with conventional cigarettes.

Committees conclusions and recommendations

28. Tobacco smoking and smokeless tobacco for oral or nasal use are carcinogenic to humans, and have been classified by IARC as Group 1 carcinogens.

29. The aerosol generated by heat-not-burn tobacco products contains a number of compounds of concern, some of which are carcinogens, and there will be a risk to the health of anyone using these products.

30. For non-smokers who start to use these products, this will be an increase in risk, compared to if the products were not used. The Committees were particularly concerned for young people, who do not smoke, starting to use these products, due to the potential for longer exposure over the remainder of their lives compared to adults and to possible differences in sensitivity.

31. As the exposure to compounds of concern in the aerosol is reduced compared to conventional cigarette smoke, it 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.

32. The risks associated with use of heat-not-burn tobacco products cannot be quantified due to gaps in the information available and uncertainties in the dose-response relationship of the chemicals and potential adverse health outcomes. In addition, the levels of the different compounds in the aerosol vary compared to the levels in smoke from conventional cigarettes and therefore it is not possible to extrapolate from epidemiological data on smoking risks, particularly given the complexity of the interactions that occur between these compounds in producing adverse health effects.

33. As these products contain nicotine and are designed to deliver similar levels of nicotine to conventional cigarettes, their use will not reduce nicotine exposure or its risk to health and possibility of addiction from nicotine.

34. Most of the data on heat-not-burn tobacco products has been provided by the product manufacturers. To date there has been limited independent confirmation of the manufacturers' findings, and for public health reassurance the Committees consider it important to obtain independent verification of the manufacturers results.

35. Further information on the population impact of availability of these products should be collected, including uptake of these products by smokers and non-smokers and their age profile, whether product switching or dual use occurs including with e-cigarettes, uptake of smoking as a result of use of these products by non-smokers, and overall population exposure, including bystanders, to compounds of concern.

36. In addition to the requested comparison of novel heat-not-burn tobacco products with conventional cigarettes, it is of interest to compare the risks from these products to those from e-cigarettes. This will be borne in mind when the COT considers e-cigarettes, but is not possible to address based on the data presented to the Committees as part of the current evaluation.

37. Overall, the Committees conclude that while there is a likely reduction in risk for smokers switching to heat-not-burn tobacco products, there will be a residual risk

and it would be more beneficial for smokers to quit smoking entirely. This should from part of any long-term strategy to minimise risk from tobacco use.

COT, COC and COM
COT 2017/04; December 2017

References

NHS (2017). Stop smoking in pregnancy. Available: http://www.nhs.uk/conditions/pregnancy-and-baby/pages/smoking-pregnant.aspx (accessed 07/09/2017)

COMMITTEES ON TOXICITY, CARCINOGENCITIY AND MUTAGENICITY OF CHEMICALS IN FOOD, CONSUMER PRODUCTS AND THE ENVIRONMENT (COT, COC and COM)

Toxicological evaluation of novel heat-not-burn tobacco products

List of COT, COC and COM information needs for assessment of novel heat-not-burn tobacco products sent to the manufacturers of products notified to Public Health England by November 2016.

Information needs for COT, COM and COC evaluation of heat not burn tobacco products

Cigarette smoking has been associated with many health problems; for example addiction, cancer, and cardiovascular effects. In evaluating heat not burn products we wish to consider both hazard identification of aspects that may be new to heat not burn products (for example nanoparticles and device related issues) as well as comparing risk for known chemicals, and considering the risks associated with combined use of burn and heat not burn products.

Aspects relating to the Tobacco containing product:

- Constituents and Chemical composition
- Additives
- Temperature of heating, and chemical processes occurring at that temperature
    - How these differ from heating and burning processes occurring in conventional cigarettes – i.e. what is new chemistry

Aspects relating to the delivery device

- Releases (e.g. metals – nickel in particular was mentioned)
- What is the overlap with devices such as e-cigarettes, and any devices assessed by MHRA

Exposure

- Chemicals in the mainstream 'smoke'
- Nicotine levels
- Chemicals released to the environment

- What the user is inhaling
- What is in the air surrounding the user including what is exhaled by the user, resulting in passive/bystander exposure
- What is in the general environment as a result of use of the product

- How is air quality assessed
    - What particulate matter is in the aerosol
    - What nanoparticles arise from use
    - Other chemicals released during and after use

- Likely age groups for anticipated use – attractiveness of use to younger age groups
- Appropriate use levels
- Accidental exposure, and routes of exposure – especially to children
- Potential for deliberate mis-use or overdose – e.g. reports of use of e-cigarette fluids as eye drops

- Cumulative exposures, including to nicotine, arising from use in conjunction with conventional or electronic cigarettes
- Consider potential for formation of cancer-causing chemicals as a result of combination e.g. with dietary chemicals even if no longer present in 'smoke'

Health effects

For each set of data it is important to know how the evaluation or tests were carried out, e.g. according to standard methods or otherwise. COT, COM and COC would require documentation of the methods and statistical analyses undertaken, as well as dose response data on the biological effects observed.

- Acute effects
    - Mutagenicity endpoints e.g.
        - DNA Strand breaks
        - Clastogenicity
        - Aneuploidy
        - Gene mutation (Point mutation, Deletion, Rearrangement or Recombination)
        - Genotoxicity test types (Bacterial, Mammalian in vitro or in vivo, Site of contact – oral and respiratory, Target organ, Germ cell)

- Chronic effects
    - Cancer effects
    - Respiratory toxicity
        - Lung lipid metabolism
    - Systemic toxicity
        - Hepatotoxicity
        - Cardiovascular toxicity

- Sensitisation potential

- Systems biology data

- Epidemiological data
- Volunteer studies or Clinical assessment
    - Pharmacokinetics and Pharmacodynamics
    - Biomarkers assessed – including relevant early markers
        - Cancer
        - Cardiovascular
- Post Market Assessment

- Specific toxicity effects of nicotine at the exposure levels resulting from use of these products

Committee on TOXICITY

COMMITTEES ON TOXICITY, CARCINOGENICITY AND MUTAGENICITY OF CHEMICALS IN FOOD, CONSUMER PRODUCTS AND THE ENVIRONMENT (COT, COC and COM)

Toxicological evaluation of novel heat-not-burn tobacco products – non-technical summary

Introduction

1. The COT, with support from the COC and the COM, was requested to assess the toxicological risks from novel heat-not-burn tobacco products, and compare these risks to those from conventional cigarettes.

2. To date, two novel heat-not-burn tobacco products have been notified to PHE in accordance with the Tobacco and Related Products Regulations 2016.

What are novel heat-not-burn tobacco products?

3. In heat-not-burn tobacco products, processed tobacco is heated in a controlled device instead of being burnt as is the case for conventional tobacco products.

4. A recent consultation by HM Treasury[1] noted there is a range of heat-not-burn tobacco products where:

   a. processed tobacco is heated directly to produce vapour

   b. processed tobacco is designed to be heated in a vaporiser

   c. devices produce vapour from non-tobacco sources, where the vapour is then passed over processed tobacco in order to flavour the vapour

5. The two products assessed by the Committees fall into the first and last of these groups, and as a result the temperature to which the tobacco is heated varies considerably between them. For one product where the tobacco is heated directly, a maximum heating temperature of up to 350 °C was reported, while for the other product in which the tobacco is heated by a vapour, the maximum temperature of the tobacco was reported to be less than 50 °C. For comparison, when tobacco in cigarettes is burnt it reaches temperatures of at least 800 °C.

[1] Tax treatment of heated tobacco products, published 20 March 2017: https://www.gov.uk/government/consultations/tax-treatment-of-heated-tobacco-products/tax-treatment-of-heated-tobacco-products (accessed 19/06/2017)

Information obtained

6. The two manufacturers of products notified in the UK before November 2016 were asked to present the relevant toxicity data they hold. In addition to the manufacturers' data, a literature search was undertaken to identify any available independent data on these products. This was very limited.

Exposure

7. Investigations on both products that were assessed by the Committees, showed a decrease in the harmful and potentially harmful compounds (HPHCs) to which the user would be exposed, compared to the HPHCs from a conventional cigarette[2]. For both products, there were some HPHCs where the reduction was approximately 50%, and the reduction in other HPHCs was greater than 90%.

8. The Committees also requested data on additional contaminants from the devices themselves. The available data presented and discussed with the manufacturers provided no evidence for exposures other than from compounds also present in conventional cigarette smoke.

9. The design of the devices means that any potential sidestream emissions from them will be very different to those from the burning tip of conventional cigarettes. In terms of environmental exposure to bystanders, assessments showed that while some of the measured components increased above background with the use of the heat-not-burn tobacco products, much greater increases occurred following use of conventional cigarettes.

Toxicity data

10. In compiling the list of information requested by the Committees for this evaluation, there was a focus on cancer, respiratory, cardiovascular and liver-related health effects.

Epidemiological data

11. Both products are already available on the market in the UK and other countries around the world. Post-marketing surveillance is being undertaken by both manufacturers in these countries, but it is too early for epidemiological information on health impacts to be available.

Committees' discussion

12. A number of differences were identified between the two products notified in the UK, the most obvious being the temperature to which the tobacco is heated, which will potentially have an impact on the number and amount of compounds that thereby become volatile and can be inhaled by the user. There is also a difference in the source of the nicotine. In the product where the tobacco is heated directly, the

[2] Throughout the statement, unless otherwise stated, comparison was between the product and the Kentucky 3R4F reference cigarette.

nicotine is derived from the tobacco in the device, while for the other product the nicotine is present within the liquid that is aerosolised and passed through the tobacco.

13. The Committees were unable to assess the absolute risk of heat-not-burn tobacco products given the nature of the data available.

14. The data indicated that the aerosol generated from these products contains HPHCs, some of which are mutagenic and carcinogenic, and therefore there will be some risk to health from use of these products. The normal recommendation of the Committees is that exposure to such chemicals is kept as low as reasonably practicable, but it was recognised that these products could provide harm reduction for people who would otherwise smoke cigarettes.

15. There would likely be a reduction in risk for conventional smokers deciding to use heat-not-burn tobacco products instead of smoking cigarettes. However, stopping smoking entirely would lead to the greater reduction in risk.

16. A reduction in risk would also be experienced by bystanders where smokers switch to heat-not-burn tobacco products.

17. The Committees were concerned over the potential for non-smokers including children and young people, who would not otherwise start to smoke cigarettes, to take up using these products, as they are not without risk. There was also concern over whether the use of these products would lead to cigarette smoking by non-smokers. Information on this should be obtained before the overall impact on public health can be assessed.

18. The data considered by the Committees was not sufficient to comment on the relative risks of heat-not-burn tobacco products and e-cigarettes, though this is of interest.

19. The Committees considered the potential risks from use of these products during pregnancy. The current UK advice[3] to pregnant women is to stop smoking entirely. However, the advice states: "If using an e-cigarette helps you to stop smoking, it is much safer for you and your baby than continuing to smoke". There is no direct data on the risk to the unborn child following use of heat-not-burn tobacco products by the mother. Based on reduced exposure to compounds of concern with heat-not-burn tobacco products compared to conventional cigarettes, the Committees considered that, though the aim should be for pregnant women to stop smoking entirely, the risk to the unborn baby is likely to be reduced if using these products during pregnancy instead of smoking.

20. The Committees emphasised that nicotine itself is addictive, and can have harmful effects on health. In addition, users of any nicotine product would use it in such a way, and in such quantity, as to achieve a similar effect to that they were used to from their previous smoking products. Depending on the concentrations of

[3] Stop smoking in pregnancy. Available at: http://www.nhs.uk/conditions/pregnancy-and-baby/pages/smoking-pregnant.aspx (accessed 07/09/2017)

nicotine in different products, relative exposure to other compounds of concern could be increased or decreased in the process of achieving the desired nicotine effect. For example a user might take a fewer or greater number of puffs, or use these products more often or for longer than they did with conventional cigarettes.

Committees' conclusions

21. It is well recognised that using tobacco is carcinogenic and its use has other harmful effects on human health.

22. Using heat-not-burn tobacco products involves breathing in a number of compounds of concern, some of which are carcinogens.

23. The levels of the different compounds in the aerosol from heat-not-burn tobacco products are different to the levels in smoke from conventional cigarettes.

24. Heat-not-burn tobacco products contain nicotine and are designed to deliver similar levels of nicotine to conventional cigarettes; their use will not reduce nicotine exposure or the risk to health from and possibility of addiction to nicotine.

25. The Committees conclude that there will be a risk to health from using heat-not-burn tobacco products.

26. It is currently not possible to quantify this risk. Heat-not-burn tobacco products are new and there is insufficient data available to enable a full assessment.

27. The exposure to compounds of concern in using heat-not-burn tobacco products is reduced compared to that from conventional cigarette smoke. It is likely that there is a reduction in overall risk to health for conventional smokers who switch to heat-not-burn tobacco products.

28. While the Committees conclude there is a likely reduction in risk for smokers switching to heat-not-burn tobacco products, a risk remains and it would be more beneficial for smokers to quit smoking entirely.

29. A reduction in risk would be expected to be experienced by bystanders where smokers switch to heat-not-burn tobacco products.

30. The risk to the unborn child from use of these products by mothers during pregnancy is difficult to quantify and current NHS advice is to stop smoking entirely. The Committees consider that the risk to the unborn baby is likely to be reduced if these products were used during pregnancy instead of smoking, although the aim should be to stop smoking entirely.

31. Overall, the Committees conclude there are toxicological risks from novel heat-not-burn tobacco products though data on impacts to human health is very limited. Compared with the known risks from conventional cigarettes, they are probably less harmful. Even so, smokers would do better to quit entirely.

COT, COC and COM
COT 2017/04; December 2017

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BRITISH AMERICAN TOBACCO

FOR IMMEDIATE RELEASE

British American Tobacco publishes a series of studies supporting the reduced-risk potential of glo

- glo, a tobacco heating product (THP), heats rather than burns tobacco
- Studies reveal that the numbers of toxicants and the levels at which they are detected in glo emissions are significantly lower than those in cigarette smoke
- In contrast to cigarette smoke, studies reveal glo vapour to have little or no impact on human cells in the lab, in some cases having the same impact as air
- Based on these and other test results, glo has the potential to be significantly reduced risk compared to cigarettes

November 2017, Southampton, UK: Scientists at British American Tobacco have conducted a series of tests that help establish glo as having the potential to be reduced risk compared to traditional cigarettes. glo is a tobacco-heating product that heats rather than burns tobacco and does not produce cigarette smoke. It is currently available in five markets: Japan, Korea, Switzerland, Canada and Russia.

The tests used were specifically developed to help assess the relative risk of products like glo. The tests included analysing how people use glo, the content of the vapour and what that vapour does to cells in certain laboratory tests. The results are combined to create an overall picture that reveals glo vapour to be relatively simple compared to cigarette smoke and to have much less, or no (depending on the particular test used), impact on cells in the lab compared to smoke.

"A key part of our company strategy is developing and commercialising a range of products that offer consumers potentially less risky alternatives to conventional cigarettes," said Dr James Murphy, Head of Reduced Risk Substantiation at British American Tobacco. "This is a rapidly evolving category and both consumers and regulators rightly want as much information as possible about the products available. That is why we believe a science-based approach is vital to gathering the evidence we need to demonstrate the reduced-risk potential of glo," Murphy said.

Test One - What's in the Vapour?

Understanding what is in the vapour produced by glo is important because it will show what a consumer may be exposed to when they use the product. It will also reveal the difference in toxicant emissions between glo vapour and cigarette smoke.

It is widely understood that it is the toxicants in smoke that cause most smoking-related diseases. Removing combustion from the equation, thereby removing smoke and reducing the number and levels of smoke toxicants, should, therefore, theoretically go some way towards

creating a potentially reduced-risk product. glo does not produce smoke because it heats rather than burns tobacco.

Scientists at BAT first studied how people used glo and used this information to programme puffing robots in the lab. The robots then puffed on glo to produce vapour in a realistic way.

This vapour was then passed through filters, which on visual inspection reveal the stark difference between glo vapour and smoke from cigarettes, see Figure 1. However, when understanding what's in an aerosol, what you can't see can be just as important as what you can see.

For this reason, a series of further analyses were conducted comparing the chemical composition of glo vapour with that of smoke. The results reveal the relatively simple composition of glo vapour compared to conventional cigarette smoke. An example of the kinds of results obtained can be seen in Figure 2. Scientists found substantial reductions in the numbers and levels of toxicants in the glo vapour for all toxicant groups measured. In fact, most cigarette smoke toxicants could not be detected in the glo vapour. Overall, there are around 90-95% less toxicants in glo vapour, so it should in principle expose consumers to less toxicants compared to smoke*.

Test Two - Vapour vs Smoke

A further batch of tests was employed to compare glo vapour with smoke in terms of the impact on living cells in the lab.

Puffing robots were again used, but this time in combination with a special system that allows living cells grown in the lab to be exposed to aerosols. One such system was developed to mimic the way human lung cells are exposed to aerosols in real-life. Using this system, it was shown that glo vapour has a much-reduced, or no (depending on the test used), biological impact on cells in the lab, compared to conventional cigarette smoke.

Unlike cigarette smoke, glo vapour was not toxic to human airway cells and did not cause mutations in DNA or promote the development of tumours in the tests used*. In many cases, the results were similar to those obtained when the cells were exposed to air.

Test Three – Second-Hand Vapour?

Cigarette smoke enters the environment when smokers exhale but also when cigarettes smoulder, which they do even when not being actively smoked. glo is different from cigarettes in that it doesn't smoulder between puffs, as it does not burn tobacco. However, there is often a visible vapour cloud produced when people use products like glo. Because of this, perhaps it is not surprising that some people ask the question: is there anything in the exhaled vapour that by-standers should be worried about?

For this reason, scientists at BAT analysed indoor air quality and the tobacco odour of an environmentally controlled room where volunteers used glo over a period of four hours. Air from the room was sampled and compared to air from the room when volunteers smoked cigarettes as well as air from the room when no products were used. These tests were

conducted in the room at different air flows, to simulate a home, office or hospitality environment.

In the air sampled from the glo room, most toxicants measured could not be detected at all. Overall, the results reveal substantial reductions in numbers and levels of environmental toxicants for glo use compared to cigarette smoking*. Additionally, tobacco odour on hair, clothes and skin was not an issue in the room when people used glo.

Assessing Reduced Risk

When taken together the results of these, and other studies, show that there is a wide gap between glo and conventional cigarettes in terms of the aerosols they produce, with glo emitting substantially reduced numbers and levels of certain known toxicants as compared to those from conventional cigarettes. glo vapour also has much-reduced or no biological impact on human cells in the biological tests performed as compared to cigarette smoke.

This means that when ranked along an emissions spectrum, cigarettes are at one end of a spectrum (high toxicant levels) and glo is at the other end (low toxicant levels).

'When taken together with the reduced levels of responses seen in the biological tests, these results place cigarettes and glo at opposite ends of an emissions spectrum, although more long-term studies will be needed to substantiate if this translates to a reduction in risk,' said Murphy.

Does this mean that glo is safer than cigarettes?

One test alone cannot prove reduced risk. However, taken together these initial results indicate that glo has the potential to be substantially reduced risk compared to cigarettes. However, we are in the process of conducting longer term studies to better understand these products and until these studies are completed, we cannot say at this stage that these products are less harmful than other tobacco products.

"We've long been committed to research in this area and to communicating to consumers and regulators that the information on our products is based on sound, evidence-based science. This is just the beginning," Murphy said.

These results were published in a special issue of the Journal Regulatory Toxicology and Pharmacology.

British American Tobacco's Commitment to NGPs

British American Tobacco has invested more than US$2.5 billion over six years in developing and commercialising a world-leading portfolio of products in the Next Generation Products (NGPs) category. British American Tobacco currently has NGPs in 16 markets, with three of four consumers using THPs in Tokyo using glo, BAT has a bold ambition to realise revenue of more than £5bn from NGPs by 2022.

ENDS

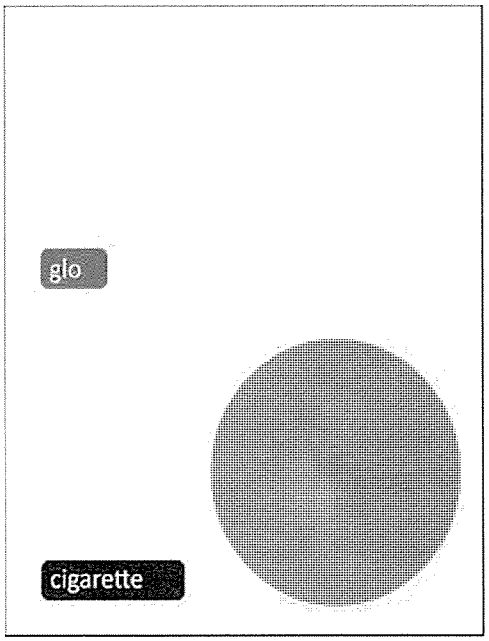

Figure 1: Filter pads with glo aerosol (top) and smoke from a reference cigarette (bottom).

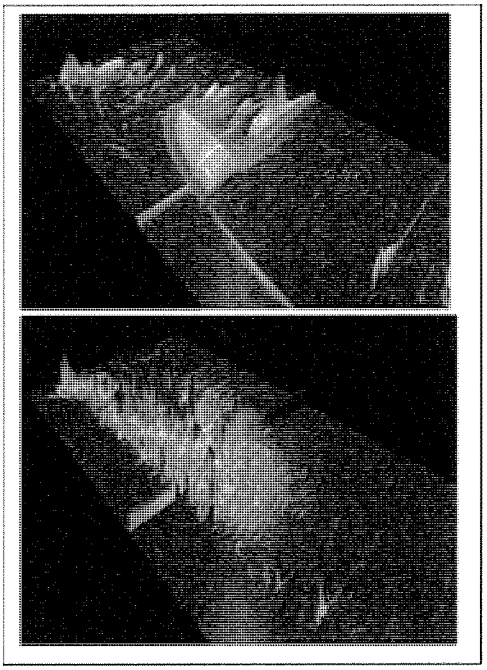

Figure 2: The number of peaks in the top graph (glo) are smaller than in the bottom graph (cigarette) reflecting the fact that glo produces a simpler aerosol, contains less compounds than smoke from a cigarette (bottom).

NOTES to Editors

About British American Tobacco: British American Tobacco is a global tobacco and next generation product company with brands sold in more than 200 markets. It employs more than 50,000 people worldwide and has over 200 brands in its portfolio, with its cigarettes chosen by one in eight of the world's one billion smokers. Leading global brands include Dunhill, Kent, Pall Mall and Lucky Strike.

About Next Generation Products (NGP): Next Generation Products is part of the British American Tobacco Group and is focused on developing and delivering high-quality alternative nicotine and tobacco products for adult smokers in the key areas of Vapour and Tobacco Heating Products. For more information see www.govype.com and www.bat-science.com.

About Tobacco Harm Reduction: The only way to avoid the risks associated with tobacco use is not to consume tobacco at all, and the best way to reduce the risks is to stop using tobacco. However, the concept of harm reduction is increasingly being considered in relation to tobacco use. Harm reduction is about finding practical ways to minimise the health impact of an inherently risky activity or behaviour, without seeking to stop it entirely. It is a key element of BAT's business strategy and is being discussed by some regulators. We think it's important to work towards producing consumer-acceptable, potentially reduced-risk products. We believe that tobacco regulatory policies should include harm reduction approaches for the millions of adults globally who will continue to consume tobacco products.

The Public Health impact of e-cigarettes and other Next-Generation Products: Many in the public health community believe e-cigarettes offer great potential for reducing the public health impact of smoking. Public Health England, an executive body of the UK Department of Health, recently published a report saying that the current expert estimate is that using e-cigarettes is around 95% safer than smoking cigarettes. The Royal College of Physicians have said that the public can be reassured that e-cigarettes are much safer than smoking and that they should be widely promoted as an alternative to cigarettes.

What's in the vapour? The results reported here are based on a comparison between the smoke from combusted tobacco in a standard 3R4F reference cigarette (approximately 9 mg tar), and the vapour from heated tobacco in glo, in terms of the 9 types of harmful components which the World Health Organisation recommends to reduce in cigarette smoke.

* These qualities do not necessarily mean this product is less harmful than other tobacco products.

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NEXT GENERATION PRODUCTS

ANDS role in supporting public health strategies

There is a growing body of evidence that non-combustible Alternative Nicotine Delivery Systems (ANDS) are potentially less harmful to health than cigarettes, and may play a powerful role in reducing smoking prevalence and the associated health impacts of smoking. Enactment of a balanced regulatory policy is crucial to realising the potential benefit of these products.

A. **The harm caused by smoking is primarily attributable to the constituents of tobacco smoke and not nicotine itself, and there is a need to recognize the public health potential of less harmful nicotine products for smokers who do not want to quit nicotine use.**

"it's the other chemical compounds in tobacco, and in the smoke created by setting tobacco on fire, that directly and primarily cause the illness and death, not the nicotine." *Dr Scott Gottlieb, US FDA commissioner, July 2017.*[1]

Scientists widely agree that it's largely the toxicants found in cigarette smoke that cause smoking related diseases – not the nicotine itself. Public health organisations, including the International Agency for Research on Cancer (IARC), the UK's Royal College of Physicians and the UK's National Institute for Health and Care Excellence (NICE) generally agree that nicotine, while addictive, is not the primary cause of smoking-related diseases and the harm of smoking is primarily caused by other constituents of tobacco smoke. IARC states that nicotine does not cause cancer directly,[2] and NICE has stated that "nicotine inhaled from smoking tobacco is highly addictive. But it is primarily the toxins and carcinogens in tobacco smoke – not the nicotine – that cause illness and death."[3]

While smokers are aware of the risk of smoking, some find it difficult or do not want to quit nicotine. The challenge has been in providing alternative nicotine products that appeal to smokers and expose them to less toxic chemicals than cigarettes. A report by the UK Royal College of Physicians states that, "as most of the harm caused by smoking arises not from nicotine but from other components of tobacco smoke, the health and life expectancy of today's smokers could be radically improved by encouraging as many as possible to switch to a smoke-free source of nicotine"[4].

B. **There are decades of research demonstrating that Swedish snus is substantially safer than smoking and Sweden has shown that a majority of smokers may, given the availability of a socially acceptable and affordable reduced risk alternatives, switch from smoked tobacco to a non-combusted alternative nicotine product.**

"Snus has both contributed to decreasing initiation of smoking and, when used subsequent to smoking, appears to facilitate smoking cessation. All these effects suggest that the availability and use of snus has been a major factor behind Sweden's record-low prevalence of smoking and the lowest level of tobacco-related mortality among men in Europe."[5]

Swedish snus is an oral tobacco which many experts agree involves substantially less health risk than cigarette smoking. Sweden was the first country to fund an educational campaign on the risk of

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[1] Gottlieb S, Protecting American Families: Comprehensive Approach to Nicotine and Tobacco, July 2017.
[2] https://cancer-code-europe.iarc.fr/index.php/en/ecac-12-ways/tobacco/199-nicotine-cause-cancer
[3] Smoking: harm reduction (PH45), NICE, UK – last reviewed March 2017.
[4] *Nicotine without smoke: Tobacco harm reduction,* a report by the Tobacco Advisory Group of the UK Royal College of Physicians, April 2016
[5] Ramström L., Int. J. Environ. Res. Public Health 2016, 13(11), 1110

smoking, and at the same time taxed snus at a lower level than cigarettes.[7] In the latest Eurobarometer survey (March 2017),[6] Sweden boasted the lowest level of daily smoking prevalence by far in Europe (5%) while EU wide daily smoking prevalence is 24%. Snus has regained popularity in Sweden over cigarettes from 1970 and has consistently grown over time since then. While the overall daily consumption of tobacco (including snus) in Sweden is close to the daily consumption of the EU as a whole (25%), Sweden had the lowest level of lung cancer and COPD mortality (two diseases for which the main risk factor is smoking) in 2016 out of 10 comparable countries.[7] Tobacco as a risk factor for death in Sweden fell by 11.5% between 2005 and 2016, ranking 5th as a risk factor in 2016 as compared to 3rd in 2005.[9] In 2017, Sweden counted the most ex-smokers in the EU, at 41% compared to the EU average of 26%.[8] The Swedish experience with snus helps prove the concept that smokers can transition to non-combusted alternative nicotine delivery systems, with consequent decreases in smoking prevalence and the number of deaths associated with smoking.

C. A more recent innovation, e-cigarettes, is increasingly being recognized as also having the ability to drive down smoking prevalence.

"Changes in prevalence of e-cigarette use in England have been positively associated with the success rates of quit attempts."[8]

The UK government has recognised the potential role that e-cigarettes (and other novel products which expose users to less toxic chemicals) can have in reducing smoking prevalence, in its latest tobacco control strategy for England.[9] The government does not tax nor regulate e-cigarettes as strictly as cigarettes and the latest stop smoking campaign in England featured e-cigarettes as one of the ways to quit smoking. E-cigarettes have been positively associated with successful quit smoking attempts in England and smoking prevalence has fallen to 16% in 2017, the second lowest in the EU, after Sweden.[8] The latest evidence review of e-cigarettes undertaken by Public Health England (PHE), an agency of the UK Department of Health, concludes that quit smoking success rates in England are at the highest rates ever observed and that it is plausible that e-cigarettes are contributing to this. According to PHE, "the evidence suggests that [e-cigarettes] have contributed tens of thousands of additional quitters in England annually".[10]

D. The most recent evidence review by Public Health England (PHE) has reiterated that vaping is likely to carry a small fraction of the risk compared to smoking for users that switch completely.

"Vaping poses only a small fraction of the risks of smoking and switching completely from smoking to vaping conveys substantial health benefits over continued smoking. Based on current knowledge, stating that vaping is at least 95% less harmful than smoking remains a good way to communicate the large difference in relative risk unambiguously so that more smokers are

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[6] Eurobarometer, report 458, issued May 2017: March 2017 survey data.
[7] http://www.healthdata.org/sweden
[8] Beard E *et al*, BMJ 2016;354:i4645http://dx.doi.org/10.1136/bmj.i4645
[9] Towards a smokefree generation, A tobacco control plan for England, Department of health, July 2017.
[10] McNeill A, Brose LS, Calder R, Bauld L & Robson D (2018). Evidence review of e-cigarettes and heated tobacco products. A report commissioned by Public Health England. London: Public Health England.

encouraged to make the switch from smoking to vaping."[11] Public Health England, February 2018, based on their previous evidence review report published in 2015, and a review of all peer reviewed literature published since then as well as survey data and other government's databases and reports.

The PHE report is the result of one of the most extensive reviews of peer reviewed literature, surveys, reports and databases undertaken and by a highly respected public body.

The PHE Report also concluded:

- One assessment of the published data on emissions from cigarettes and e-cigarettes calculated the lifetime cancer risks. It concluded that the cancer potencies of e-cigarettes were largely under 0.5% of the risk of smoking.
- Comparative risks of cardiovascular disease and lung disease have not been quantified but are likely to be also substantially below the risks of smoking. Among e-cigarette users, two studies of biomarker data for acrolein, a potent respiratory irritant, found levels consistent with non-smoking levels.
- There have been some studies with adolescents suggesting respiratory symptoms among e-cigarette experimenters. However, small scale or uncontrolled switching studies from smoking to vaping have demonstrated respiratory improvements.

A report by the UK Royal College of Physicians also concluded that: "... **in the interests of public health it is important to promote the use of e-cigarettes, NRT** *(Nicotine Replacement Therapy)* **and other non-tobacco nicotine products** as widely as possible as a substitute for smoking in the UK."[12] There is a growing consensus that e-cigarettes expose users to much lower levels of toxic chemicals. One study that compared exposure to nicotine, tobacco-related carcinogens, and toxins among smokers of combustible cigarettes and former smokers with more than 6 months use of e-cigarettes, found that long-term e-cigarette–only use is associated with substantially reduced levels of measured carcinogens and toxins relative to smoking only combustible cigarettes. The authors also found no evidence that long-term e-cigarette–only use was associated with greater levels of carcinogens or toxins than NRT-only use.[13] Taking into account several parameters such as cessation, initiation and relative harm, a recent model estimated that switching cigarette smokers to e-cigarette use over a 10-year period would lead to 1.6 to 6.6 million fewer premature deaths in the US under a pessimistic and optimistic scenario respectively. [14]

E. **The emerging scientific evidence about Tobacco Heating Products (THP), also known Heat not Burn (HNB), is also pointing towards the potential for substantially reduced risk compared to cigarettes.**

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[11] McNeill A, Brose LS, Calder R, Bauld L & Robson D (2018). Evidence review of e-cigarettes and heated tobacco products. A report commissioned by Public Health England. London: Public Health England.

[12] *Nicotine without smoke: Tobacco harm reduction,* a report by the Tobacco Advisory Group of the UK Royal College of Physicians, April 2016.

[13] Shahab L. *et al.*, Annals of Internal Medicine, Vol. 166 No. 6, 21 March 2017

[14] Levy DT, et al. Tob Control 2018;27:18–25. doi:10.1136/tobaccocontrol-2017-0537S9

"It is likely that there is a reduction in overall risk to health for conventional smokers who switch to heat-not-burn tobacco products".[15] UK Committee on Toxicity, December 2017.

"The available evidence suggests that heated tobacco products may be considerably less harmful than tobacco cigarettes. "[13] Public health England, February 2018.

Given the understanding that it is the toxicants in cigarette smoke that cause most smoking-related diseases, THPs which remove burning tobacco and smoke from the equation and thereby reduce the number and levels of toxicants, should theoretically lead to a potentially reduced-risk product. Emerging evidence, assessed by PHE and the UK government's Committee on Toxicity seems to support this theory. The evidence base will continue to evolve but it is clear that THPs are yet another consumer acceptable option for current smokers to consume nicotine and at the same time avoid cigarette smoke.

F. **A ban on the use of all flavours will undermine the public health potential of new potentially reduced risk tobacco and nicotine products.**

Scientific research conducted so far suggests that flavours are not what attracts young people to e-cigarettes. For example, in a study by Shiffman et al., (2015)[16] teenagers were asked to rate their interest in using e-cigarettes on a scale of 0-10 and were offered a list of flavours. They reported minimal interest in flavours (average = 0.41 out of 10), much less so than adult smokers (1.73 out of 10), and their interest did not vary much across flavours.

This is supported by a study by Pepper et al., (2013)[17] which analysed whether adolescent males were willing to try e-cigarettes, and specifically looked at whether there was a difference in respondents' willingness to try plain versus flavoured varieties. The study found that "[t]*he same proportion of respondents were willing to try plain e-cigarettes or to try flavored e-cigarettes.*"

However, the availability of flavoured e-cigarettes can be important component for some smokers looking for an alternative to conventional cigarettes. This is further supported by a study by Farsalinos et al., (2013) which found that "[t]*he average score for importance of flavours variability in reducing or quitting smoking was 4 ("very important")*" and that "*the majority of participants stated that restricting variability of flavours would make the EC experience less enjoyable while almost half of them answered that it would increase craving for tobacco cigarettes and would make reducing or completely substituting smoking less likely.*" The study concluded that "*EC liquid flavourings play a major role in the overall experience of dedicated users and support the hypothesis that they are important contributors in reducing or eliminating smoking consumption.*"[18]

In short, research to date finds that flavours are an important part of the attraction for adults to switch from smoking to vaping but are a generally irrelevant consideration for teenagers.

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[15] Toxicological evaluation of novel heat-not-burn tobacco products – non-technical summary, UK Committee on Toxicology, December 2017.

[16] Shiffman et al., (2015) *The impact of flavor descriptors on non-smoking teens' and adult smokers' interest in electronic cigarettes*. Nicotine Tob Res 17(10)

[17] Pepper et al., (2013) *Adolescent Moles' Awareness of and Willingness to Try Electronic Cigarettes*, which found that flavours did not increase the attractiveness of e-cigarettes to teenagers.

[18] Farsalinos et al., (2013) *Impact of Flavour Variability on Electronic Cigarette Use Experience: An Internet Survey*

Public health experts have also confirmed the importance of maintaining the availability of flavoured products. For example:

- The ex-director of UK anti-smoking charity ASH UK, Clive Bates has stated that "[n]*on-users should understand that flavours are an important aspect of vaping and integral to the experience. They are also part of a migration away from tobacco. Initial switchers tend to favour tobacco flavours but gradually move on to non-tobacco flavours often as part of a permanent switch from smoking.*"[19]

- Jeff Stier, a Senior Fellow at the National Center for Public Policy Research in Washington DC, has also stated that: *"we're also beginning to see scientific data pointing to the benefits of flavours helping people not only quit smoking, but more importantly, stay off cigarettes.*" He further added that "[h]*umans learn by association. When we associate the pleasure of nicotine with the burnt tobacco, we think we like burnt tobacco. What flavors help us do is disassociate the pleasure of the nicotine with the burnt tobacco.* "[20]

G. Many specialists in the areas of tobacco control, nicotine science and public health policy are calling for balanced regulation of ANDS because of their potential to contribute to the reduction of smoking prevalence and the projected health impacts of tobacco consumption. Regulation should enable novel nicotine product innovations to enhance their ability to compete with cigarettes and drive down smoking prevalence.

"Armed with the recognition of the risk continuum, and the reality that all roads lead back to cigarettes as the primary cause of the current problem, we need to envision [...] a world where less harmful alternative forms, efficiently delivering satisfying levels of nicotine, are available for those adults who need or want them."[21] Dr Scott Gotlieb, FDA commissioner, July 2017

"There is a need for regulation to reduce direct and indirect adverse effects of e-cigarette use, but this regulation should not be allowed significantly to inhibit the development and use of harm-reduction products by smokers."[22] UK Royal College of Physicians, April 2016.

Given the potential public health benefit of ANDS, these products need a regulatory framework that is different from cigarettes and encourage smokers to switch, such as lower taxes, factual advertisement and a wider range of flavours. It is also important that a broad range of products is available to appeal to the range of different preferences of smokers. Regulation is critical to creating responsible growth and consumer access and awareness. Such regulation should be evidence based, proportionate, take account of the relative risks of products and not treat these products in the same way as combustible tobacco.

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[19] Counterfactual, February 2015. www.clivebates.com

[20] http://www.jeffstier.org/18998/q-a-defending-electronic-cigarettes-to-the-white

[21] Gottlieb S, Protecting American Families: Comprehensive Approach to Nicotine and Tobacco, July 2017.

[22] *Nicotine without smoke: Tobacco harm reduction,* a report by the Tobacco Advisory Group of the UK Royal College of Physicians, April 2016

BACKGROUND

Public Health England (PHE) is an executive agency of the UK Department of Health and Social Care. PHE is the expert national public health agency, providing scientific advice designed to promote the health and well-being of the nation. PHE, along with other public health authorities in the UK, continues to take leadership in the debate on e-cigarettes and has influenced the progressive UK policy regarding tobacco harm reduction and e-cigarettes. For example, the government's new Tobacco Control Plan for England includes a commitment to 'maximise the availability of safer alternatives to smoking'[1]

On 06 February 2018, PHE published an updated evidence report on e-cigarettes and tobacco heating products (THPs)[2]. This report updates a previous report from PHE in 2015[3]. PHE's 2015 study concluded that "The current expert estimate [is] that using [e-cigarettes] is around 95% safer than smoking." Since then, tobacco heating products have come to the market in the UK and the new report also provides evidence on this product type for the first time.

In October 2017, PHE announced that its annual government-sponsored stop smoking campaign, "Stoptober"[4], would support the use of e-cigarettes for the first time as an alternative to smoking. The campaign featured e-cigarettes in its TV adverts.

This 2018 evidence update is based on a comprehensive independent review of the published peer-reviewed scientific literature, survey data and other reports and databases made available since the publication of the last PHE review in January 2015, up until August 2017. It covers e-cigarette use among young people and adults, public attitudes, the impact of e-cigarettes on smoking prevalence, an update on risks to health and the role of nicotine, as well as a review of tobacco heating products. Key findings and quotations are set out below.

A. PHE report on relative risk of e-cigarettes when compared to smoking:

Key findings: Vaping poses only a small fraction of the risks of smoking and switching completely to e-cigarettes conveys substantial health benefits over continued smoking. E-cigarettes use is still considered at least 95% less harmful than smoking cigarettes and switching completely to e-cigarettes conveys substantial health benefits over smoking. Passive vaping has no identified health risks for bystanders.

Relevant quotes from the report:

"New studies did not demonstrate substantial new risks and thus did not change the conclusions of previous reviews that e-cigarettes were substantially less harmful than smoking".

"Vaping poses only a small fraction of the risks of smoking and switching completely from smoking to vaping conveys substantial health benefits over continued smoking. Based on current knowledge, stating that **vaping is at least 95% less harmful than smoking remains a good way to communicate the large**

[1] https://www.gov.uk/government/publications/towards-a-smoke-free-generation-tobacco-control-plan-for-england
[2] https://www.gov.uk/government/publications/e-cigarettes-and-heated-tobacco-products-evidence-review/evidence-review-of-e-cigarettes-and-heated-tobacco-products-2018-executive-summary and https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/679262/Evidence_review_of_e-cigarettes_and_heated_tobacco_products_2018.pdf
[3] https://www.gov.uk/government/news/e-cigarettes-around-95-less-harmful-than-tobacco-estimates-landmark-review
[4] https://www.nhs.uk/oneyou/stoptober/home?gclid=CjwKCAjwxo3OBRBpEiwAS7X62TMrdcX8YnoOh3G-4NQW_YzpdvFHuIaxADGfGEqBQvwPtuZIHz15nxoC4kAQAvD_BwE#cSBUXfe7hOpFHT5g.97

difference in relative risk unambiguously so that more smokers are encouraged to make the switch from smoking to vaping. It should be noted that **this does not mean e-cigarettes are safe.**"

"One assessment of the published data on emissions from cigarettes and e-cigarettes calculated the lifetime cancer risks. It concluded that **the cancer potencies of e-cigarettes were largely under 0.5% of the risk of smoking.**"

"To date, there is **no clear evidence that specific flavourings pose health risks** but there are suggestions that inhalation of some could be a source of preventable risks."

"To date there have been **no identified health risks of passive vaping to bystanders.**"

B. PHE report on nicotine safety

Key findings: Nicotine plays a very minor role in the harmfulness of tobacco smoking. Misperceptions on the relative risks of nicotine and tobacco need to be addressed to encourage more switching from smoking to less harmful nicotine delivery systems.

Relevant quotes from the report:

"Overall, there is evidence that nicotine plays a very minor role in the harmfulness of tobacco smoking. The risk profile may be different with inhaled nicotine but this would appear unlikely."

"While nicotine has effects on physiological systems that could theoretically lead to health harms, at systemic concentrations experienced by smokers and e-cigarette users, long-term use of nicotine by 'snus' (a low nitrosamine form of smokeless tobacco) users has not been found to increase the risk of serious health problems in adults, and use of nicotine replacement therapy by pregnant smokers has not been found to increase risk to the foetus."

"**Perceived relative harm of e-cigarettes compared with cigarettes has continued to increase**; less than half of adults in Great Britain think e-cigarettes are less harmful than smoking."

"Widespread misperceptions about the relative risks of nicotine and tobacco need to be addressed and corrected."

"Policies on tobacco and e-cigarettes should have at their core the recognition that nicotine use *per se* presents minimal risk of serious harm to physical health and that its addictiveness depends on how it is administered."

"As e-cigarettes have evolved, their nicotine delivery has improved. This could mean that their addiction potential has increased, but this may also make them more attractive to smokers as a replacement for smoking. It is not yet clear how addictive e-cigarettes are, or could be, relative to tobacco cigarettes."

C. PHE report on e-cigarettes use in youth and gateway effect.

Key findings: E-cigarettes are attracting very few young people who have never smoked into regular use; and e-cigarettes do not appear to be undermining the long-term decline in cigarette smoking in the UK among young people.

Based on surveys by credible independent tobacco control organizations in the UK, e-cigarettes use in young never-smokers remains very low, while cigarette smoking in youth keeps declining. No causal links between

e-cigarette use and subsequent cigarette trial or subsequent progression to regular smoking has been established (no reliable evidence of a gateway effect).

Relevant quotes from the report:

"the main factor which challenges the 'vaping leads to smoking' hypothesis is what is happening with rates of youth tobacco cigarette use in the UK (and indeed in North America where the other studies were conducted). During the period when surveys show that young people are experimenting with EC, including some non-smokers, tobacco cigarette smoking rates have continued to decline. "

"If EC use was causing smoking at the population level, these reductions in youth cigarette smoking [in the UK] would have significantly slowed or indeed reversed in the UK. This is not happening, and suggests that EC are not currently undermining what decades of efforts to prevent youth smoking uptake have achieved.

"Despite some experimentation with these devices among never smokers, **e-cigarettes are attracting very few young people who have never smoked into regular use.**"

"E-cigarettes do not appear to be undermining the long-term decline in cigarette smoking in the UK among young people."

"Never smokers in the UK who try EC are more likely to have tried smoking subsequently than those who have not tried EC. A causal link has not been established and neither has progression to regular smoking. The 'common liability' hypothesis seems a plausible explanation for the relationship between EC and smoking experimentation. "

D. PHE report on e-cigarettes as a positive contribution to the tobacco control objective of reducing smoking prevalence

Key findings: Evidence suggests that e-cigarettes have contributed to the recent accelerated decline in smoking in the U.K. Health professionals should provide behavioural support to smokers who want to use an e-cigarette to help them quit smoking.

Relevant quotes from the report:

"In the first half of 2017, **quit success rates in England were at their highest rates so far observed and for the first time, parity across different socioeconomic groups was observed.** It is plausible that e-cigarettes have contributed to this."

"Recent estimates of additional quitters resulting annually from the availability of e-cigarettes, using the same dataset but two different methods, resulted in similar figures within the range of 16,000-22,000. [...] While caution is needed with these figures, **the evidence suggests that e-cigarettes have contributed tens of thousands of additional quitters in England.**"

"EC use alone or in combination with licensed medication and behavioural support from a Stop Smoking Service, appear to be helpful in the short term. However, fewer smokers use an EC as part of a quit attempt with a Stop Smoking Service compared with licensed medication. If ECs are contributing to higher success rates, Stop Smoking Services in England may be missing an opportunity to maximise cessation outcomes for smokers who use their service."

"Stop smoking practitioners and health professionals should provide behavioural support to smokers who want to use an e-cigarette to help them quit smoking."

E. PHE report on e-cigarette growth having plateaued and consumers misperceptions about the relative risks of e-cigarettes and nicotine compared to tobacco

Key Findings:

- The growth of e-cigarette usage in the UK has recently slowed.
- There are widespread misperceptions about the relative risks of e-cigarettes and nicotine compared to tobacco which need to be addressed and corrected.
- The EU Tobacco Products Directive requires health warnings for e-cigarettes which may be causing consumers to over-estimate their health risks. It further prevents consumer information regarding the reduced risk characteristics of e-cigarettes compared to smoking on packaging. Consideration should be given to reviewing the Directive to address these issues.

Relevant quotes from the report:

"The consequences of this inaccurate or inadequate reporting [of scientific studies] are that the general public is misled. This could induce smokers to carry on smoking rather than switching and EC users to relapse to smoking."

"Misperceptions of nicotine and different nicotine-containing products need to be addressed. These have deteriorated further since the 2015 PHE report in 2015 which called for clear and accurate information on relative harms."

"**Restrictions on communicating relative risks of e-cigarettes in comparison with combustible tobacco should be reconsidered.** In any future review of the EU Tobacco Products Directive, consideration should be given to the wording of the health warning on nicotine *per se* given public misperceptions of its **harmfulness.**"

"Clear messages, based on current evidence about nicotine, its relationship with harms, and its addictiveness, compared with smoking, are necessary and could have a marked impact on public health."

"It would be tragic if thousands of smokers who could quit with the help of an e-cigarette are being put off due to false fears about their safety."[7]

F. PHE Report on Pricing

Key findings: E-cigarettes are available in a wide range of prices in the marketplace and affordable to a range of e-cigarettes users. E-cigarettes should remain affordable to encourage smokers to switch and quit smoking.

Relevant quotes from the report:

"**Any changes in the pricing need to ensure that e-cigarettes are affordable to smokers** to avoid discouraging smokers from switching away from smoked tobacco which could be counterproductive in public health terms. There should therefore be a competitive advantage for the prices of e-cigarettes to combustible tobacco products."

G. PHE Report on Heated Tobacco Products

Key findings: Tobacco smoke, not nicotine is what causes harm to smokers and therefore where nicotine can be delivered without tobacco smoke there is potential to minimise harm. THPs may be considerably less harmful compared to combustible cigarettes, but more research is needed. Less harmful alternatives to combustible cigarettes should have more favourable regulatory treatment.

Relevant quotes from the report:

"The available evidence suggests that heated tobacco products may be considerably less harmful than tobacco cigarettes and more harmful than e-cigarettes. "

"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 found varies between studies."

"Depending on emerging evidence on their relative risk compared to combustible tobacco and e-cigarettes, regulatory levers such as taxation and accessibility restrictions should be applied to favour the least harmful options alongside continued efforts to encourage and support complete cessation of tobacco use".

Note: *PHE highlights that more independent research is needed on THPs. An updated review on THP is in preparation and will be published by PHE in the future.*

H. **Statements by PHE officials in the press on health services and role of e-cigarettes**

The PHE press release and related interviews by the Public Health England officials used the report to advocate that:

- Hospitals should sell e-cigarettes and provide patients with vaping lounges
- Patients should be allowed to vape in private rooms and purchase e-cigarette devices in hospital shops to help stop them smoking regular cigarettes.
- Government officials should also help manufacturers license e-cigarettes as medical quitting aids so as to allow NHS (UK National Health Service) GPs (General Practitioners) to prescribe the devices to patients trying to stop smoking.

Relevant quotes in the press

"There are two parts to being a smoke-free hospital, one is not allowing smoking on the premises, the other is helping every smoker to quit.....There is no reason why a hospital shouldn't designate some indoor areas where patients and visitors can vape." [5,6]

"Every minute someone is admitted to hospital from smoking, with around 79,000 deaths a year in England alone. Our new review reinforces the finding that vaping is a fraction of the risk of smoking, at least 95% less harmful, and of negligible risk to bystanders. Yet over half of smokers either falsely believe that vaping is as harmful as smoking or just don't know. It would be tragic if thousands of smokers who could quit with the help of an e-cigarette are being put off due to false fears about their safety."[7]

Note: *BAT can reference the above statements from PHE and its officials but should not present them as BAT's position.*

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[5] http://www.telegraph.co.uk/news/2018/02/06/nhs-patients-should-allowed-vape-indoors-even-beds/
[6] http://www.bbc.co.uk/news/health-42950607
[7] https://www.gov.uk/government/news/phe-publishes-independent-expert-e-cigarettes-evidence-review.

The following list contains the classification decisions (other than those subject to a reservation) taken by the Harmonized System Committee (**60th Session – October 2017**) on specific products, together with their related Harmonized System code numbers and, in certain cases, the classification rationale.

Advice

Parties seeking to import or export merchandise covered by a decision are advised to verify the implementation of the decision by the importing or exporting country, as the case may be.

No	Product description	Classification	HS codes considered	Classification rationale
1.	Blanched green shell mussels. The product is obtained by subjecting green shell mussels which have been partially shelled (half-shell) to a blanching/ thermal treatment process in order to open the shell . The partially shelled (half shell) is then frozen and packed. The retail package is labelled "Cook before consumption"	0307.32	03.07 and 16.04	GIRs 1 and 6.
2.	Quinoa, normally used for human consumption, which has undergone the removal of the saponin layer after harvest. The saponin layer is removed by washing, mechanical processing or by a combination of both. However, the shape of quinoa which has undergone washing or mechanical processing is not different from that of the original grain. Accordingly, the method used to remove the saponin layer is not discernible solely by the shape of the quinoa grain.	1008.50	10.08 and 11.04	GIRs 1 and 6
3.	Powder of konjac tuber consisting of 87.5 % by weight of glucomannan, 8.9 % by weight of moisture, and 1.6 % by weight of ash.	1212.99	12.12 and 13.02	GIRs 1 and 6
4.	The product is refined and modified fish oil from anchovies, with vitamin E (tocopherol) added as an antioxidant. The oil is highly concentrated omega-3 fatty acids EPA (eicosapentaenoic acid) and DHA (docosahexaenoic) bound in the form of triglycerides (400 mg/g of product and 300 mg/g of product, respectively). The triglycerides constitute 90 % of the product, and the remaining 10 % of the ingredients consists mainly of mono- and diglycerides. The product is exported in barrels and will be used in the manufacture of food supplements.	1516.10	15.04, 15.16 and 21.06	GIRs 1 and 6

No	Product description	Classification	HS codes considered	Classification rationale
5.	Composite meal, frozen and put up in a cardboard box (Box 1). Inside Box 1, in addition to jasmine rice, there is another cardboard box (Box 2). The jasmine rice is filled directly into Box 1 without any further packing. Box 2 sits on top of the portion of rice inside Box 1. Box 2 contains slices of chicken meat, vegetables and a red curry sauce. Before consumption, the meal must be reheated - still in the cardboard boxes - in a microwave oven. The total net weight of the meal is 350 grams.	1904.90	16.02 and 19.04	GIRs 1, 3 (b) and 6.
6.	Roasted laver (Yakinori) – dried green laver (100 %) for wrapping rice. The manufacturing process includes : washing the cultured green laver; cutting the green laver into rectangular sheets (size 19 cm x 21 cm) using a cutting machine; drying; roasting; inspection and packing.	2008.99	20.08 and 21.06	GIRs 1 and 6.
7.	Roasted seaweed – dried seaweed (100 %) for wrapping rice. Manufacturing process : the dried seaweed must be inspected using a metal detector and an impurities detector, before being placed in a roasting machine and then packed.	2008.99	20.08 and 21.06	GIRs 1 and 6.
8.	Seasoned laver – laver (90 %), corn oil (6 %),sesame oil (3 %) and salt (1 %). The manufacturing process includes : freezing the laver at a temperature of -18 °C; roasting the laver at a temperature of 180 °C – 200 °C for 5 seconds; seasoning the laver by adding salt, sesame oil and corn oil (during the process, green tea powder, kimchi powder or olive oil may be added to enhance the taste); reroasting the laver at a temperature of 330 °C for 5 seconds.	2008.99	20.08 and 21.06	GIRs 1 and 6.

No	Product description	Classification	HS codes considered	Classification rationale
9.	Mixture of 50 % by weight of dried basil (Ocimum basilicum) and 50 % by weight of dried wild marjoram (Origanum vulgare). The product is put up in a plastic bag for retail sale, containing 5 grams. It is intended to be used as a seasoning for sauces.	2103.90	21.03 and 21.06	GIRs 1 and 6.
10.	"Crab Flavour", is a free-flowing yellow-orange powder. It consists of various odoriferous substances (natural aromatics, identical to natural aromatics, and aromatic preparations), carriers, food additives, dyes and fats. It is an ingredient to be used in the manufacture of a flavouring preparation ("Crab Flavour"), which is subsequently utilised in the manufacture of snacks (crisps, crackers). The product is presented in polyethylene containers of 25 kg.	2103.90	21.03 and 21.06	GIRs 1 and 6.
11.	This product is based on fish oil from anchovies, and consists of fatty acids in ethyl ester form (enriched in omega-3 fatty acids EPA and DHA). Furthermore, vitamin E (tocopherol) has been added to the product as an antioxidant. The product is exported in barrels and will be used in the manufacture of food supplements.	2106.90	15.04, 15.16 and 21.06	GIRs 1 and 6
12.	Tobacco capsule, for use with a specialized device consisting of a "cartridge" and "battery	2403.99	24.03	GIRs 1 and 6

No	Product description	Classification	HS codes considered	Classification rationale
13.	Silica fume, also called "Microsilica®", is an amorphous silica polymorph. The product is composed of ultrafine amorphous silicon dioxide (≥ 80 % by weight) particles formed as a by-product during the manufacture of silicon or ferrosilicon alloys. Silica fume is formed when silicon monoxide, emitted as the quartz reduces, mixes with oxygen. The main impurities include carbon, silicon, silicon carbide and oxides of alkaline (earth) metals. As silica fume generated from raw materials which vary in composition depending on the source, the concentration of individual impurities in silica fume will vary up to a maximum of 5 % by weight. The total amount of the impurities will not exceed 20 % by weight. Silica fume is a very effective pozzolanic material used as an additive to Portland cement concrete to improve its properties, in particular its compressive strength, bond strength, and abrasion resistance.	2811.22	26.21 and 28.11	GIR 1(Note 1a to Chapter 28) and 6
14.	Two products called "casimersen (INN) and "golodirsen (INN).	2934.99	29.34 and 39.11	GIRs 1 and 6
15.	Nicotinic acid ("niacin"), also known as vitamin B_3, is an organic compound with the formula $C_6H_5NO_2$ and, depending on the definition used, one of the 20 to 80 essential human nutrients. This colourless, water-soluble solid is a derivative of pyridine, with a carboxyl group (COOH) at the 3-position.	2936.29	2936.24 and 2936.29	GIRs 1 and 6
16.	Nicotinamide ("niacinamide"), is another form of vitamin B3 where the carboxyl group has been replaced by a carboxamide group (CONH2). Nicotinic acid and nicotinamide are convertible to each other.	2936.29	2936.24 and 2936.29	GIRs 1 and 6.

No	Product description	Classification	HS codes considered	Classification rationale
17.	The product is a white coloured cream enclosed in a plastic bottle. Accompanying documentation provided indicates that it is a mild cleansing/moisturizing product to wash the entire face and neck, moisturize the skin and then to be rinsed off with water. The stated surfactant components are disodium cocoamphodiacetate and PEG-100 stearate.	3401.30	33.04 and 34.01	GIRs 1 and 6
18.	The product is a clear brown coloured gel with brown grains that is enclosed in a plastic bottle labelled in part, "Nu skin liquid body lufra, 250 ml, Manufactured in the U.S.A." The accompanying documentation provided indicates that it is a mild, soap-free cleansing/exfoliator product to wash the face and body, exfoliate the skin and then to be rinsed off with water. In addition to containing finely ground walnut husks, the stated surfactant components are sodium C14-16 olefin sulfonate, ammonium laureth sulfate, cocamidopropyl betaine, sodium methyl oleoyl taurate, and PEG/PPG-18/18 dimethicone.	3401.30	33.04 and 34.01	GIRs 1 and 6
19.	Paddle used for kayaking and with Stand Up Paddle (SUP) Boards, consisting of a 3 piece, break-apart paddle made of plastics, with adjustable height and shaped handle. It has an additional paddle blade that can be snapped-on instead of the removable T-handle, converting the SUP paddle into a kayak paddle. The angled shape and size of the blade is indicated to provide better and longer stroke than a regular kayak paddle..	3926.90	39.26 and 95.06	GIRs 1and 6

No	Product description	Classification	HS codes considered	Classification rationale
20.	A cover made of plastics and specifically designed for smartphones. The cover" has a magnet that interlocks with a built-in Hall Integrated Circuit in the front part of the smartphone. The magnet senses whether the cover is open or closed and allows the cover to perform the User Interface. A transparent window on the front of the cover provides the ability to respond to incoming calls and check messages without opening the cover	4202.32	39.26 and 42.02.	GIR 1 and 6
21.	Footwear made of plastics known as "sandals for adults" and "sandals for children". The footwear in question consists of outer soles and uppers of plastics; assembled by the injection moulding process; the upper does not cover the toe, heel and/or ankle but covers the whole foot area. The upper is neither fixed to the sole nor assembled by stitching, riveting, nailing, screwing, plugging or similar processes, hence there are no holes in the outer sole part which may cause penetration of water to the foot.	6402.99	64.01 and 64.02	GIR 1and 6
22.	The products are shower enclosure : aluminium framed, and chrome corner entry enclosures with glass doors not exceeding 6mm thick, chrome polished finish, chrome aluminium profile, plastic grey wheels and plastic connection parts, plastic handle, magnetic strips and rubber seal, compensation channel for easy wall mounting, on all sides and tempered Superior gliding system. The dimensions are size : 900 mm x 900 mm; height 1850 mm No shower tray and the second product have a superior gliding system, neat chrome finish. width : 900 mm x 900 mm; height : 1850 mm; door glass: 5 mm thick, tempered safety glass and no shower tray.	7020.00	70.07, 70.20 and 76.10	GIR 1 and 3 (b).

No	Product description	Classification	HS codes considered	Classification rationale
23.	Glass shower enclosures with square hinge frameless enclosure with 8 mm tempered safety glass; chrome stabilizing arms, superior brass hinged pivot system, algae-resistant magnetic latex seals and, neat chrome finish; door width : 900 mm; panel width : 900 mm; height : 1850 mm; door width : 900 mm; panel width : 900 mm; height : 1850 mm; door glass : 8 mm thick, tempered glass; panel glass : 8 mm thick, tempered glass. No shower tray.	7020.00.	70.07, 7020 and 76.10	GIR 1
24.	The manganese-aluminium briquettes consist of compacted metal powder in the form of grey cylinders, tablets, pillow block briquettes, or other similar compressed solids (collectively, "briquettes"). They consist 75–95% of pure manganese powder, 5–25 % of pure aluminium powder, up to 1 % of a surfactant in the form of an oil hydrocarbon, and, upon individual customer request, up to 1 % of a fluxing agent in the form of, e.g., aluminium inorganic salts. The briquettes are used to produce certain aluminium alloys in particular those of the 3000 series in which manganese is the chief alloying element.	8111.00	38.24 and 81.11	GIRs 1 (Notes 3 and 7 to Section XV)

No	Product description	Classification	HS codes considered	Classification rationale
25.	Chromium-aluminium briquettes are compacted metal powder in the form of grey cylinders, tablets, pillow block briquettes, or other similar compressed solids (collectively, "briquettes"). They consist 75–90 % of 99 % pure chromium powder, 10–25 % of pure aluminium powder, up to 1 % of a surfactant in the form of an oil hydrocarbon, and, upon individual customer request, up to 1 % of a fluxing agent in the form of, e.g., aluminium inorganic salts, potassium fluoroaluminate, potassium fluorosilicate, or potassium fluorotitanate. The briquettes are used to produce certain aluminium alloys, specifically those of the 7000 series in which chromium is an alloying element.	8112.29	38.24 and 81.12	GIRs 1 (Notes 3 and 7 to Section XV) and 6.
26.	Horizontal Laminar Flow Clean Bench : made of steel and designed for a variety of industries and applications, such as intravenous (IV) admixture preparation, drug compounding, plant cell culture, media preparations, pharmaceutical procedures, electronic assembly and limited experimental research. It is used to protect only the product and not the operator or the environment. It comes equipped with a blower/motor system, motor speed controller, HEPA supply filter with removable screen, washable, re-useable pre-filter, and fluorescent lamps for the work surface.	8414.80	84.14 and 84.21	GIRs 1 and 6.
27.	Vegetable cutter, weighing 7.5 kg equipped with a 220 V electric motor, designed for cutting vegetables in different types of cut, slice, grated and shred, by interchangeable blades. The machine consists of body covers, stand frame, handle and slicing blade mounted on a slicing cabinet with motor. The slicing capacity for cabbages is 90 kg per hour by using dual-blade disk slicer.	8438.60	84.38 and 85.09	GIRs 1 and 6.

No	Product description	Classification	HS codes considered	Classification rationale
28.	Vegetable Cutter, weighing 5 kg equipped with a 220 V electric motor, designed for slicing vegetables into coarse, medium and fine pieces. The machine is compact with a weight of 5kg. This machine consists of a blade kit with coarseness adjusting plates and a motor. Its slicing capacity for cabbages is 120-200 kg per hour (2.0 - 3.6 kg per minute).	8438.60	84.38 and 85.09	GIRs 1 and 6
29.	The product is an electronic interactive whiteboard ("Smart Board"), size 78 inches, consisting of a touch-sensitive, dry-erase surface with multi-touch functionality, which accepts touch input from a pen or a finger. The whiteboard features integrated speakers. The product is generally delivered complete with two pens, device driver software and a user guide. The interactive whiteboard can serve as a surface to display the screen of an ADP machine, projected by the video projector. It is able to accept or deliver data in a form which can be used by the ADP machine.	8471.60	84.71 and 90.17	GIRs 1(Note 5 (C) to Chapter 84) and 6.
30.	Finished inner ring for a flanged tapered roller bearing (internal diameter : 54 mm).	8482.99	84.82 and 87.08	GIRs 1 (Note 2 (b) to Section XVI) and 6.
31.	Packaged insulated gate bipolar transistor (IGBT) module consisting of 6 switches in parallel connection with the IGBT and Free Wheeling Diode (FWD), and 3 NTC (Negative Temperature Coefficient) Thermistors. The module is used inside of an inverter of hybrid, electric or fuel cell vehicles to convert DC power to AC power.	8504.40	85.04 and 85.36	GIRs 1 (Note 2 (a) to Section XVI) and 6

No	Product description	Classification	HS codes considered	Classification rationale
32.	Future book set", consisting of four components, packaged together in a paperboard box for retail sale : - Two "Future Books"(a Reading and a "Play Book"), which essentially are printed books of paper material without any electric elements such as the electric circuit inside. - A "Future Book Pad" which actually is a book-shaped plastic pad made to fit the size and shape of "the Future Book". The Pad incorporates a loudspeaker, an electronic film which represents coordinates, a printed circuit assembly, a socket for sound pack and a battery. Users unfold the pad. - A "sound pack" which is a storage device having a capacity of 128 MB. It stores audio content of the book. The sound pack is to be inserted into the socket of the "Future Book Pad", which reproduces the audio content stored in the sound pack. --An Emission Pen used for pointing and indicating a specific spot on the book.	8519.81	49.01, 85.19, 85.23 and 95.03	GIRs 1, 3 (b) and 6.
33.	Colour monitor, comprising of a 27-inch flat-panel display. It is capable of directly connecting to an ADP machine via one VGA or two HDMI connectors. This monitor does not include a channel selector, a video tuner or speakers.	8528.52	85.28	GIRs 1 and 6
34.	Colour monitor, comprising of a 32-inch flat-panel display. It is capable of directly connecting to an ADP machine via two HDMI, three USB 2.0, or one Display Port 1.2 connector. This monitor does not include a channel selector, a video tuner or speakers	8528.52	8528.52 and 8528.59	GIRs 1 and 6
35.	Colour monitor, comprising of a 55-inch (138.78 cm) flat-panel display. It is capable of directly connecting to an ADP machine via the following connectors : one HDMI, one DVI-D, one VGA, one YPbPr, one USB 2.0, one RJ-45 (Ethernet), an infrared (IR) input/output jack and an audio input/output jack.	8528.52	8528.52 and 8528.59	GIRs 1 and 6

No	Product description	Classification	HS codes considered	Classification rationale
36.	Thin-film Solar Module (dimensions : L x W x H : 1409 x 1009 x 46 mm). The front of the module, fitted with an anodized aluminium alloy frame with low iron non- tempered glass, contains 630 photovoltaic cells arranged in 14 strings of 45 photovoltaic solar cells which are connected in series. These strings are connected in parallel and have two terminals of polarity (+) and (-). A junction box (dimensions : L x W x H : 74 x 74 x 18 mm) is attached to the rear of the module. Inside the junction box is one bypass diode, to protect the cells. Two connection "solar cables" (double insulation, protection of UV, water, temperature and ozone) of a length of 900 mm and having "solar connectors" are also connected to the terminals of the strings inside the junction box.	8541.40	85.01 and 85.41	GIR 1 (Note 2 to Chapter 85) and 6.
37.	IC checking instrument, the instrument is used to check and analyze IC. The internal software system of the instrument writes the checking program before the IC to be measured is placed. Then the output data including wave, frequency, voltage, current, etc, is collected. At the same time, this instrument can also check wafers by changing the connecting parts.	9030.82	9030.82 and 9030.90	GIR 1 and 6
38.	A set containing three cans of modelling compound in different colours, head with ears, electric drill, tweezers, dentist tool, mirror or braces roller and toothbrush presser, made of plastics.	9503.00	34.07 and 95.03	GIR 1 and 3 (b)
39.	A set containing five cans of modelling compound in different colours; 4 cutters to create circle, square, star, and heart-shaped cookies, a textured rolling pin and an extruder, made of plastics.	9503.00	34.07 and 95.03	GIR 1 and 3 (b)
40.	Stand Up Paddleboard (SUP) with Medium Density Expanded Polystyrene (EPS) core, wood reinforcement and glass.	9506.29	95.06	GIRs 1 and 6

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TAXATION AND CUSTOMS UNION
Customs Policy, Legislation, Tariff
Combined Nomenclature, Tariff Classification, TARIC and integration of trade measures

Brussels, 7 November 2017
TAXUD/A4/AB/akn
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CUSTOMS CODE COMMITTEE

TARIFF AND STATISTICAL NOMENCLATURE SECTION

Summary Report of the 182nd meeting of the Customs Code Committee

(SUB-SECTION AGRICULTURE/CHEMISTRY)

http://ec.europa.eu/transparency/regcomitology/index_en.htm

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Customs Code Committee
Tariff and Statistical Nomenclature Section
(SUB-SECTION AGRICULTURE/CHEMISTRY)

Summary Report of the 182nd meeting of the Customs Code Committee held in Brussels from 16th to 17th October 2017

AGENDA

1. **Approval of the agenda of the 182nd meeting of the Customs Code Committee.**
2. **Adoption of the minutes of the 179th meeting of the Customs Code Committee.**
3. **Measures referred to in Article 57(4) of Regulation (EU) No. 952/2013 (draft Commission Implementing Regulations) submitted to the Committee for an opinion, in accordance with the examination procedure referred to in Article 285(4) of Regulation (EU) No. 952/2013.**

3.1 Draft Commission Implementing Regulation amending Commission Implementing Regulation (EU) No 211/2012 concerning the classification of certain goods in the Combined Nomenclature, TAXUD/2613261/2017.

4. **Measures referred to in Article 9(1)(e) of Regulation (EEC) No. 2658/87 (draft Commission Implementing Regulations) submitted to the Committee for an opinion, in accordance with the examination procedure referred to in Article 10 of Regulation (EEC) No. 2658/87.**

4.1 Draft Commission Implementing Regulation amending Additional note 2(f) to Chapter 27 of the Combined Nomenclature, TAXUD/1254095/2017-REV 1.

4.2 Draft Commission Implementing Regulation amending Additional note 10 to Chapter 22 of the Combined Nomenclature, TAXUD/2613244/2017.

5. **Decisions referred to in Article 34(11) of Regulation (EU) No. 952/2013 (draft Commission Implementing Decisions) submitted to the Committee for an opinion, in accordance with the advisory procedure referred to in Article 285(2) of Regulation (EU) No. 952/2013.**

   (none)

6. **Explanatory Notes referred to in Article 9(1)(a) of Regulation (EEC) No. 2658/87 (draft Explanatory Notes to the Combined Nomenclature) submitted to the Committee for an opinion, in accordance with the examination procedure referred to in Article 10 of Regulation (EEC) No. 2658/87.**

6.1 *Draft Commission Proposal for an amendment of the Explanatory Notes to the Combined Nomenclature (subheadings 2710 19 11 to 2710 19 29), TAXUD/2613182/2017.*

6.2 *Draft Commission Proposal for an amendment of the Explanatory Notes to the Combined Nomenclature (subheading 2306 50 00), TAXUD/2613222/2017.*

7. Items submitted to the Committee for discussion under Articles 34 and 57 of Regulation (EU) No. 952/2013 or under Article 8 of Regulation (EEC) No. 2658/87.

7.1. *Tariff classification of reishi mushroom powder, TAXUD/2613335/2017.*

7.2. *Tariff classification of guarana seeds, TAXUD/2613300/2017.*

7.3. *Tariff classification of a masterbatch of essential oils in encapsulated dispersions of ethylene-vinyl acetate (EVA) or low density polyethylene (LDPE) containing not more than 12 % of essential oils and sodium benzoate, TAXUD/3751174/2017.*

7.4. *Tariff classification of brown fused alumina slag, TAXUD/2613347/2017.*

7.5. *Possible creation of a new Additional note 14 to Chapter 22, TAXUD/2613308/2017.*

7.6. *Tariff classification of Konjac sponges, TAXUD/2613278/2017.*

7.7. *Possible creation of a new Additional note 5 to Chapter 15, TAXUD/2613284/2017.*

7.8. *Tariff classification of encapsulated products containing colostrum, TAXUD/2613361/2017.*

7.9. *Tariff classification of inulin syrup, TAXUD/3751132/2017.*

7.10. *Tariff classification of special sugars, TAXUD/3751234/2017.*

7.11. *Tariff classification of anti-freezing preparations and similar products of Chapter 38, TAXUD/3751249/2017.*

7.12. *Possible amendment of the Combined Nomenclature Explanatory Note to heading 2309 ("analytical methods"), TAXUD/3751297/2017.*

8. Any other business.

8.1. *List of pending cases - files to be closed.*

8.2. *Results of the Project Group concerning the chemical chapters of HS/CN from 9th to 10th October 2017.*

8.3. *Information on the file regarding the tariff classification of novel tobacco products ('heat-not-burn').*

ANNEXES:

I	Attendance list
II-V	Draft measures

1. **Approval of the agenda of the 182nd meeting of the Customs Code Committee.**

All Member States were represented for the votes (see the attendance list in Annex I to these minutes).

The Chair thanked the Member States for the cooperation as regards their opinion by written procedure (Article 3(5) of Regulation (EU) No 182/2011 and Article 9 of the Rules of Procedure for the Customs Code Committee) on one measure, with the vote taking place on 04/09/2017. The measure has been published on 28/09/2017. As regards two other draft measures, Member States have requested the matters in question to be examined at a forthcoming Committee meeting. The written procedures for those drafts have therefore terminated without result. The related measures are to be found under items 4.1 and 6.2 of the current agenda.

One item was added to the agenda under AOB: item 8.4 "Tariff classification of an eczema cream".

The agenda was then approved by the participants.

2. **Adoption of the minutes of the 179th meeting of the Customs Code Committee.**

One Member State made the following comment:

Item 7.6 (Tariff classification of a product named "potty liner"):

This Member State confirmed its disagreement with the conclusion of the last Customs Code Committee to classify such a product under heading 9619. It does not regard the "potty liner" as similar to the products of this heading and wondered whether a classification regulation would be necessary. He noted there are still divergences (in particular concerning a product described as "dog pads"). The issue is about whether a product that is actually not worn next to the skin should be classified under heading 9619. This Member State cannot accept classification in heading 9619 as it sees a discrepancy with the wording of the HSEN.

Another Member State said that it does not have more detailed information on this issue. Some Member States are not fully agreeing with the classification and not all BTIs have been revoked yet.

The Chair said that there is a multitude of products covered by heading 9619. The product described by the asking Member State is not covered by the case "potty liner" and therefore the "dog pads" would qualify for a new case. The Chair recommended to this Member State to revisit this specific question. If necessary, a new submission may be presented if divergent views persist. DG TAXUD will reflect internally how to proceed.

A second Member State made the following comment:

Item 7.11 (Tariff classification of brown fused alumina slag):

This Member State has some additional remarks and would welcome the inclusion of the following arguments in the report.

The current text reads as follows:

"The Member State having issued the other BTI considered its classification under heading 2620 justified due to the high iron content of the product, because it is

constituted of different ferro-metallic combinations and because this product is not directly coming from the iron industry."

This Member State wishes to emphasize that its delegation – during its intervention – has tried to explain that it has not classified this product to Chapter 26 solely based on the high content of iron, but due to the fact that brown fused alumina slag is:

- a residue;
- a result of the production of fused aluminium oxide (fused alumina) from bauxite (aluminium ore);
- according to the information provided the product does not seem to be used as an additive in the manufacture of other alloys or as de-oxidant, de-sulphurising agent or for similar uses in ferrous metallurgy and generally is not usefully malleable;
- the product meets the description of heading 2620 as it contains slag, ash and residues (other than from the manufacture of iron or steel), containing metals, arsenic or their compounds;
- the product meets the provisions of Note 3 (a) to Chapter 26;
- this product has not been excluded from heading 2620.

A third Member State made the following comment:

Item 7.10 (Tariff classification of products with a high alcohol content):

It is stated in the Minutes that this Member State "indicated that they as well could not support draft 2) and suggested to make use of a quantitative limit / threshold". Actually the delegation said that the previous proposal defining the scope of HS subheading 2207 20 was much more helpful than the current one defining the scope of headings 3814 and 3820, because with ethanol mixtures one might even end up in heading 3824. Finally the delegation concluded by saying that the submitted proposal is better than doing nothing. During the round of the table the delegation supported the proposal.

Furthermore, the delegation strongly opposed Regulation (EU) No 211/2012 and asked how recital number (4) in the proposed Regulation creating a new Additional Note 1 to Chapter 38 ("Denaturing is usually achieved with small quantities of denaturants") goes together with this regulation classifying mixture of ethanol and 30 % of gasoline as denatured alcohol.

The remaining items of the minutes were adopted as read.

3. **Measures referred to in Article 57(4) of Regulation (EU) No. 952/2013 (draft Commission Implementing Regulations) submitted to the Committee for an opinion, in accordance with the examination procedure referred to in Article 285(4) of Regulation (EU) No. 952/2013.**

3.1 *Draft Commission Implementing Regulation amending Commission Implementing Regulation (EU) No 211/2012 concerning the classification of certain goods in the Combined Nomenclature, TAXUD/2613261/2017.*

The Committee examined an amendment of Commission Implementing Regulation (EU) No 211/2012 in order to clarify the classification of denatured alcohol of CN code 2207 20 00.

The Committee delivered a positive opinion on the draft measure as set out in Annex II.

4. **Measures referred to in Article 9(1)(e) of Regulation (EEC) No. 2658/87 (draft Commission Implementing Regulations) submitted to the Committee for an opinion, in accordance with the examination procedure referred to in Article 10 of Regulation (EEC) No. 2658/87.**

4.1 *Draft Commission Implementing Regulation amending Additional note 2(f) to Chapter 27 of the Combined Nomenclature, TAXUD/1254095/2017-REV 1.*

The Committee examined a draft Commission Implementing Regulation amending Additional note 2(f) to Chapter 27 of the Combined Nomenclature.

The Chair reminded that this item was not voted at the previous Committee meeting because the draft has been significantly modified during the inter-service consultation between the Commission services. One of the main modifications was to transfer into the text of Additional note 2(f) the text of the footnote of this Additional note. Consequently, the Member States considered that a new examination was necessary before the vote.

One Member State proposed to amend slightly the formulation of whereas (3) in order to modify where the "saponification index inferior to 4" applies: it consists in mentioning that it applies in "Additional note 2(f), first paragraph, first indent" instead of just "Additional note 2(f)". Four other Member States agreed and no other Member State disagreed with this proposal.

The Committee delivered a positive opinion on the draft measure as set out in Annex III.

4.2 *Draft Commission Implementing Regulation amending Additional note 10 to Chapter 22 of the Combined Nomenclature, TAXUD/2613244/2017.*

The Committee examined an amendment of Additional note 10 to Chapter 22 of the Combined Nomenclature.

The Committee delivered no opinion on the draft measure as set out in Annex IV.

5. **Decisions referred to in Article 34(11) of Regulation (EU) No. 952/2013 (draft Commission Implementing Decisions) submitted to the Committee for an opinion, in accordance with the advisory procedure referred to in Article 285(2) of Regulation (EU) No. 952/2013.**

(none)

6. **Explanatory Notes referred to in Article 9(1)(a) of Regulation (EEC) No. 2658/87 (draft Explanatory Notes to the Combined Nomenclature) submitted to the Committee for an opinion, in accordance with the examination procedure referred to in Article 10 of Regulation (EEC) No. 2658/87.**

6.1 *Draft Commission Proposal for an amendment of the Explanatory Notes to the Combined Nomenclature (subheadings 2710 19 11 to 2710 19 29), TAXUD/2613182/2017.*

The Committee examined a draft Commission Proposal for an amendment of the Explanatory Notes to the Combined Nomenclature (subheadings 2710 19 11 to 2710 19 29).

The submitting Member State disagreed with the change of the title of the gas chromatographic (GC) profile of products of CN code 2710 19 25 and the deletion of all the graphic profiles of products of CN code 2710 19 29 requested by another Member State. No other Member State expressed its agreement with the abovementioned changes requested by this Member State.

One Member State signalled an error in the French version of the CNEN to subheading 2710 19 11: in the phrase defining kerosene, the term "légère" should be replaced by the term "moyenne".

The Committee delivered a positive opinion on the draft measure as set out in Annex V.

6.2 *Draft Commission Proposal for an amendment of the Explanatory Notes to the Combined Nomenclature (subheading 2306 50 00), TAXUD/2613222/2017.*

The Committee examined a draft for CNENs to subheading 2306 50 00 regarding edible coconut powder derived from partially defatted coconut flesh. During the previous meeting of the Committee the majority of the Member States decided to classify the above-mentioned product under subheading 2306 50 00 instead of subheading 1106 30 90. However, the vote by written procedure (see item 1) was stopped due to an objection by one Member State.

This Member State claimed that the proposed classification contradicts the HSENs to heading 1106, part C, as production of coconut powder of heading 1106 always requires (at least partially) degreasing of the raw material; otherwise just coconut paste and no coconut powder can be produced. Consequently, heading 1106 would be an empty heading. Therefore classification under Chapter 23 should be avoided. Two Member States supported the view of the previous one.

The submitting Member State stressed that coconut powder was produced from coconut flesh and not just coconut, which provides some essential product properties.

A second Member State emphasized that partially defatted coconut products are not excluded from heading 0801 by HSENs to that heading or by the HSENs to Chapter 08. Therefore, CNENs shall be drafted permitting a partially degreasing for products of that heading.

A third Member State asked how laboratories may distinguish between partially defatted coconut powder produced from copra and partially defatted coconut powder made from fresh coconut flesh.

A fourth Member State suggested classifying both products under subheading 2306 50.

The Chair explained that partially defatted coconut powder made from copra has to be classified under heading 1208 ("Flours and meals of oil seeds or oleaginous fruits, other than those of mustard") in accordance with Note 2 to Chapter 12 as copra is an oleaginous fruit explicitly mentioned in the HSENs to heading 1208.

A round of the table showed that the draft measure did not receive sufficient support. Consequently, the Chair withdrew the item from the vote. The issue will be discussed at the earliest convenience, possibly at a forthcoming Project Group meeting.

7. Items submitted to the Committee for discussion under Articles 34 and 57 of Regulation (EU) No. 952/2013 or under Article 8 of Regulation (EEC) No. 2658/87.

7.1 *Tariff classification of reishi mushroom powder, TAXUD/2613335/2017.*

The Committee examined the classification of reishi mushroom powder. The Chair explained that the product at issue is not covered by Note 2 to Chapter 7. This Note defines the meaning of the term "vegetable" within headings 0709 to 0712 by including edible mushrooms. All products of the above mentioned headings are used as food or side dishes in the same way as vegetables are used.

The Chair said that all scientific literature consulted (mentioned in the non-paper) unanimously explained that reishi is not used as a kind of food due to its thick, corky and tough fruit bodies in combination with its bitter taste. The product is however used in Japanese and Chinese traditional medicine. In addition, the CNENs to heading 0712 exclude dried products, such as reishi mushroom, which are not used as vegetables but are used primarily in pharmacy, etc. Therefore the product at issue should be classified under heading 1211.

The submitting Member State explained that the product is imported in bulk and afterwards repacked in sachets made up for retail sale (50 g, 100 g, etc.). It suggested classifying reishi mushroom powder under heading 0712 and justified it by referring to a non-binding third country classification ruling, classifying a similar product under heading 0712. The submitting Member State claimed that reishi is comparable with other Asian mushrooms (e.g. shiitake). Shiitake is mainly used in East Asian cuisine and classified in Chapter 7, despite its marginal used in medicine or pharmacy. The submitting Member State added that a random Google search or Wikipedia consultation concerning reishi mushroom clearly indicates the possible use of reishi for human consumption. Reishi might be used as a flavouring matter for soups or for the preparation of infusions.

A second Member State made clear that consulting scientific literature provides an objective result, but the random consultation of the internet provides subjective results and therefore do not facilitate clarifying the situation.

A third Member State consulted BioLib (an international encyclopaedia for plants, fungi, insects and animals) which clarified that reishi is not edible. Therefore the product should be excluded from Chapter 7 and classified under heading 1211.

A fourth Member State stressed that the product is edible because it is consumed by humans. Reishi mushrooms might be comparable with truffles, which are mainly used for seasoning and still classified under Chapter 7 and not Chapter 9.

A fifth Member State supported the previous one and added that several food products might have a positive effect on health, but they are not automatically classified under heading 1211.

A sixth Member State referred to Regulation (EU) 2016/996 classifying powdered, dried leaves of the moringa tree under heading 1212. The classification issue was comparable with the current situation as also heading 1211 was under consideration. Heading 1211 was excluded due to the general used of moringa powder.

A round of the table indicated that the represented Member States are divided between both headings at issue and no majority for either classification could be reached.

The Chair concluded by saying that the concerned Member States shall provide scientific references via CIRCABC supporting their classification opinion. Subsequently, this question will be discussed at the upcoming PG meeting.

7.2 *Tariff classification of guarana seeds, TAXUD/2613300/2017.*

The Committee examined the classification of ground guarana seeds, neither roasted nor otherwise prepared.

One Member State explained that guarana seeds are not consumed to take in nutritive substances or to achieve the feeling of satiety, what is the case for food. They are mainly consumed (e.g. as a beverage or food supplement) because of their stimulating effects due to their high caffeine content. Therefore, children and pregnant women should avoid consuming these seeds. Consequently, guarana seeds should be classified under heading 1211 as seeds of a kind used primarily in pharmacy.

A second Member State suggested introducing a new HS-subheading for this product under Chapter 9 as their use is comparable with coffee or tea. The Chair explained that this is not feasible to solve the current classification issue.

The submitting Member State said that it is aware of the stimulating effects of guarana seeds, but their use is not "primarily in pharmacy" as required for a classification under heading 1211. These seeds are mainly used for the production of beverages (as stated in statistics mentioned in the submission) and therefore not primarily in pharmacy. Consequently, the product should be classified under heading 1212.

A round of the table indicated that 22 Member States (representing 69 % of the population) were in favour of the proposal classifying guarana seeds under heading 1212. 4 Member States (representing 28.8 % of the population) would prefer classification under heading 1211; 2 Member States were not represented.

Although the duty rates under both headings are identical, taking a measure is deemed necessary in order to draw a distinction line between headings 1211 and 1212 which are at first glance quite similar. At closer inspection however the scope of those headings is quite different. At HS level there is in the HSEN to heading 1211 a not exhaustive list of products included in that heading which gives regularly cause to classification issues between headings 1211 and 1212. Therefore, at the level of the CNENs, lists of products are being built up where the correct classification on EU level is at stake. The current product is the third entry in the list under the CNEN to heading 1212.

The Chair concluded by saying that a draft amendment of the Combined Nomenclature Explanatory Notes will be subject to an inter-service consultation and subsequently presented for vote at a forthcoming Committee meeting or by written procedure.

7.3 *Tariff classification of a masterbatch of essential oils in encapsulated dispersions of ethylene-vinyl acetate (EVA) or low density polyethylene (LDPE) containing not more than 12 % of essential oils and sodium benzoate, TAXUD/3751174/2017.*

The Committee examined the tariff classification of a masterbatch of essential oils in encapsulated dispersions of ethylene-vinyl acetate (EVA) or low density polyethylene (LDPE) containing not more than 12 % of essential oils and sodium benzoate.

One Member State proposed a simplified version of the draft proposal with only the main components mentioned; that version was examined by the Committee.

Other Member States preferred to classify both products in heading 3808 because the main characteristic of these masterbatches is their repelling effect due to the presence of the essential oils. Another Member State agreed with the submitting Member State.

A round of the table indicated that a majority of 17 Member States (representing 65,3 % of the population) agreed with the proposal.

For the first product of the draft (masterbatch with essential oils), 2 Member States abstained and 4 Member States were against, nevertheless there is a qualified majority in favour of the proposal for classification in Chapter 33.

For the second product of the draft (masterbatch with essential oils and insecticide) all represented Member States except one, which favoured classification under heading 3901, were in favour of the proposal for classification in Chapter 38.

Considering that the case is also related to a discussion in the field of autonomous duty suspensions concerning such products, this measure will also serve to avoid divergent views on the classification of such products in that field.

The Chair concluded by saying that an inter-service consultation will be launched concerning this proposal.

7.4 *Tariff classification of brown fused alumina slag, TAXUD/2613347/2017.*

The Committee examined the tariff classification of brown fused alumina slag.

One Member State presented a new version of the draft regulation with a modification of the classification under heading 7205 based on the results of an X-ray analysis of the product in their laboratory.

A second Member State considered that the product mentioned in their related BTI is not the same product which was analysed by the first Member State and preferred a classification under heading 7202.

The Chair indicated that the new version of the draft regulation (as presented by the first Member State) should not be further discussed.

A third Member State considered that the product is fulfilling the conditions of Note 3(a) to Chapter 26 and should therefore be classified under heading 2620.

A fourth and a fifth Member State proposed to mention Note 1(c) to Chapter 72 at the beginning of the reasons.

The first Member State proposed to mention Subheading note 2 to Chapter 72 at the beginning of the reasons.

A round of the table indicated that a majority of the represented Member States (20 Member States, representing 77.2 % of the population) was in favour of the proposal in

its amended version. A minority (5 Member States, representing 18.6 % of the population) would prefer classification under heading 2620.

The Chair concluded by saying that an inter-service consultation will be launched concerning this proposal.

7.5 *Possible creation of a new Additional note 14 to Chapter 22, TAXUD/2613308/2017.*

The Committee examined the possible creation of a new Additional note 14 to Chapter 22 in order to create a robust legal measure to eliminate any divergent views on the classification of specific products of headings 2206 and 2208, in particular "fermented alcoholic bases, not for retail sale but intended for use as an ingredient in the formulation / manufacture of a range of alcoholic beverages". In particular, the rulings in three Court cases in this field (C-150/08 'Siebrand'; C-196/10 'Paderborner'; C-532/14 and C-533/14 'Toorank') should be taken as guidance.

The Chair added that existing CNENs to heading 2206 and 2208, published in 2013 and referring to the rulings in Court cases C-150/08 'Siebrand' and C-196/10 'Paderborner', should be repealed once the new Additional note has been created to avoid confusion.

The Committee welcomed the draft but proposed some changes to the text and its structure.

One Member State remarked that maybe CNENs might be still needed to clarify certain details.

A second Member State said that the problem of innovative products will not be completely removed and suggested to draft the text in a more general way.

A third Member State suggested introducing also organoleptic criteria as in some products added sugar "masks" the smell/taste of alcohol. Furthermore, glycerol as a marker for fermentation could be introduced as well.

A fourth Member State warmly welcomed the draft which is deemed to put an end to a discussion between customs, excise and trade lasting for the past 16 years. In addition, this Member State will provide a presentation on the classification of alcoholic mix drinks, held at a FISCALIS Seminar in 2015, which could maybe offer some additional input.

A fifth Member State pointed out its written contribution shortly before the meeting, proposing some re-wording of the draft.

A sixth Member State pointed out that it too provided a written contribution shortly before the meeting, containing more elaborate changes to the draft. As the issue is quite complex, more work on the text is needed.

The Chair thanked the Member States for their contributions and said that a revision of the working document will be uploaded shortly on CIRCABC as working document TAXUD/2613308/2017-REV 1, showing the proposed changes by two Member States - as shown on the screen during the Committee meeting - to prepare the discussion at a forthcoming Project Group meeting.

A seventh Member State remarked that it would like to keep certain parts of the text in opposition to the suggestions made by the sixth Member State.

The Chair concluded by saying the item will be discussed again in the Committee once the Project Group has discussed the issue in detail and the suggested amendments are put into context.

7.6 *Tariff classification of Konjac sponges, TAXUD/2613278/2017.*

The Committee examined the classification of konjac sponges.

The Chair explained that the submitting Member State presented two classification issues. The first regarding the natural polymer glucomannan and the second regarding a so-called konjac sponge which is produced from glucomannan using a specific production process. In the meantime glucomannan was classified by the HSC at its 60th meeting under heading 1212 (once the reservation period has ended, a WCO Classification Opinion will be issued in January 2018). Therefore the Committee limits itself to discuss the classification of the konjac sponge.

A second Member State explained that the product should be classified under heading 3924 as "Tableware, kitchenware, other household articles and hygienic or toilet articles, of plastics" due to its main component which is the polymer glucomannan. This polymer is modified during the production process resulting in a plastic with new properties (different from the original glucomannan). Therefore glucomannan complies with the requirements mentioned in Note 1 to Chapter 39, which defines the expression "plastic" throughout the nomenclature. The raw materials resulting in a plastic product do not necessarily need to be polymers themselves. Plastics can be made from monomers too and therefore heading 3924 is not restricted to plastic products manufactured from polymers.

A third Member State stated that it issued a BTI under heading 1404 as "Vegetable products not elsewhere specified or included". Heading 3924 was not considered as specific enough as the konjac sponge is biodegradable and the raw material glucomannan was not regarded as a kind of plastics due to its classification under heading 1212. However, the motivation presented by the previous Member State, classifying the product under heading 3924, is reasonable.

A fourth Member State explained that heading 1404 covers mainly raw materials, but the product in question is a manufactured commodity mainly made from a polymer. Therefore it should be classified under heading 3924.

A round of the table indicated that a clear majority of the represented Member States (24, representing 94.4 % of the population) including the two Member States, which issued BTIs under heading 1404, would classify the konjac sponge under heading 3924, taking into account the above-mentioned reasons for the classification. Two Member States were abstaining (3.6 %) and two Member States absent (2.2 %).

The Chair concluded by saying that the Committee provided a clear classification opinion without contrary points of view. Consequently, there is no need for taking a measure. The Member States with possibly concerned BTIs are invited to review their related classification decisions and eventually revoke contradicting BTIs. The file is closed.

7.7 *Possible creation of a new Additional note 5 to Chapter 15, TAXUD/2613284/2017.*

The Committee examined a draft proposal for a new Additional note 5 to Chapter 15 with regard to the judgment of the Court of Justice of the European Union in Joined Cases C-410/08 to C-412/08 ('Swiss Caps').

Two Member States questioned the seventh recital, which defines the scope of Chapter 15 using the HSENs to heading 2106. They were however in favour of the proposed text for the new Additional note.

A round of the table indicated that all represented Member States were in favour of the draft proposal.

The Chair concluded by saying that that an inter-service consultation will be launched concerning this proposal.

7.8 *Tariff classification of encapsulated products containing colostrum, TAXUD/2613361/2017.*

The Committee examined a draft proposal repealing Commission Implementing Regulation (EU) No 716/2012 (classifying two kinds of encapsulated colostrum powders under heading 1901). As these products fall into the scope of goods covered by Additional note 4 to Chapter 19 (introduced by Commission Implementing Regulation (EU) 2017/1343) it is appropriate to apply the rules set out by that Additional note to the encapsulated colostrum powders and classify them under heading 2106 as well.

The Member States did not make any remarks. A round of the table indicated that all represented Member States were in favour of the draft proposal.

The Chair concluded by saying that that an inter-service consultation will be launched concerning this proposal.

7.9 *Tariff classification of inulin syrup, TAXUD/3751132/2017.*

The Committee examined an amendment to Additional note 6 to Chapter 17 with regard to inulin syrup. The "Proficiency Test on Sugars and Sugar Containing Products 2016" revealed that the involved customs laboratories interpret the phrase "fructose in free form or as sucrose" mentioned in Additional note 6 to Chapter 17 differently.

The participants of that ring test used different formulas to calculate the sugar content of the inulin syrup sample. In the interest of maintaining legal certainty and avoiding a legal void, it is necessary to amend that Additional note by adding a new paragraph to the existing text providing a formula for the calculation of the sugar content in inulin syrups.

A round of the table indicated that all represented Member States were in favour of the draft proposal.

The Chair concluded by saying that that an inter-service consultation will be launched concerning this proposal.

7.10 *Tariff classification of special sugars, TAXUD/3751234/2017.*

The Committee examined a proposal with a view to splitting heading 1701 91 as well as amending the CNENs to CN code 1701 99 10 and Additional note 3 to Chapter 17.

The submitting Member State explained that this proposal should enable better tracking of the trade flows of cane sugar. Therefore, the existing HS subheading 1701 91 covering "cane or beet sugar containing added flavoring or coloring matter, in solid form" should be split in two CN-subheadings, one covering "white sugar containing added flavoring" and the other "other sugars".

In addition, the submitting Member State claimed that the customs definition of white sugars – mentioned in the CNENs and Additional note 3 to Chapter 17 – is too vague in order to differentiate properly between sugar from beets and sugar from cane due to the fact that cane sugar with a sucrose content of ≥99.5 % by weight might still have a slight yellowish coloring (and not a pure white color like beet sugar with a sucrose content of ≥99.5 % by weight). Therefore the definition of "white sugar" within the CN should be aligned with the definition of the Common Market Organisation (CMO) of agricultural products mentioned in Regulation (EU) No 1308/2013. Namely, by determining the color of white sugars using the ICUMSA method (mentioned in Annex III, letter B, part II of that Regulation) and applying a threshold of <6 color-in-solution points (one point is equal to 7.5 units of coloring determined by that method).

A second Member State explained that the proposal of amending the definition with regard to white sugar in the CN would mix up two different areas of legislation (customs and agriculture). For example, custom legislation requires a minimum sucrose content of ≥99.5 % by weight so that a sugar can be regarded as white sugar while the standard of the CMO requires a minimum polarization of 99.7°. The main customs issue is that cane sugar with a sucrose content of ≥99.5 % by weight might be colored by natural ingredients of the sugar cane or by added coloring matter. Therefore a high sucrose content of ≥99.5 % by weight does not necessarily result in a white color and consequently a proper classification might be difficult. A third Member State supported the view of the previous one.

A fourth Member State stressed that a TARIC code existed until 2014 which differentiated between cane sugar and other sugars. This approach might be easier to achieve the above-mentioned aim.

The Chair pointed out that the products concerned by that issue have a total annual trade volume of just 250.000 tons and are classified under several subheadings of heading 1701, including CN code 1701 91 00 which was proposed to be split. Therefore, one of the two new subheadings would just partially cover the above-mentioned annual trade of cane sugar products. In principle, the creation of a new statistical CN code requires a turnover of at least 30 million Euros per year. However, the total annual import volume under the current CN code 1701 91 00 is for 2016 just 1.898.111 € / 1.141 t. Consequently, splitting would not be feasible from the statistical perspective.

Furthermore, the submitting Member State was asked to check whether the proposal was not containing a contradiction between the proposed new subheadings and the proposed new Additional note 3 to Chapter 17.

A round of the table indicated that just a small minority of the represented Member States could support the proposal as presented.

The Chair concluded by saying that the submitting Member State should review its proposal and provide (if possible) statistical data justifying a split of subheading 1701 91. The file is kept open for the time being.

7.11 *Tariff classification of anti-freezing preparations and similar products of Chapter 38, TAXUD/3751249/2017.*

The Committee examined the tariff classification of anti-freezing preparations and similar products of Chapter 38, in particular a preliminary draft for a new Additional note to Chapter 38 dealing with a description of products covered by heading 3820.

The Chair pointed out that this draft was partly elaborated based on information from industry that shared their inside knowledge. DG TAXUD found it however complicated to bring all elements together in a way that fits all needs and remains open for further discussion on this subject.

One Member State stated that it cannot support the draft as it leaves too much room for interpretation. The definition of "other substances" is too vague and this Member State is seeing itself in an uncomfortable situation considering that different Member States have different rules on denaturing ethyl alcohol. Denaturants and their concentration differ between the Member States and so does classification for some products. The distinction between products of headings 2207 and 3820 remains unclear.

A second Member State understands the frustration of the first Member State as regards the distinction between products of headings 2207 and 3820 but is not opposed to the draft although it does not offer a perfect solution. Some elements of the presented draft however could be taken on board when possibly drafting a new measure addressing the general issue of the classification of such products.

A third Member State received the draft with mixed feelings as it sees clearly the problem but has concerns with thresholds. The reference in the draft to Additional note 12 to Chapter 22 seems questionable and should be removed.

A fourth Member State remarked that classification Regulations with products in the range of approx. 90 % by weight of ethyl alcohol exist and wondered on the effectiveness of the drafted measure.

A fifth Member State wondered whether products of heading 3820 are limited to those containing denatured ethyl alcohol, following the wording of the draft.

A sixth Member State said that, after having discussed the draft with its customs laboratory, the draft could be worded a lot easier by indicating simply the intended end-use of the products, their main components, that they are denatured according to EU legislation and that they are ready-to-use. The indication of temperature levels is not needed.

The Chair said that a recent contribution from industry goes into the same direction: also there it was mentioned that such products should - upon importation - be ready-for-use as a screen wash, with exception of any water content. Furthermore, there should not be any threshold for ethyl alcohol.

A seventh Member State stated that it too cannot accept the draft: the indication of temperatures is not important; such products should contain surfactants and the use as antifreeze preparations and washing liquids should be obvious.

An eighth Member State would welcome the idea to distinguish between products of headings 2207 and 3820 by applying a threshold. Therefore the draft does not work; as regards the reference in the draft to Additional note 12 to Chapter 22 this Member State also is of the opinion that it should be removed.

The Chair said the preliminary draft is withdrawn as it lacks support from the Committee as presented. As regards the comments from the first Member State that

"different Member States have different rules on denaturing ethyl alcohol", the Chair pointed out that this refers to excise legislation. Such issues are not to be dealt with by this Committee but the Excise Committee.

The Chair referred to Article 27, paragraph 5, of Council Directive 92/83/EEC on the harmonization of the structures of excise duties on alcohol and alcoholic beverages. There it is clearly stated that if a Member State finds that a product which has been exempted from excise duty gives rise to evasion, avoidance or abuse, it may refuse to grant exemption or withdraw the relief already granted. The Member State shall advise the Commission which has to transmit the communication to the other Member States. A final decision shall then be taken at the Excise Committee.

The Chair underlined that the Customs Code Committee is in charge of tariff classification, in the first place linked to products crossing the external border of the EU. Products crossing excise borders inside the EU are not in the scope of discussions of this Committee.

The Chair concluded by saying that the file is closed. The general issue concerning the classification of such products will be however discussed at a forthcoming Project Group meeting.

7.12 *Possible amendment of the Combined Nomenclature Explanatory Note to heading 2309 ("analytical methods"), TAXUD/3751297/2017.*

The Chair explained that, following the publication of the amendment to the CNEN to Heading 2309 on 08/06/2017, DG TAXUD received concerns from several parties (incl. third countries and trade associations) affected by that publication as regards the new threshold of 5 % replacing the previous one of 0.5 % by weight for starch.

The unintended effect of such a new threshold is that imports previously classified under subheading 2309 10 11 (benefitting from a "free" duty rate) have now to be classified under subheading 2309 10 90 instead, underlying a duty rate of 9.6 %.

Since an amendment to the CNENs can neither expand nor restrict the scope of a CN subheading, DG TAXUD is of the opinion that such a measure should be again amended in order to restore the previous situation and that new initiatives should be taken in order to ensure both legal and analytical certainty. In particular, the recently published CNENs should be amended and therefore a draft has been prepared for discussion.

The Member States expressed their understanding and supported the opinion and intention of DG TAXUD to issue at the earliest convenience an amendment of the said CNEN with a view to go back in principle to the situation before 08/06/2017, i.e. re-introducing the threshold of 0.5 % by weight of starch.

Two Member States strongly demanded a fundamental long-term solution with regard to the general analytical problem linked to products of heading 2309. That analytical problem is caused by the wording of the structure of the CN codes of heading 2309 due to WTO customs duty rates which show considerable differences. Considering that the goal of economic operators is to import in principle all dog and cat food, put up for retail sale, under zero duty, it would be perhaps better to re-negotiate at WTO level the duty rates under heading 2309 so that all products, regardless of their components (starch, glucose, maltodextrine, etc.), can be imported under zero duty. As a consequence, the problematic CN structure could be abolished. This would make the complex and sometimes impracticable analysis of products of heading 2309

superfluous. Therefore these Member States would appreciate if the Commission (in particular DG AGRI) took the initiative in that respect.

As regards a possible retroactive application of that amendment and the possible remission/repayment of customs duties, DG TAXUD is investigating that aspect. The Committee will be kept informed about the developments in this case.

A Member State proposed shortly before the meeting a revision of the draft. That revision had been distributed via CIRCABCB and was also shown and discussed in the Committee.

A round of the table indicated that all but one of the represented Member States agreed to the revised draft of an amended CNEN to heading 2309. However, the Committee suggested strongly discussing also the long-term issues of the analytical methods to be applied concerning such products.

Several Member States asked about the correct procedure to be followed as regards revoking BTIs issued for such products in heading 2309. The Chair indicated that Member States may consider flexibility when it comes to revocation of BTIs pursuant to the new CNEN on dog and cat food, since there will be soon a return to the previous situation. Sufficient time should be dedicated to examining the situation of each single BTI that might be concerned.

The Chair concluded by saying that an inter-service consultation will be launched concerning this proposal. The long-term issues of the analytical methods to be applied concerning such products will be discussed at a forthcoming Project Group meeting.

8. Any other business.

8.1 *List of pending cases - files to be closed.*

The Chair indicated that one further case has been received after the 22nd September 2017 (date of the list of pending cases). None of the Member States indicated new submissions to be expected.

No remarks were made as regards the remaining items on the list.

8.2 *Results of the Project Group concerning the chemical chapters of HS/CN from 9th to 10th October 2017.*

The Chair provided an oral summary as the written report is not yet available. The report will be presented to the Committee for endorsement at the next meeting.

As regards the issue of "synthetic nicotine" (nicotine obtained by chemical synthesis in connection with the new CN 2018 subheadings 2939 79 10 and 2939 79 90), the Project Group proposed an amendment of the CNEN to subheadings 2939 79 10 and 2939 79 90 with the phrase "These subheadings include alkaloids obtained by synthesis". A draft measure will be presented for discussion at a forthcoming Committee meeting.

8.3 *Information on the file regarding the tariff classification of novel tobacco products ('heat-not-burn').*

The Chair informed the Committee that classification of novel tobacco products ('heat-not-burn') - also described as EHTP (Electrically Heated Tobacco Products) was

discussed at the recent meeting of the Harmonized System Committee (HSC) of the WCO. A large majority of contracting parties voted for classification of these products in subheading 2403.99. The HSC will issue a classification opinion at its next session (March 2018) reflecting this decision, which will be deemed final once the deadline for entering reservations has expired on 31/12/2017, provided no reservation is entered by any contracting party.

The Chair concluded that the file can be closed as no measure is to be taken on EU level. As regards the other type of product contained in the file, the CHTP (Carbon Heated Tobacco Product), the Chair explained that this product is actually not traded in the EU. Since it has not caused any divergences, no action is required.

8.4 *Tariff classification of an eczema cream.*

The Chair informed the Committee that the delegation of one Member State asked for advice with regard to the classification of an eczema cream. The interested Member State explained that according to the information leaflet, the product blocks harmful bacteria, which reduces complaints such as itching, redness and skin irritation, thus stimulating skin repair. Details about the composition of the products were provided and a sample was circulated among the delegations. The question is whether this particular eczema cream should be classified as a therapeutic/prophylactic product under heading 3004 or under heading 3304 as a preparation for the care of the skin (other than medicaments).

After a round of the table, despite the abstention of some Member States due to the lack of information about the exact content of the active substances, the majority of the represented Member States proposed classifying the abovementioned cream under heading 3304 as a preparation for the care of the skin.

The interested Member State thanked the Committee for the useful feedback and said that it has gathered sufficient information to proceed with the case in its administration.

ANNEX I

ATTENDANCE LIST

Chair	**Mr BLAHA**	**DG TAXUD/A/4**
Commission Services	**Ms ANDRONI**	**DG TAXUD/A/4**
	Mr BRUNERIE	**DG TAXUD/A/4**
	Mr BARNER	**DG TAXUD/A/4**
	Mr SCHEPERS	**DG TAXUD/A/4**
	Mr FRANCESCANGELI	**DG TAXUD/A/4**
Items 7.11, 7.12	**Mr JOUANGRAND**	**DG TAXUD/A/4**
Items 7.10, 7.12	**Mr DELCROIX**	**DG TAXUD/A/4**
Item 7.12	**Mr VIRVILIS**	**DG AGRI/A/5**
Item 7.12	**Mr BERTRAND**	**DG AGRI/G/4**

Member States	**Authorities or bodies / represented by**
Austria	**Bundesministerium für Finanzen**
Belgium	**Federale Overheidsdienst Financiën / Laboratory**
Bulgaria	**Customs Directorate**
Croatia	**Customs Directorate**
Cyprus	**Ministry of Finance / Customs and Excise Department**
Czech Republic	**General Directorate of Customs / Laboratory**
Denmark	**Told- og Skattestyrelsen**
Estonia	**Tax and Customs Board**
Finland	**Finnish National Board of Customs**
France	**Direction Générale des Douanes / Laboratoire des Douanes**
Germany	**GZD (Generalzolldirektion)**
Greece	**Represented by the Permanent Representation [items 3, 4, 6]**
Hungary	**National Tax and Customs Administration**
Ireland	**State Laboratory**
Italy	**Agenzia delle Dogane e dei Monopoli**
Latvia	**National Customs Board**
Lithuania	**Customs Department / Customs Laboratory**
Luxembourg	**Douanes et Accises**
Malta	**Represented by the Netherlands [items 3, 4, 6]**
Netherlands	**Ministerie van Financiën / Customs Laboratory**
Poland	**Ministry of Finance – Customs Department**
Portugal	**ATA (Autoridade Tributária e Aduaneira)**
Romania	**National Customs Authority**
Spain	**Departamento de Aduanas e Impuestos Especiales**
Slovenia	**Financial Administration of RS – Customs Tariff Division / Customs Laboratory**
Slovakia	**Customs Directorate / Department of Customs Tariffs**
Sweden	**Swedish Customs**
United Kingdom	**HM Revenue and Customs / Campden BRI & Group**

Candidate Countries	
none	---

ANNEX II

COMMISSION IMPLEMENTING REGULATION (EU) .../...

of XXX

amending Implementing Regulation (EU) No 211/2012 concerning the classification of certain goods in the Combined Nomenclature

THE EUROPEAN COMMISSION,

Having regard to the Treaty on the Functioning of the European Union,

Having regard to Regulation (EU) No 952/2013 of the European Parliament and of the Council of 9 October 2013 laying down the Union Customs Code[1], and in particular Article 57(4) and Article 58(2) thereof,

Whereas:

(1) In order to ensure uniform application of the Combined Nomenclature ('CN') annexed to Council Regulation (EEC) No 2658/87[2], it is necessary to adopt measures concerning the classification of certain goods.

(2) By Commission Implementing Regulation (EU) No 211/2012[3], a product consisting of a mixture of ethyl alcohol (70 % by weight) and gasoline (automotive petrol) conforming to EN 228 (30 % by weight) has been classified under CN code 2207 20 00.

(3) By Implementing Regulation (EU) No 626/2014[4], the Commission introduced an Additional note 12 to Chapter 22 of Part Two of the Combined Nomenclature. The reasons for classifying the product concerned by Implementing Regulation (EU) No 211/2012 under CN code 2207 20 00 should be aligned with the rules set out in that Additional note in order to avoid potential divergences in tariff classification of specific mixtures of ethyl alcohol with other substances and to ensure the uniform application of the Combined Nomenclature within the Union. The description of the

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1 OJ L 269, 10.10.2013, p. 1.

2 Council Regulation (EEC) No 2658/87 of 23 July 1987 on the tariff and statistical nomenclature and on the Common Customs Tariff (OJ L 256, 7.9.1987, p. 1).

3 Commission Implementing Regulation (EU) No 211/2012 of 12 March 2012 concerning the classification of certain goods in the Combined Nomenclature (OJ L 73, 13.3.2012, p. 1).

4 Commission Implementing Regulation (EU) No 626/2014 of 10 June 2014 amending Annex I to Council Regulation (EEC) No 2658/87 on the tariff and statistical nomenclature and on the Common Customs Tariff (OJ L 174, 13.6.2014, p. 26).

product set out in the Annex to Implementing Regulation (EU) No 211/2012 should also make it clear that the product is used as raw material to produce fuels for motor vehicles.

(4) Implementing Regulation (EU) No 211/2012 should therefore be amended accordingly.

(5) The measures provided for in this Regulation are in accordance with the opinion of the Customs Code Committee,

HAS ADOPTED THIS REGULATION:

Article 1

The Annex to Implementing Regulation (EU) No 211/2012 is replaced by the text set out in the Annex to this Regulation.

Article 2

This Regulation shall enter into force on the twentieth day following that of its publication in the *Official Journal of the European Union.*

This Regulation shall be binding in its entirety and directly applicable in all Member States.

Done at Brussels,

For the Commission
On behalf of the President,
Stephen QUEST
Director-General
Directorate-General for Taxation and Customs Union

"ANNEX

Description of goods	Classification (CN Code)	Reasons
(1)	(2)	(3)
A product of the following composition (% by weight): – ethyl alcohol 70 – gasoline (automotive petrol) conforming to EN 228 30 The product is used as raw material to produce fuels for motor vehicles.	2207 20 00	Classification is determined by general rules 1 and 6 for the interpretation of the Combined Nomenclature, Additional note 12 to Chapter 22 and by the wording of CN codes 2207 and 2207 20 00. The product is a mixture of ethyl alcohol and gasoline (automotive petrol). The percentage level of

It is transported in bulk.		gasoline (automotive petrol) in the product renders it unfit for human consumption but does not prevent the use of the product for industrial purposes (see also the Harmonized System Explanatory Notes to heading 2207, fourth paragraph). The product is therefore to be classified under CN code 2207 20 00 as a denatured ethyl alcohol."

ANNEX III

COMMISSION IMPLEMENTING REGULATION (EU) .../...

of XXX

amending Annex I to Council Regulation (EEC) No 2658/87 on the tariff and statistical nomenclature and on the Common Customs Tariff

THE EUROPEAN COMMISSION,

Having regard to the Treaty on the Functioning of the European Union,

Having regard to Council Regulation (EEC) No 2658/87 of 23 July 1987 on the tariff and statistical nomenclature and on the Common Customs Tariff[1], and in particular Article 9(1)(e) thereof,

Whereas:

(1) Regulation (EEC) No 2658/87 established a nomenclature of goods (hereinafter referred to as the "Combined Nomenclature") which is set out in Annex I to that Regulation.

(2) Additional note 2(f) to Chapter 27 of the Combined Nomenclature defines the family of products referred to as "fuel oils". These products are classified either in subheadings 2710 19 51 to 2710 19 68 or in subheadings 2710 20 31 to 2710 20 39, depending on their physico-chemical properties and characteristics.

(3) One such physico-chemical characteristic is the saponification number. "Fuel oils" of additional note 2(f), first paragraph, first indent shall have a saponification number of less than 4. This rule applies to products in subheadings 2710 19 51 to 2710 19 68. However, an exception is made for products in subheadings 2710 20 31 to 2710 20 39 (products containing fatty acid mono-alkyl esters or "FAMAE") where the saponification number exceeds 4. That exception is currently set out in a footnote to additional note 2(f).

(4) The exception currently in a footnote to additional note 2(f) needs to be extended to take account of developments in technology, in particular the development of renewable fuels containing animal or vegetable fats or oils. It also needs to be extended to tackle the potential for the counterfeiting of diesel fuels that is generally achieved by adding small quantities of vegetable or animal fats or oils to gas oils in order to change their classification from gas oils (which are subject to excise duties) to other products (which are not subject to excise duties). In particular, the addition of vegetable oils serves to change the distillation parameter and to obtain a saponification number equal to or exceeding 4. The addition of small quantities of such substances does not change their essential character as fuel oils from a physico-

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[1] OJ L 256, 7.9.1987, p. 1.

chemical point of view. They are still used as fuel oils. Removing the requirement in these cases for the saponification number to be less than 4 will therefore ensure that such products are classified correctly as fuel oils, not as other products.

(5) The current exception for products containing FAMAE also needs to be extended so that it covers products where the saponification number equals 4, not just products where it exceeds 4.

(6) Additional note 2(f) to Chapter 27 should be amended accordingly to ensure its uniform interpretation throughout the Union.

(7) Regulation (EEC) No 2658/87 should therefore be amended accordingly.

(8) The measures provided for in this Regulation are in accordance with the opinion of the Customs Code Committee,

HAS ADOPTED THIS REGULATION:

Article 1

In Chapter 27 of the Combined Nomenclature set out in Annex I to Regulation (EEC) No 2658/87, additional note 2(f) is amended as follows:

(1) in the first paragraph, the first indent, including the footnote, is replaced by the following:

"–not exceeding that shown in line I of the following table when the sulphated ashes content is less than 1 % by the ISO 3987 method and the saponification number is less than 4 by the ISO 6293-1 or 6293-2 method (except where the product contains one or more bio-components, in which case the requirement in this indent for the saponification number to be less than 4 does not apply),";

(2) the following fourth paragraph is inserted:

"The term "bio-components" means animal or vegetable fats, animal or vegetable oils, or mono-alkyl esters of fatty acids (FAMAE).".

Article 2

This Regulation shall enter into force on the twentieth day following that of its publication in the Official Journal of the European Union.

This Regulation shall be binding in its entirety and directly applicable in all Member States.

Done at Brussels,

For the Commission
The President
Jean-Claude JUNCKER

ANNEX IV

COMMISSION IMPLEMENTING REGULATION (EU) .../...

of XXX

amending Annex I to Council Regulation (EEC) No 2658/87 on the tariff and statistical nomenclature and on the Common Customs Tariff

THE EUROPEAN COMMISSION,

Having regard to the Treaty on the Functioning of the European Union,

Having regard to Council Regulation (EEC) No 2658/87 of 23 July 1987 on the tariff and statistical nomenclature and on the Common Customs Tariff[1], and in particular Article 9(1)(e) thereof,

Whereas:

(1) Regulation (EEC) No 2658/87 established a nomenclature of goods (hereinafter referred to as the "Combined Nomenclature" or the "CN"), which is set out in Annex I to that Regulation.

(2) Additional note 10 to Chapter 22 of Part Two of the CN stipulates that for the purposes of subheadings 2206 00 31 and 2206 00 39 fermented beverages, other than those put up in bottles with 'mushroom' stoppers held in place by ties or fastenings, with an excess pressure of not less than 1,5 bar, measured at a temperature of 20 °C, are regarded as 'sparkling'.

(3) Subheading note 1 to Chapter 22 of Part Two of the CN stipulates that for the purposes of subheading 2204 10, the expression 'sparkling wine' means wine which, when kept at a temperature of 20 °C in closed containers, has an excess pressure of not less than 3 bar.

(4) Council Directive 92/83/EEC[2] states that 'other sparkling fermented beverages', falling not only within headings 2204 and 2205 but also within CN code 2206 00 91, as applicable at the time of the adoption of the Directive (currently CN codes 2206 00 31 and 2206 00 39), have an excess pressure of 3 bar or more.

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[1] OJ L 256, 7.9.1987, p. 1.

[2] Council Directive 92/83/EEC of 19 October 1992 on the harmonization of the structures of excise duties on alcohol and alcoholic beverages (OJ L 316, 31.10.1992, p. 21).

(5) It cannot be justified, scientifically or otherwise, to have different thresholds as regards the excess pressure for sparkling fermented beverages, regardless of their classification within CN codes 2204, 2205 or 2206.

(6) In the interest of legal certainty, it is necessary to amend Additional note 10 to Chapter 22 of Part Two of the CN by replacing the existing threshold of 'not less than 1,5 bar' by '3 bar or more'.

(7) In order to ensure consistency and uniform interpretation of the Combined Nomenclature throughout the Union with regard to the definition of 'sparkling beverages', Additional note 10 to Chapter 22 of Part Two of the CN should be amended.

(8) Regulation (EEC) No 2658/87 should therefore be amended accordingly.

(9) The Customs Code Committee has not issued an opinion within the time limit set by its Chair,

HAS ADOPTED THIS REGULATION:

Article 1

In Chapter 22 of Part Two of the Combined Nomenclature set out in Annex I to Regulation (EEC) No 2658/87, the second indent of Additional note 10 is replaced by the following:

"- *fermented beverages otherwise put up, with an excess pressure of 3 bar or more, measured at a temperature of 20 °C.*".

Article 2

This Regulation shall enter into force on the twentieth day following that of its publication in the *Official Journal of the European Union.*

This Regulation shall be binding in its entirety and directly applicable in all Member States.

Done at Brussels,

For the Commission
The President
Jean-Claude JUNCKER

ANNEX V

Explanatory Notes to the Combined Nomenclature of the European Union

Pursuant to Article 9(1)(a) of Council Regulation (EEC) No 2658/87[1], the Explanatory Notes to the Combined Nomenclature of the European Union[2] are hereby amended as follows:

*On page 125, the explanatory note to subheadings **'2710 19 11 to 2710 19 29 Medium oils'** is replaced by the following text:*

"2710 19 11 to 2710 19 29	**Medium oils** See additional note 2(c) to this chapter. Kerosene is used for a wide range of different purposes, for example as fuel for airplanes engines or for heating. Kerosene is a medium oil with a distillation range according to the EN ISO 3405 method (equivalent to the ASTM D 86 method) approximately between 130 °C to 320 °C. The images attached to this explanatory note are merely indicative of chromatograms of one category of products classifiable in each of the three subheadings concerned."

*On page 125, the explanatory note to subheading **'2710 19 21 Jet fuel'** is replaced by the following text:*

"2710 19 21	**Jet fuel** This subheading covers kerosene type jet fuel. This jet fuel complies with the provisions of additional note 2(c) to this chapter. The gas chromatographic profile of kerosene-type jet fuel, for instance the most commonly used jet fuel A-1, is characteristic of an oil obtained by the distillation of a crude oil and also by other petrochemical processes. The chain length of the alkanes varies between about 10 and 18 carbon atoms. The aromatic content may be up to 25 % by volume. Its flash point is generally above 38 °C according to the ISO 13736 method. The freezing point is usually not above -40 °C.

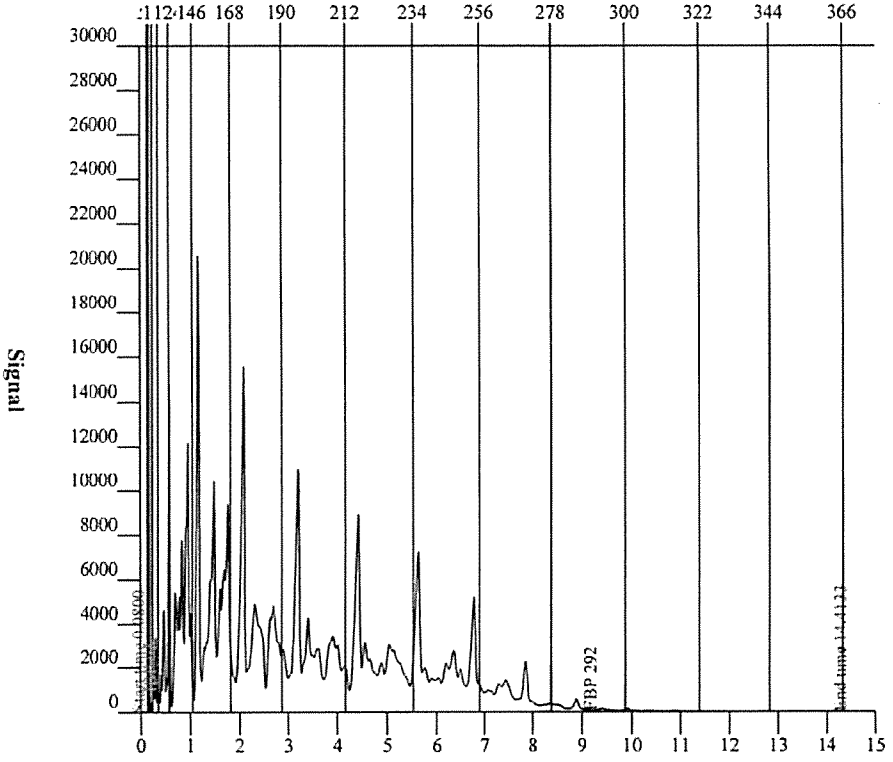
---

(1) Council Regulation (EEC) No 2658/87 of 23 July 1987 on the tariff and statistical nomenclature and on the Common Customs Tariff (OJ L 256, 7.9.1987, p. 1).

(2) OJ C 76, 4.3.2015, p. 1.

Jet fuel may contain the following additives: antioxidants, corrosion inhibitors, icing inhibitors, tracer dyes.

GAS CHROMATOGRAPHIC PROFILE OF JET FUEL TYPE A-1 (KEROSENE) SimDis ASTM D 2887 extended (equivalent to the ISO 3924 method)



ASTM D 86 correlation (STP 577) — Distribution

Recovered Vol. %	BP °C	Recovered Vol. %	BP °C	Recovered Vol. %	BP °C	Recovered Vol. %	BP °C
IBP	139,7	20,0	167,3	70,0	210,1	FBP	260,7
5,0	153,0	30,0	174,3	80,0	221,5		
10,0	159,4	50,0	190,1	90,0	234,9		

"

*On page 127, the explanatory note to subheading **'2710 19 25 Other'** is replaced by the following text:*

"2710 19 25 Other

This subheading covers kerosene other than jet fuel. The kerosene of this subheading complies with the provisions of additional note 2(c) to this chapter.

The gas chromatographic profile of "other" kerosene is characteristic of an oil obtained by the distillation of a crude oil.

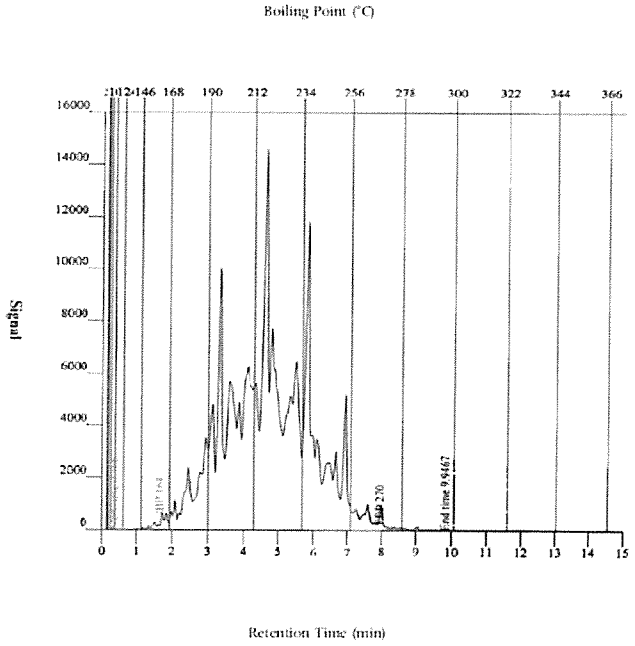
This subheading also includes:

- oils used in lamps, with a low aromatic and olefin content to prevent the formation of soot during combustion;
- oils with a narrow range of distillation, with a gas chromatographic profile composed only by a fraction of the GC image below.

In some cases chemical markers are present.

This subheading excludes mixtures of kerosene with other mineral oils or organic solvents.

GAS CHROMATOGRAPHIC PROFILE OF KEROSENE OTHER THAN JET-FUEL SimDis ASTM D 2887 extended (equivalent to the ISO 3924 method)



ASTM D 86 correlation (STP 577) — Distribution

Recovered Vol. %	BP °C	Recovered Vol. %	BP °C	Recovered Vol. %	BP °C	Recovered Vol. %	BP °C
IBP	193,4	20,0	210,1	70,0	220,1	FBP	247,3
5,0	201,8	30,0	211,4	80,0	223,4		
10,0	206,2	50,0	214,8	90,0	229,6		

"

*On page 129, the explanatory note to subheading '**2710 19 29 Other**' is replaced by the following text:*

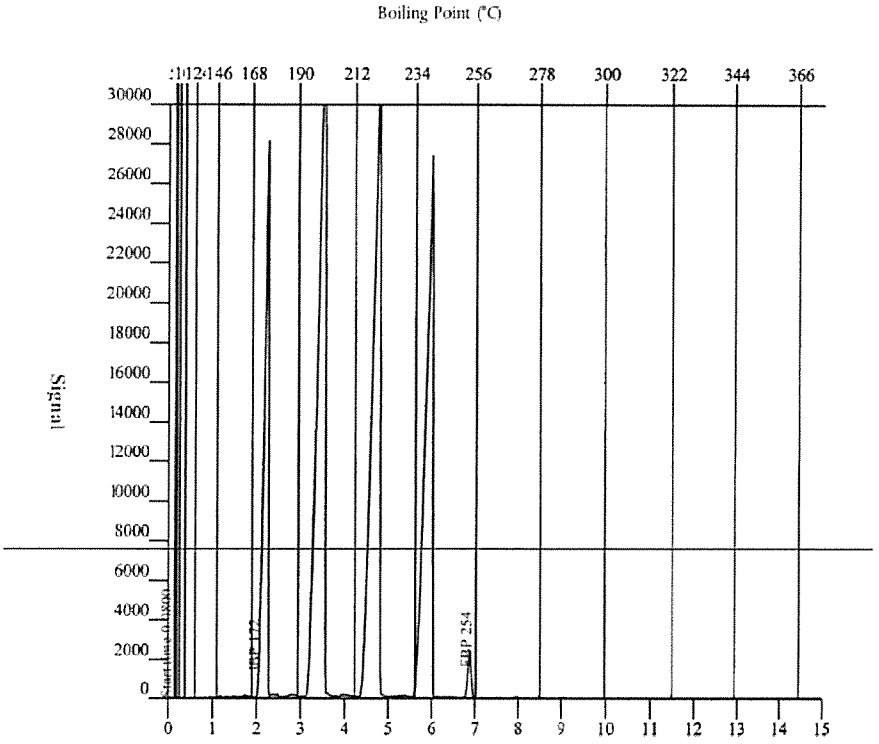
"**2710 19 29** **Other**

This subheading covers medium oils other than kerosene of subheadings 2710 19 21 and 2710 19 25. The oils of this subheading comply with the provisions of additional note 2(c) to this chapter.

Usually, products of this subheading are obtained by one or more chemical-physical processes which can significantly alter the chemical composition of those products so as to make them suitable for certain industrial uses. In certain cases, the modification of molecular composition of those products can be detected using GC or SimDis while for other kinds of products more accurate determinations are necessary (e.g. gas chromatography–mass spectrometry (GC-MS)).

An example of a SimDis profile of these oils is represented by n-paraffin as shown below.

GAS CHROMATOGRAPHIC PROFILE OF A N-PARAFFIN SimDis ASTM D 2887 extended (equivalent to the ISO 3924 method)



BP distribution table — Percent

Recovered Mass %	BP °C	Recovered Mass %	BP °C	Recovered Mass %	BP °C	Recovered Mass %	BP °C
IBP	172,4	30,0	199,2	60,0	219,6	90,0	239,2
5,0	174,8	35,0	199,6	65,0	220,2	95,0	240,0
10,0	176,0	40,0	200,4	70,0	220,8	FBP	254,4
15,0	188,2	45,0	200,8	75,0	221,8		
20,0	197,2	50,0	217,4	80,0	237,0		
25,0	198,4	55,0	218,8	85,0	238,2		

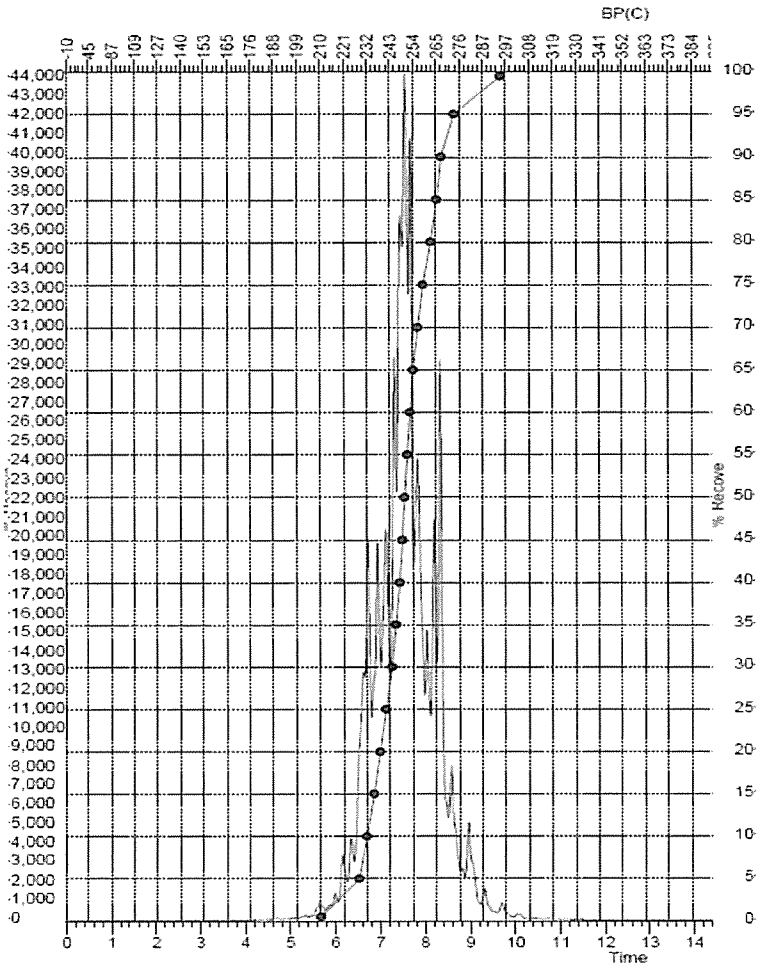
Another example of products of this subheading are those obtained by a multistep process that includes:

- extraction of linear paraffins;
- hydrogenation of the de-paraffinated residue;
- fractionation by distillation of the hydrogenated and de-paraffinated residue in products with shorter carbon cut.

These products consist of saturated hydrocarbons, mainly branched and cyclic, with an aromatic content far less than 1 %. An example of a SimDis profile for this kind of products is shown below:

ASTM D2887 extended (equivalent to the ISO 3924 Method)

Boiling point (°C)



retention time (min)

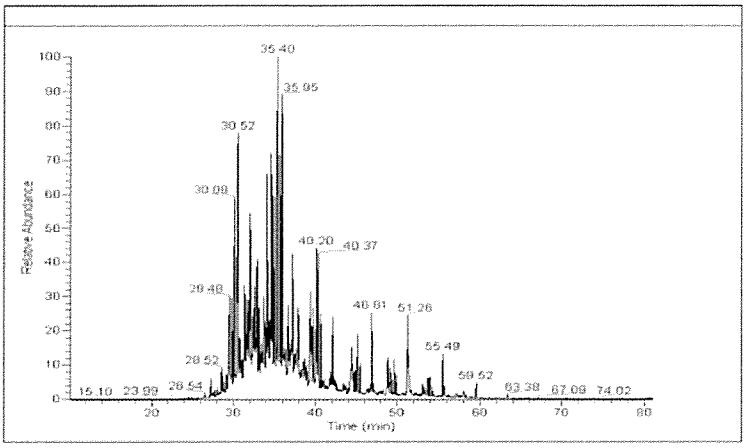
SIMDIS ASTM D 2887 extended correlation to ASTM D 86							
Recovered	BP	Recovered	BP	Recovered	BP	Recovered	BP
Mass %	°C	Mass %	°C	Mass %	°C	Mass %	°C
IBP	234,2	30,0	241,1	70,0	246,5	FBP	255,9
5,0	240,0	40,0	242,2	80,0	247,0		
10,0	240,9	50,0	243,4	90,0	250,8		
20,0	241,0	60,0	243,8	95,0	254.5		

The use of GC-MS technique may deliver a profile like that shown below as

an example:

x-axis: time (minutes)

y-axis: relative abundance



GC-MS total ion chromatogram (TIC)

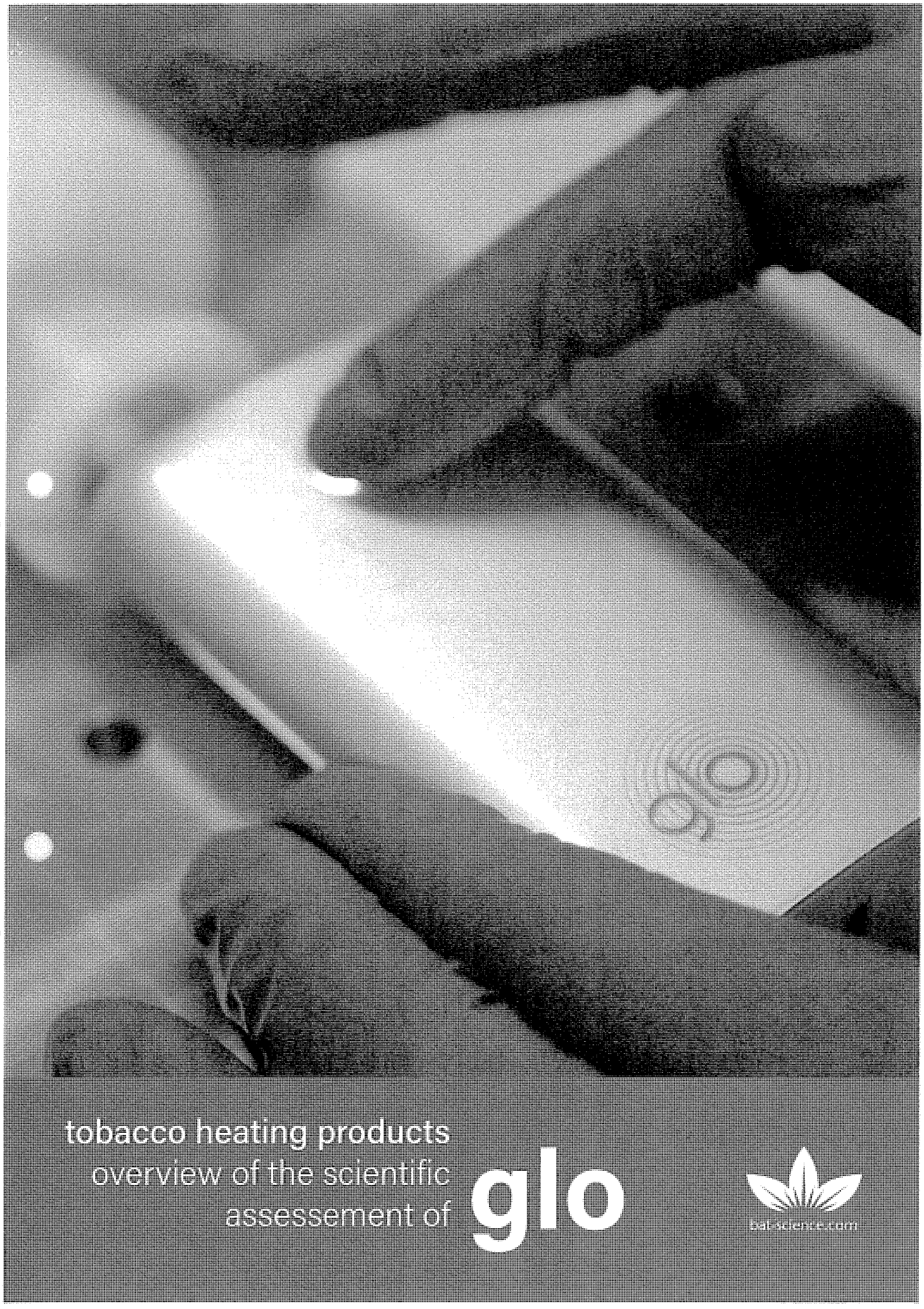
This profile has been obtained with the following experimental conditions:

Column	Zebron ZB5-MS (or similar)
Column length	30 m
I.D.	0,25 mm
d. f.	0,25 µm
Mass range	35 - 600
Ion source	250 °C
Start time	3 min
Split rate	1:60
Injector temperature	250 °C
Injection Volume	1 µL
Transfer Line	275° C
Temperature program:	
Starting temperature	40 °C
Starting time	3 min
Gradient 1	2.5 °C/min up to 270 °C
Final time	10 min

This profile shows the following distribution:

CARBON CUT						
	C10	C11	C12	C13	C14	**TOT**
n-Paraffins	0,1	0,6	4,8	1	0	**6,5**
Mono-methyl paraffins	0	1,5	14,2	15,7	1,8	**33,2**
Others iso-paraffins	0	0,9	10,6	20.1	0,6	**32.2**
Cyclo-paraffins	0	1,2	6,1	16.3	0,3	**24.0**
Decaline	0,2	2	1,4	0,6	0	**4,2**
TOT	**0,3**	**6,2**	**37,1**	**53,7**	**2,7**	**100**

"



tobacco heating products
overview of the scientific assessement of glo

tobacco heating products

It is widely known that cigarette smoking causes many human diseases including cardiovascular disease, lung disease and cancer. Novel tobacco products with reduced yields of toxicants compared with cigarettes, such as tobacco-heating products (THPs), snus and electronic cigarettes (ECs), may hold great potential for reducing the risks associated with tobacco use for smokers who choose to swap to only using such products instead of cigarettes. In the UK some public health agencies have advocated a potential role for Tobacco Heating Products in tobacco harm reduction. In 2017, the UK Independent Scientific Committee on Toxicity were asked by the UK Department of Health to study data on Tobacco Heating Products. They concluded: "*As the exposure to compounds of concern in the aerosol is reduced compared to conventional cigarette smoke, it 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.*" They acknowledged that the actual risks associated with the use of heat-not-burn tobacco products cannot be quantified for a number of reasons, such as due to gaps in the information available and that further research is required to verify the findings [Committee On Toxicology, 2017] Furthermore, a recent publication from Public Health England (PHE) concluded "*The available evidence suggests that heated tobacco products may be considerably less harmful than tobacco cigarettes*", but "*more harmful than e-cigarettes*" [McNeill, 2018] Again PHE highlighted that more independent research is needed on THPs.

In the UK several public health agencies have advocated a potential role for Tobacco Heating Products in tobacco harm reduction.

substantiating risk

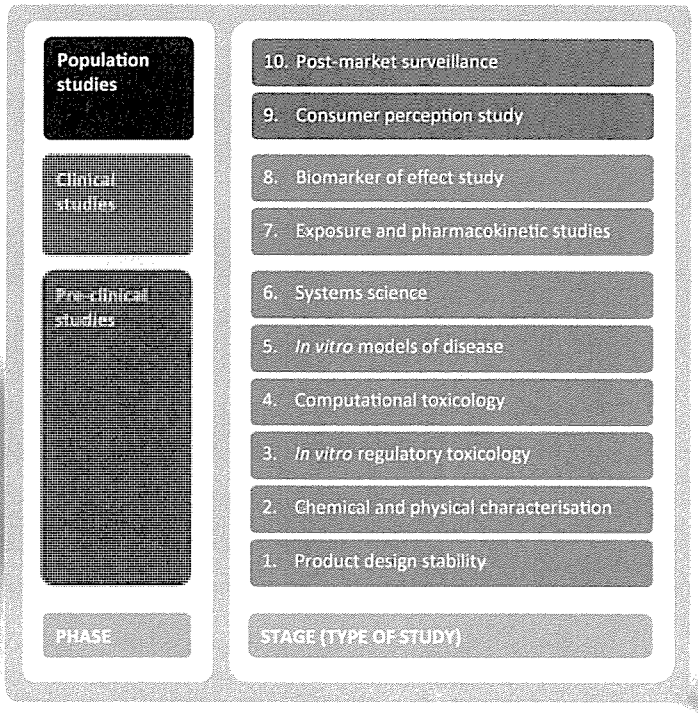
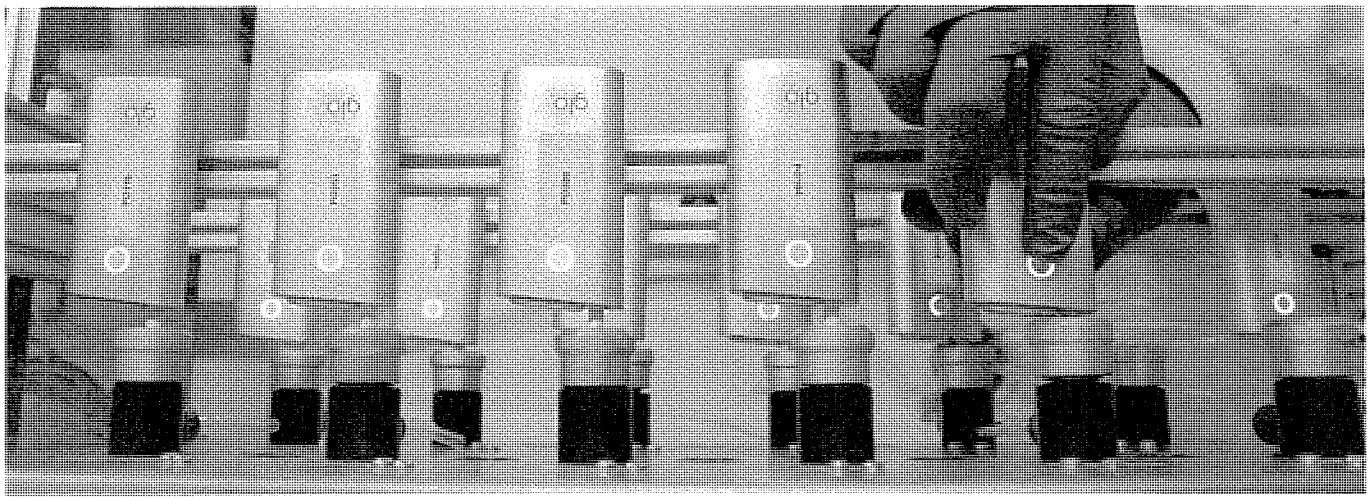


Figure 1/ Scientific framework for assessing the risk profile of glo

At British American Tobacco we risk assess all our next generation products before launch. In terms of THP consumables, ingredients are sourced at the high purity. Flavours are food grade as a minimum and any ingredient that is a carcinogen, a mutagen or a reproductive toxicant is excluded from recipes. Furthermore, regulations in the EU under the revised Tobacco Product Directive (TPD), require manufacturers to submit dossiers of information on their products disclosing ingredients and ensuring that electrical safety testing has been successfully completed and that the product has the requisite electrical safety certificates. Additionally, suitable device materials that do not leach chemicals during consumer use are selected to augment product safety.

Claims on these novel products such as 'reduced exposure' and 'reduced risk' should be substantiated using a weight of evidence approach based on a comprehensive scientific assessment. The US Food and Drug Administration (FDA), has provided draft guidance outlining a framework to assess novel products as Modified Risk Tobacco Products (MRTP) [FDA 2012]. In October 2017 the Italian government transposed the European Union Tobacco Products Directive (EU TPD) to include a regulatory framework, whereby [in a similar manner as the US] manufacturers could submit dossiers to potentially support [health-related] claims on heated tobacco products that could be printed on product packaging. Based on this, we previously proposed a scientific framework (Figure 1) comprising pre-clinical, clinical, and population studies to assess the risk profile of novel tobacco products [Murphy 2017].



TOXICOLOGICAL STUDIES

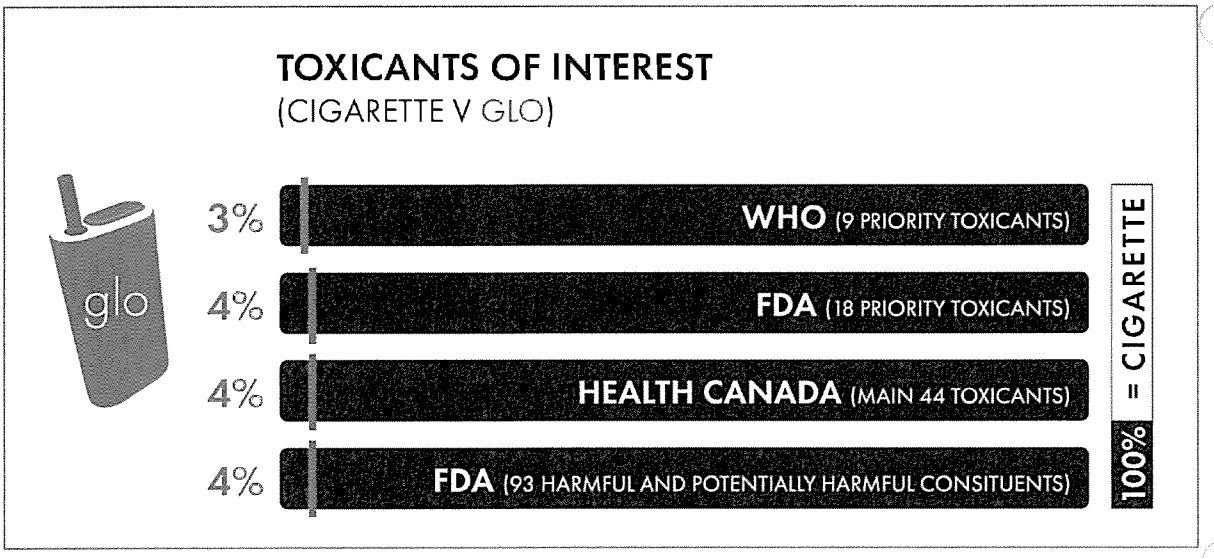


Figure 2/ Average reduction in toxicant levels in the aerosol of glo relative to a scientific reference cigarette

We have published a series of 10 papers to date, that describe both the operation of a new commercial THP (glo) and its assessment in a series of pre-clinical clinical and population based studies [Proctor 2018]. With no combustion and maximum heating of the tobacco to 240 °C ± 5 °C in glo, the tobacco consumable did not form any ash as is found with cigarette smoking [Eaton 2018]. The emissions of glo correspondingly showed around 90–95% fewer tested toxicants than those measured in cigarette smoke.[a] Furthermore, a range of analyses of physical properties concluded that the aerosol produced was respirable. [Forster 2018a] The environmental emissions were substantially reduced when consumers used glo compared with when they smoked cigarettes, to the extent that for the majority of measured constituents, the environmental emissions were at similar levels as those from the baseline measurements, when the consumers were not using any products. Furthermore, the PM10 measurement of the aerosol would conform with the recommended WHO outdoor air limit of 10 µg/m3. This reduction in environmental emissions led to a reduction in the tobacco odour on hands, hair and fabric being perceived from using glo compared with smoking cigarettes under a set of laboratory tests. The reduction in environmental emissions and tobacco odour with glo were measured versus both a flue-cured blended cigarette and US-blended cigarettes. [Forster 2018b] A series of *in vitro* toxicological studies indicated that glo was non-mutagenic, showed no tumour promotion activity [Thorne 2018] and elicited a substantially reduced cytotoxic response that was 97% reduced relative to the response from cigarette smoke [Jaunky 2018]. A separate study that used a high-content screening approach with eight end

a This is a comparison between the smoke from combusted tobacco in a 3R4F scientific reference cigarette (approximately 9 mg/cig 'tar'), and the vapour from heated tobacco in glo, in terms of the nine types of harmful components which the World Health Organisation recommends to reduce in cigarette smoke."

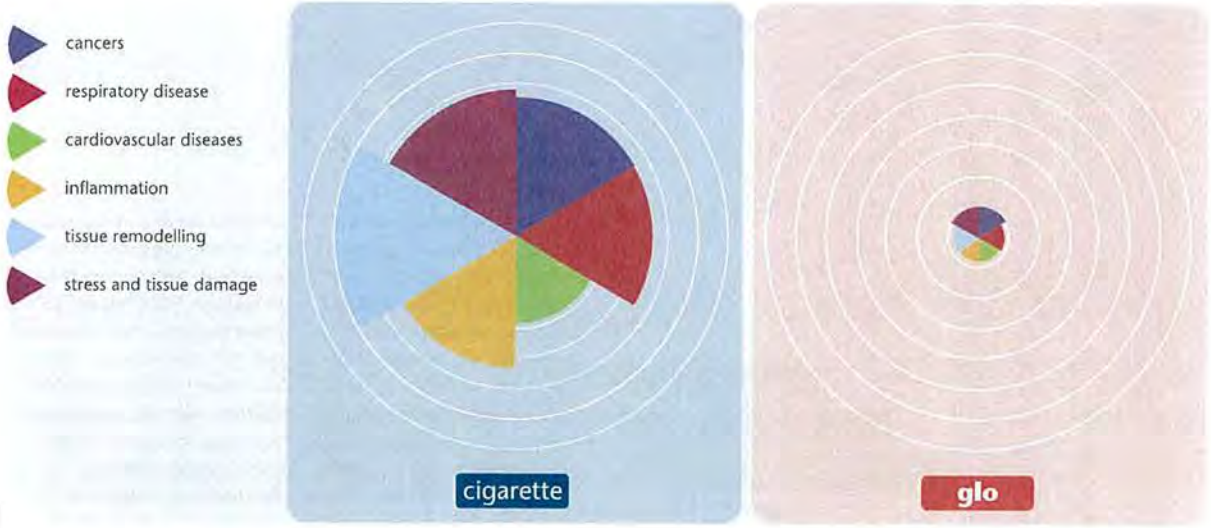


Figure 3/ In laboratory tests, glo promotes substantially less disease relevant gene changes in comparison to a scientific reference cigarette, 3R4F

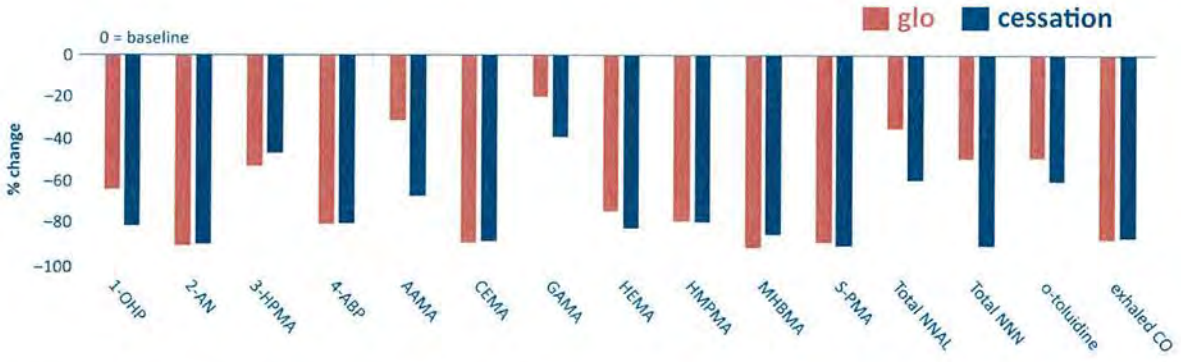
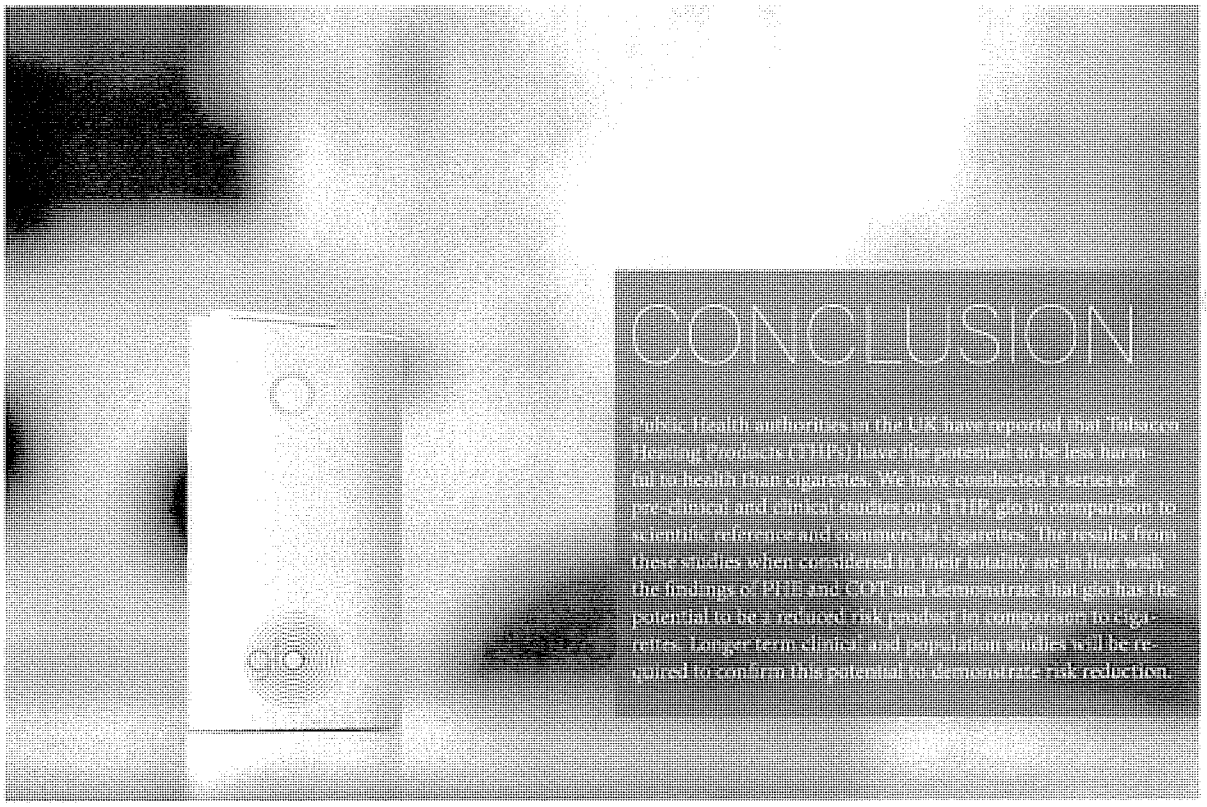


Figure 4/ Reduction in biomarkers of exposure for smokers who switched to glo or stop smoking completely (cessation) relative to continued smoking

points showed similar substantially reduced responses for glo relative to the cigarette control [Taylor 2018]. Furthermore, an *in vitro* systems biology assessment of glo showed that disease relevant mechanisms and endpoints were greatly reduced in comparison to cigarette smoke [Minet 2018]. Additionally, using the concept of the model risk continuum, the emissions and toxicological responses from glo were compared relative to cigarettes, other commercially available THPs and an e-cigarette [Murphy 2018]. The responses for glo in the studies were similar to the other Next Generation Products (the commercial THPs and the e-cigarette), which were all substantially reduced relative to the cigarettes [Murphy 2018]. Consumption levels were measured in Japan for smokers who switched to glo, in terms of the number of Neostik used daily. The number of Neostiks used daily, did not increase in comparison to their daily cigarette consumption before the switch [Gee 2018]. Furthermore, in two short term, week long clinical studies conducted in Japan [Gale 2018] and the UK [McEwan 2018], consumers uptake of nicotine was less when using glo in comparison to smoking, measured using pharmacokinetics, suggesting a lower abuse liability potential. Additionally, consumers were exposed to fewer toxicants when using glo in comparison with smoking, measured using biomarkers of exposure and in some cases, levels were reduced to

those observed when subjects stopped smoking completely [Gale 2018 and McEwan 2018]. We have recently commenced a year-long clinical study in the UK measuring consumer's exposure over a 90 day period and a variety of disease relevant risk indicators over a 360-day period, to assess individual potential risk reduction. Furthermore, a range of pre- and post-market studies are also required to substantiate them as products that can potentially reduce risk on a population level. It is anticipated that these would include risk perception studies and an assessment of the population's (current smokers, former smokers, never smokers etc) intention to use glo [Murphy 2017]. Furthermore, in the absence of epidemiology, analytical modelling techniques will also be used to assess the impact of glo on public health [Hill 2016].

a high-content screening approach with eight end-points showed similar substantially reduced responses for glo aerosol



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Food and Drug Administration (2012a). Guidance for industry modified risk tobacco product applications. Draft guidance. http://www.fda.gov/downloads/TobaccoProducts/GuidanceComplianceRegulatoryInformation/UCM297751.pdf.

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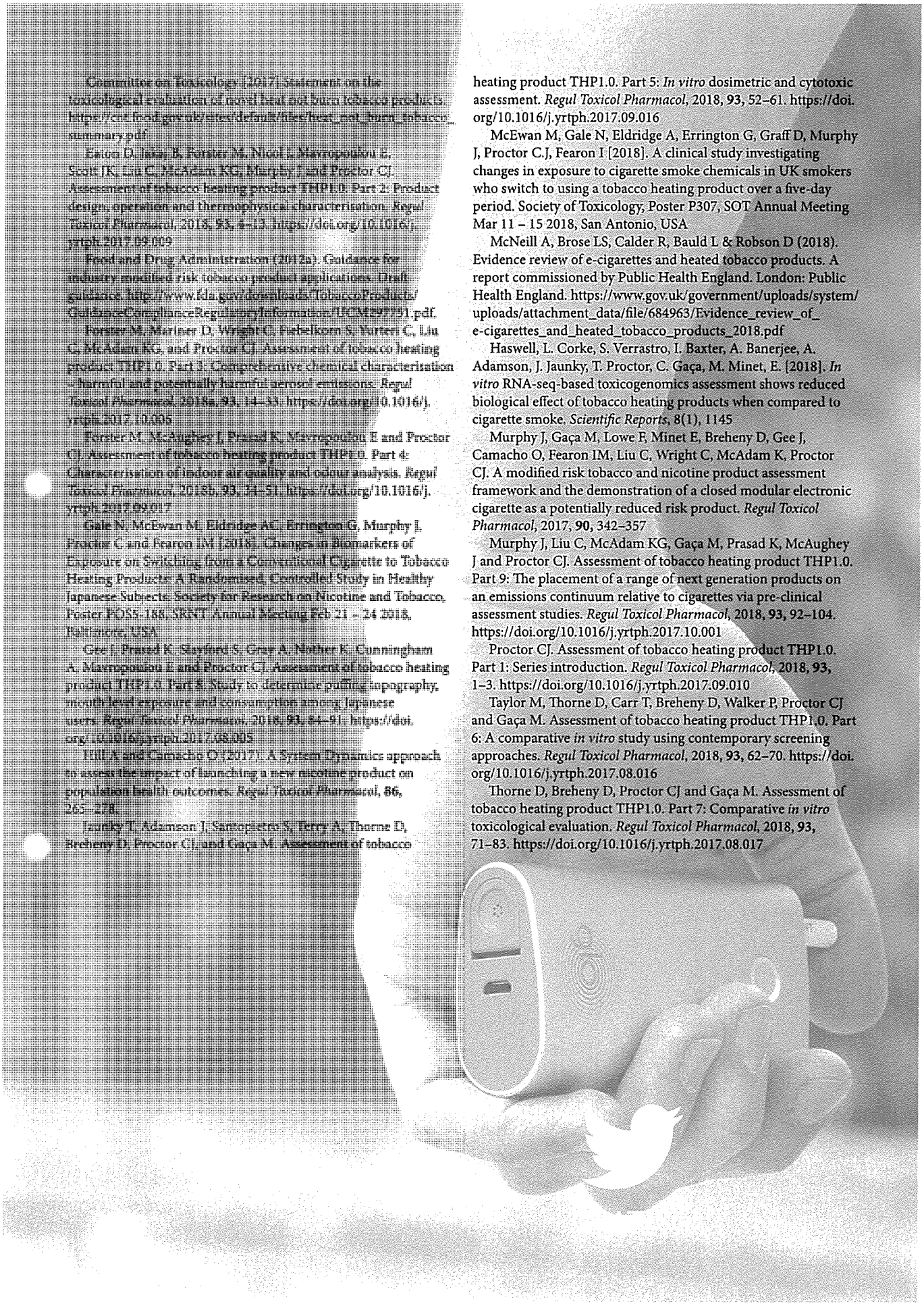
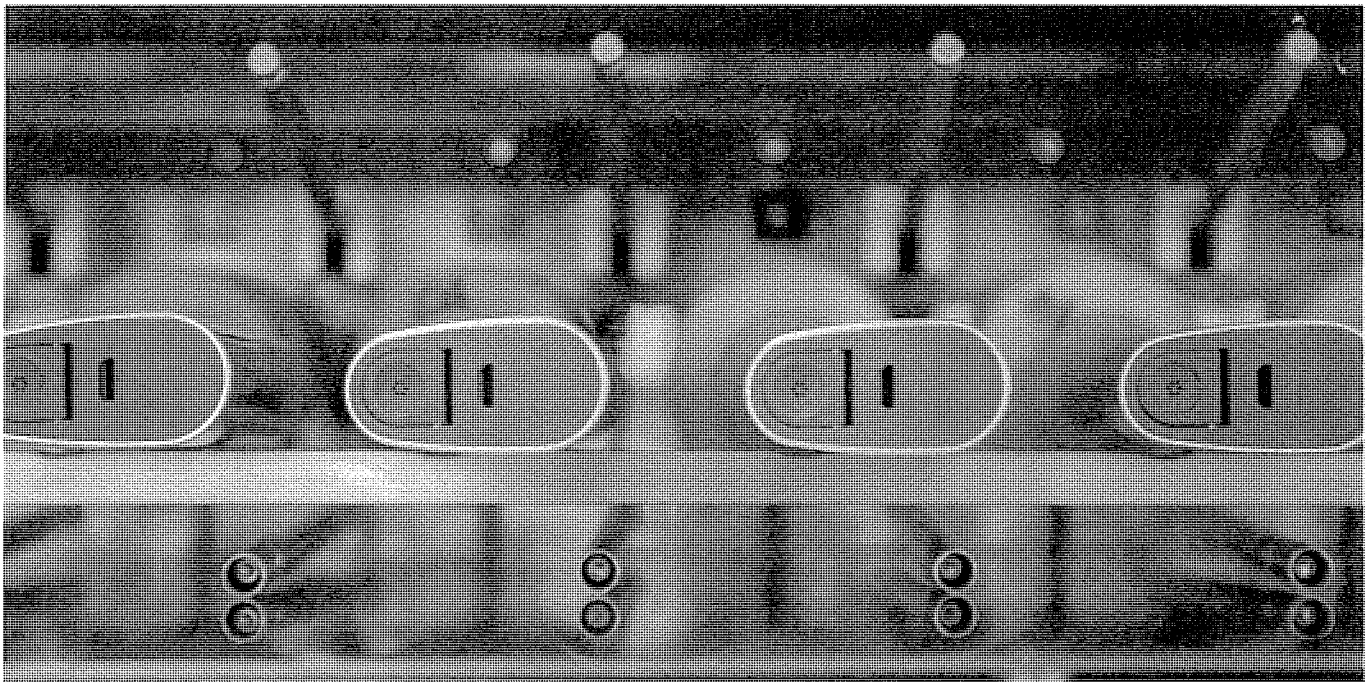


Tobacco Heating Products

glo: measurement of mainstream emissions

tobaccoscience.com



glo heats rather than combusts tobacco, forming much fewer individual compounds and lower levels of the toxicants associated with cigarette smoke.

what exactly is glo?

Cigarettes (Figure 1a) contain tobacco which when lit, combust at temperatures between 600 ~ 900 °C forming smoke which is comprised of greater than 6,500 individual compounds [Rodgman and Perfetti, 2013], of which about 150 are known as toxicants [Fowles and Dybing, 2003]. It is these toxicants which are the main drivers of smoking related diseases.

glo is a novel Tobacco Heating Product (THP), which comprises a tobacco consumable rod called a Neostik (Figure 1b), which is inserted into an electrical heating device (Figure 1c). glo heats the Neostik to a maximum temperature of 245 °C [Eaton, 2017], much below the temperature of cigarette combustion (>600 °C). It therefore heats rather than combusts the tobacco, forming much fewer individual compounds and lower levels of the toxicants associated with cigarette smoke.

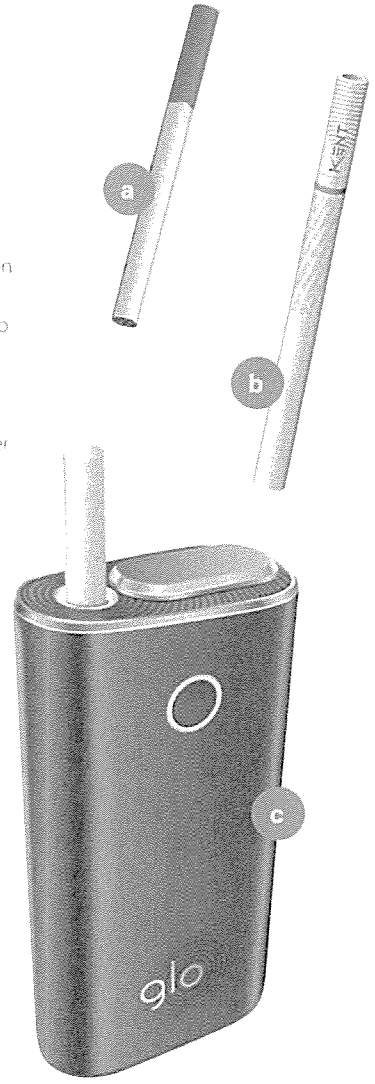
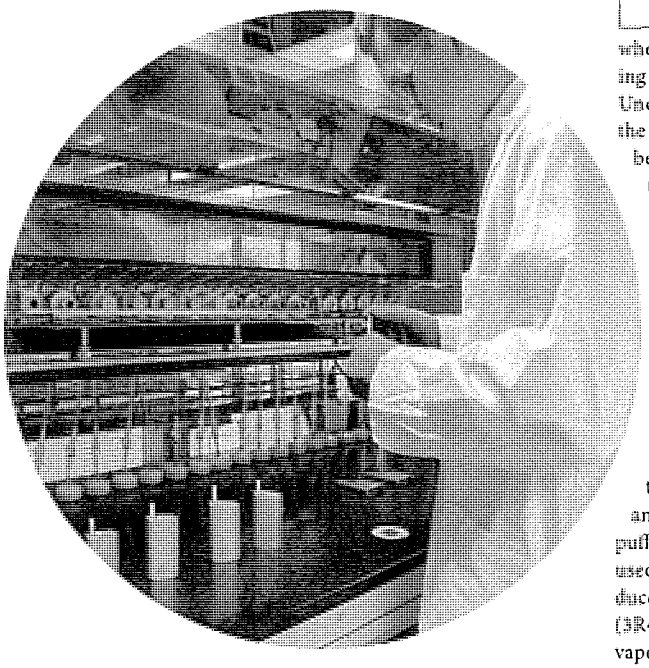


Figure 1/ Illustration of a) a cigarette, b) a Neostik and c) glo Tobacco Heating Product with a Neostik inserted in its heating chamber

PRODUCT	REGIME	PUFF VOLUME (ML)	PUFF DURATION (S)	PUFF INTERVAL (S)	VENTILATION OCCLUSION	REFERENCE
Standard puffing regime (ISO)						
3R4F	ISO	35	2	60	0%	[ISO 4387:2000]
glo	ISO*	35	2	60	0%	cf. [ISO 4387:2000]*
Intensive puffing regime (Health Canada Intense; HCI)						
3R4F	HCI	55	2	30	100%	[Health Canada 1999]
glo	HCI*	55	2	30	N/A	cf. [Health Canada 1999]*

*While there are no ISO and Health Canada methods for Tobacco Heating Products, these cigarette methodologies can be adapted to give comparative values for THPs

Table 1/ Summary of puffing regimens used for measuring the emissions from 3R4F cigarette and glo tobacco heating product



MEASURING EMISSIONS

Emissions refer to what is emitted by a product (be it smoke or vapour) when that product is being used (smoked or vaped). Understanding what is in the emissions is important because it gives an indication of what a person may be exposed to when they use the product.

Emissions are measured using laboratory based puffing engines programmed to operate according to a specific plan, or "puffing regime", that prescribes the frequency of puffs, the duration of each puff and the size/volume of the puff. The puffing machines are used to collect smoke produced by a reference cigarette (3R4F) and heated tobacco vapour from glo. There are two standard puffing regimes that are widely used, the International Standards Organisation (ISO) puffing regime, and a so-called intensive puffing regime designed by Health Canada (Table 1). The Health Canada Intense (HCI) regime may be considered to reflect extreme consumer use for cigarette smoking. This method is in regulatory usage today for reporting cigarette smoke yields in Canada. Mainstream cigarette smoke yields are often printed on cigarette packs, summarizing the emissions of Nicotine Free Dry Particulate Matter (NFDPM -, sometimes referred to as 'tar' for cigarettes), nicotine and Carbon Monoxide. These emissions are measured using laboratory based smoke machines set at the ISO puffing regime (Table 1). There are currently no standard methods for measuring Tobacco Heating Product emissions, though glo can be measured using these regimes for comparative purposes. Some adaptation of these regimes are required when testing non-combustible products, for example lighting steps do not apply and ventilation blocking may not be possible due to device construction. When modified the regimes are denoted with a "-m".

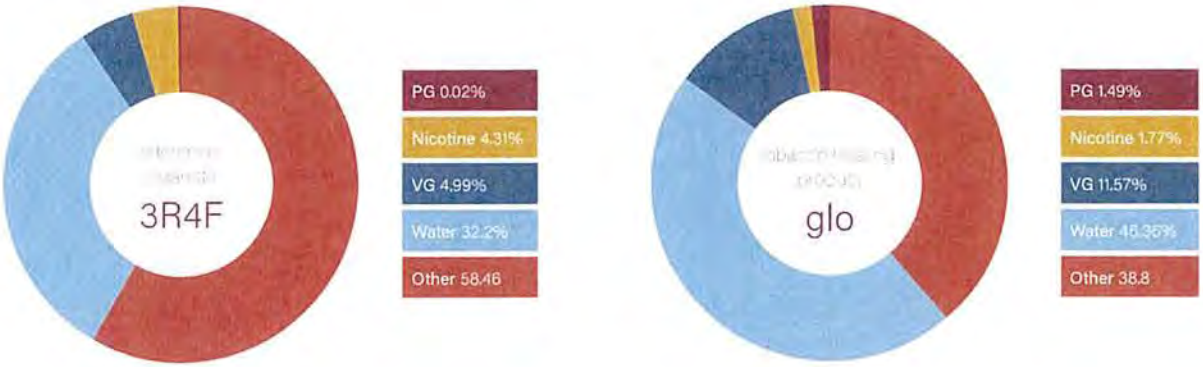


Figure 2/ Composition of the emissions from 3R4F smoke and glo tobacco vapour measured at the HCI machine puffing regimen

MAINSTREAM AEROSOL EMISSIONS

A comparison of the emissions was made between a reference cigarette, 3R4F (smoke) and glo (heated tobacco vapour) using the ISO machine puffing regimen; the data are shown in Table 2.

Cigarette smoke has quantifiable levels of NFDPM, nicotine and carbon monoxide as shown in Table 2. The levels of CO in particular from the reference cigarette demonstrates that combustion has occurred. glo on the otherhand, does not combust tobacco and while NFDPM and nicotine can be quantified, there is no detectable level of the combustion gas carbon monoxide in the aerosol as no combustion has occurred*.

Table 3 provides a comparison of a wider group of emissions from 3R4F smoke and the glo heated tobacco vapour using the more intensive HCI regime [Murphy 2017]. The results are outlined below and include information on the water, nicotine, Glycerol, Propylene Glycol and total particle content (TPM) of the aerosols.

A major difference between the ingredients in a cigarette and the Neostik is the amount of glycerol and propylene glycol used for the Tobacco Heating Product. These compounds distill into cigarette smoke and into glo vapour when the products are used. This and the fact that glo heats rather than burns tobacco suggests that the heated tobacco vapour produced by glo is very different to the smoke produced by burning a cigarette, as illustrated in Figure 3.

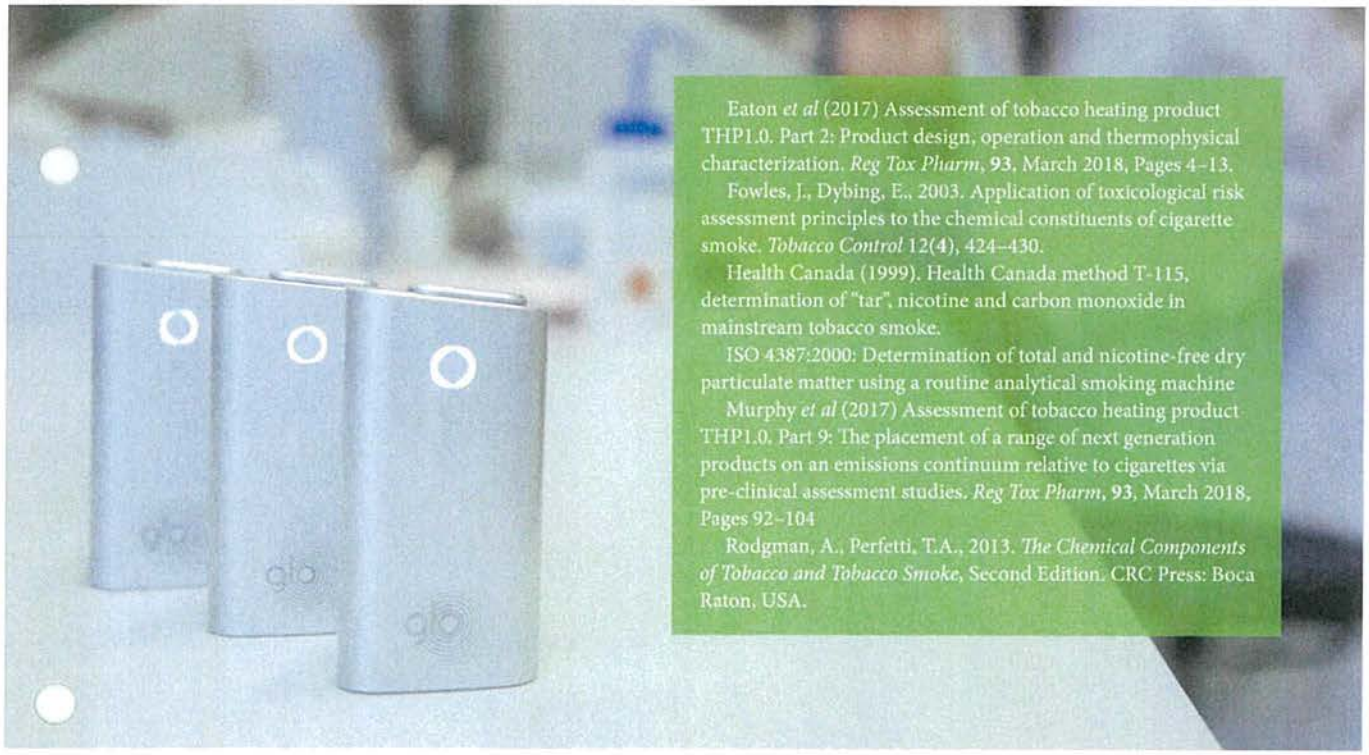
PRODUCT	NFDPM (mg/stick)	NICOTINE (mg/stick)	CARBON MONOXIDE (mg/stick)
3R4F	9.4	0.7	12
glo	4.1	0.15	Below Detection Limit

Table 2/ Emissions from a 3R4F cigarette and glo using the ISO puffing regimen

* Figure 2 illustrates the particulate part of the different aerosols measured under ISO conditions

PRODUCT	TPM (mg/stick)	OTHER (mg/stick)	WATER (mg/stick)	NICOTINE (mg/stick)	GLYCEROL (mg/stick)	PROPYLENE GLYCOL (mg/stick)	CARBON MONOXIDE (mg/stick)
3R4F	46.9	27.42	15.1	2.02	2.34	0.02	32
glo	26.1	10.13	12.1	0.46	3.02	0.39	Not quantified

Table 3/ Mainstream aerosol yields from 3R4F cigarette and glo tobacco heating product measured under an intense puffing regime



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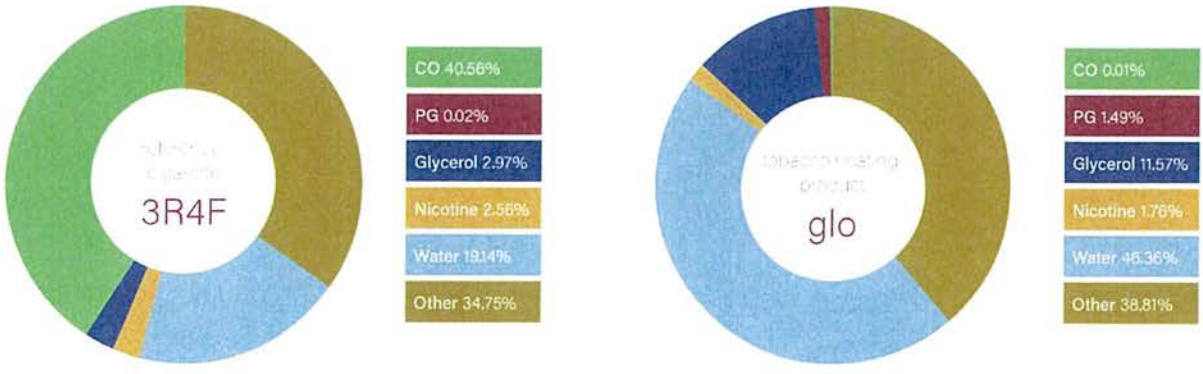

Figure 3/ Composition of the emissions from 3R4F smoke and glo tobacco vapour measured at the HCI machine puffing regimen (inclusive of Carbon Monoxide, CO)

@BAT_Sci

What is cigarette tar?

The "tar" content stated on cigarette packs in some jurisdictions is the amount of nicotine free dry particulate matter (NFDPM) that a cigarette produces when it is smoked by a smoking machine under a set of ISO specified conditions. NFDPM is measured and then reported on a per cigarette basis according to ISO 4387 standard.[1] The ISO standard is very clear about the purpose of measuring NFDPM by stating:

"This method is a machine method and allows cigarettes to be smoked using a strictly controlled set of parameters. Thus, it enables the NFDPM and nicotine from cigarettes, when smoked by this procedure, to be compared and ranked on the basis of machine yield."

Strictly speaking, NFDPM from a cigarette is only called "tar" when it is measured by ISO 4387; NFDPM values measured by any other conditions are just NFDPM values, and cannot be called "tar".

ISO 4387 standard also contains some important caveats:

"No machine smoking regime can represent all human smoking behaviours;"

This approach is similar to car emission testing under standard laboratory conditions, which does not reflect real emission levels a driver may get in real life situation.

And:

"machine smoking testing is useful to characterise cigarette emissions for design and regulatory purposes, but communication of machine measurements to smokers can result in misunderstanding about differences in exposure and risk across brands;"

Indeed, to avoid misinterpretation of cigarette smoke ISO NFDPM (tar) content by consumers, the EU requires its reporting for cigarette to ensure that the maximum level authorised is not exceeded (10 mg)[2] but does not allow disclosure of this information on the pack to avoid misunderstanding by consumers on the relative health hazards of different cigarette.[3]

Why the "tar" terminology should not apply to tobacco heating products like glo™?

The ISO 4387 standard clearly states that NFDPM for cigarette smoke is sometimes referred to as "tar" and this terminology has indeed been widely used to describe cigarette smoke in the scientific literature and public media. We do not believe the aerosol produced by a tobacco heating product like glo™ should be described as "tar" for the following reasons.

- An internationally developed equivalent of ISO4387 for tobacco heating products currently does not exit. It is technically incorrect to simply apply a test method for a cigarette to another type of products without adequate consideration of the purpose of the test, the product design, and the nature of the aerosol produced. For example, ISO4387 clearly defines the number of puffs a cigarette will produce under the test condition, judged by the so-called "butt mark". There are other technical details in ISO4387 that cannot be directly copied to test a tobacco heating product, and different test laboratories may choose to interpret these details differently, hence leading in different test results.
- "Tar" from cigarettes is well a studied and characterised chemical entity in scientific literature. Using the term "tar" to describe the aerosol produced from a tobacco heating product like glo™ would falsely imply that these products are capable of producing cigarette

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[1] *ISO 4387: Cigarettes — Determination of total and nicotine-free dry particulate matter using a routine analytical smoking machine*

[2] *DIRECTIVE 2014/40/EU, Article 3, paragraph 1(a)*

[3] *DIRECTIVE 2014/40/EU, Article 13, paragraph 1(a)*

smoke which they are not. Several scientific publications[4,5], including a recent independent study[6], demonstrated that the composition of NFDPM for cigarette smoke and tobacco heating product emissions is fundamentally different. Chemically, harmful and potentially harmful constituents found in tobacco heating products are much lower (50-90%)[7] as compared to cigarette smoke which suggests the aerosol formation process is fundamentally different. Furthermore, laboratory results have shown that the aerosol produced by glo™ has a very different biological effects as compared to cigarette smoke.[8 9 10]

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[4] *Jaccard G et al., Regulatory Toxicology and Pharmacology 90 (2017) 1e8*
[5] *Forster M et al, Regulatory Toxicology and Pharmacology 93 (2018) 14e33*
[6] *Li X et al, https://academic.oup.com/ntr/advance-article-abstract/doi/10.1093/ntr/nty005/4793230*
[7] *Committee on toxicity*
[8] *Jaunky T et al, Regulatory Toxicology and Pharmacology 93 (2018) 52e61*
[9] *Taylor M et al, Regulatory Toxicology and Pharmacology 93 (2018) 62e70*
[10] *Thorne D et al, Regulatory Toxicology and Pharmacology 93 (2018) 71e83*