



25 May 2019



# SUBMISSION TO THE CONSULTATION ON THE LEGISLATIVE PROPOSAL AMENDING THE TOBACCO AND SMOKING GOODS LAW TO EXTEND SMOKING BAN

Japan Tobacco International (**JTI**) is a leading international tobacco company with operations in more than 130 countries. It is the global owner of both Winston, the number two cigarette brand in the world, and Camel, outside the USA and has the largest share in sales for both brands. Other global brands include Mevius and LD. With its internationally recognized brand Logic, JTI is also a major player in the electronic cigarette market and has, since 2011, been present in the heated tobacco category with Ploom. Headquartered in Geneva, Switzerland, JTI employs close to 45,000 people and was awarded Global Top Employer for five consecutive years. JTI is a member of the Japan Tobacco Group of Companies. For more information, visit [www.jti.com](http://www.jti.com).

# 1. Introduction

1.1 JTI welcomes the opportunity to respond to the Ministry of Health's (**MoH**) Internet Consultation on the Legislative proposal amending the Tobacco and Smoking Goods Law to extend the smoking ban (**the Consultation**).

1.2 The MoH proposes to amend the Tobacco and Smoking Goods Law to extend the scope of products to be prohibited for use in all governmental and public institutions and services, hotels, restaurants, cafes, workplaces, public transport as well as subsidized institutions, such as those in the fields of health, charity, education, arts, culture and sports to include electronic cigarettes, heated tobacco products and other tobacco products for oral use.

1.3 JTI is of the view that electronic cigarettes, heated tobacco products and tobacco products for oral use have the potential to reduce the risk associated with smoking and should be treated differently from combustible products in regulatory treatment including restrictions on use in public places.

1.4 We believe that any regulation should be based on objective scientific evidence. In this regard, the proposed amendments are based on a weak rationale and ignore a wide range of available scientific evidence.

1.5 In this Submission, JTI therefore focuses on the factual evidence related to the Legislative proposal amending the Tobacco and Smoking Goods Law to extend the smoking ban and addresses the followings:

**Part 2:** Executive summary

**Part 3:** Evidence presented by the MoH and additional evidence to be considered

**Part 4:** A better way forward

## 2. Executive summary

2.1 JTI believes that minors should not smoke or use and should not have access to tobacco products or any other related products including electronic cigarettes. Therefore, we are committed to prevent youth smoking in the Netherlands and elsewhere.

2.2 As a responsible company, JTI is open and transparent in its dialogue with government authorities around the world regarding the regulation of products that it makes and sells.

2.3 In line with the Better Regulation principles that both JTI and the Dutch Government support, we propose more rational, proportionate and targeted alternative measures where we believe a regulatory proposal is flawed and is based on flawed, speculative evidence.

2.4 JTI believes that vaping should be differentiated from smoking in regulatory treatments including use of those products in public places, since there is a significant difference between smoking and vaping, and electronic cigarettes and heated tobacco products have the potential to reduce the risk associated with smoking.

2.5 In this regard, JTI is opposed to proposed amendment extend the scope of products to be prohibited for use in predetermined public places to include electronic cigarettes, heated tobacco products and other tobacco products for oral use.

2.6 Evidence presented by the MoH does not justify proposed measures to ban use of electronic cigarettes and heated tobacco products in public places.

- The MoH hasn't examined a wide range of available evidence such as Public Health England, the Science and Technology Committee of the UK House of Commons and other governments'

health authorities concerning the health consequences of the use of electronic cigarettes, the effect of electronic cigarettes on bystanders and their potential gateway effects<sup>1,2,3,4</sup>.

- Assertion that “See smoking, do smoking” cannot justify ban on vaping in facilities exclusively intended for adults such as workplaces, bars and pubs.
- Prevention of maintained addiction could also not be a justification to support prohibition on use of tobacco for oral use, snus and electronic cigarettes in public places.

2.7 Considering the difference between smoking and vaping, the manager or owner of the buildings should have a discretion to decide if vaping is permitted in enclosed places at the buildings, depending on the purpose and nature of their buildings. Regulations should require the manager or owner of the buildings to take appropriate measures to inform people at the building if vaping is or is not permitted to inform people in the facility about use or non-use of those products.

2.8 Youth access prevention could not be achieved by simply expanding the current scope of smoking ban. Better enforcement of measures to prevent minors from purchasing and having access to electronic cigarettes and heated tobacco products would be more effective. Such measures could include: (i) establishment of rigorous age verification system; (ii) establishment of an effective licensing and registration system for anyone selling e-cigarettes and heated tobacco products; (iii) setting or increasing the penalties against suppliers or retailers that have been found to conduct illegal sales, and (vi) restricting the sale of electronic cigarettes via internet to manufacturers only to ensure clear responsibility in the effectiveness of age verification systems.

### 3. Evidence presented by the MoH and additional evidence to be considered

3.1 In the General Notes (**Notes**), the MoH provides some justifications to expand the scope of products to be prohibited for use in public places to include electronic cigarettes, heated tobacco products and even other tobacco products for oral use. The justifications can be summarized as follows:

- I. harmfulness of use of electronic cigarettes;
- II. harmful effect of electronic cigarettes on bystanders;
- III. assertion that “See smoking, do smoking”;
- IV. gateway effect of electronic cigarettes leading to smoking; and
- V. maintained addiction when non-combustible products with nicotine are allowed for use.

3.2 Hereafter, we provide our views on those points in this part.

#### ***Harmfulness of use of electronic cigarettes***

3.3 The Notes state in the 3rd paragraph of the Section 5 that “*Research carried out by RIVM in 2015 shows that e-cigarettes are harmful for the user*”.

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<sup>1</sup> See page 20 of the report commissioned by Public Health England (February 2018) and available at: [https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment\\_data/file/684963/Evidence\\_review\\_of\\_e-cigarettes\\_and\\_heated\\_tobacco\\_products\\_2018.pdf](https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/684963/Evidence_review_of_e-cigarettes_and_heated_tobacco_products_2018.pdf)

<sup>2</sup> See page 15 of the report by the Science and Technology Committee of the UK House of Commons (August 2018) and available at: <https://publications.parliament.uk/pa/cm201719/cmselect/cmsctech/505/505.pdf>.

<sup>3</sup> See “*Impact Statement: Supporting smokers to switch to significantly less harmful alternatives*” (January 2019), page 7. Available at: [https://www.health.govt.nz/system/files/documents/pages/ris-support-smokers-to\\_switch-to-alternatives-jan-2019.pdf](https://www.health.govt.nz/system/files/documents/pages/ris-support-smokers-to_switch-to-alternatives-jan-2019.pdf).

<sup>4</sup> See page 2 of Proposal for the Regulation of Vaping Products, document for Consultation (August 2017) and available at: <https://www.canada.ca/content/dam/hc-sc/documents/programs/consultation-regulation-vaping-products/pub1-eng.pdf>

3.4 JTI agrees that electronic cigarettes are not risk-free. However, we believe that electronic cigarettes have the potential to reduce the risk associated with smoking. For example, Logic Compact that is the JTI's latest electronic cigarette brand has a product characteristic of '95% reduction in 9 toxic substances'.<sup>5</sup> We believe Logic Compact has a strong potential to be a reduced risk product, having a 95% reduction in the constituents recommended by WHO for reduction in cigarette smoke.

3.5 The views that electronic cigarettes are likely to be less harmful have been increasingly supported by public health institutions and authoritative bodies all over the world. For instance, the Science and Technology Committee of the UK House of Commons published its report on e-cigarettes in August 2018 stating that *"There is clear evidence that e-cigarettes are substantially less harmful than conventional cigarettes"*.<sup>6</sup>

3.6 Public Health England also stated in a report titled 'Evidence review of e-cigarettes and heated tobacco products 2018' that *"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"*.<sup>7</sup>

3.7 It is notable that in New Zealand, the sale and import of electronic cigarettes with nicotine have been legalized in May 2018, and the Government has been working on creation of regulatory framework for electronic cigarettes. The New Zealand Ministry of Health itself acknowledges the reduced-risk potential of electronic cigarettes in an Impact Statement that was published in January 2019, mentioning that *"it is clear that vaping is significantly less harmful than smoking"*.<sup>8</sup> In Canada, the sale and import of nicotine containing electronic cigarettes have been also legalized since May 2018. Health Canada stated in a document for consultation published in August 2017 that *"The opportunity presented by vaping products is that they may provide adult smokers with a less harmful alternative to tobacco"*.<sup>9</sup>

3.8 The MoH should examine a wide range of available evidence to make a balanced decision on regulations on electronic cigarettes.

### ***Harmful effect of electronic cigarettes on bystanders***

3.9 The Notes state in the 3rd paragraph of the Section 5 that *"In 2016, RIVM published a study into the harmful effects of e-cigarettes on bystanders. In this, RIVM states that with the use of e-cigarettes, harmful substances are exhaled, such as propylene glycol, nicotine and nitrosamines"*.

3.10 The Notes refer to a RIVM Letter Report titled 'The health risk of e-cigarettes for bystanders' published in 2016 (***RIVM report***)<sup>10</sup>. A study conducted in the RIVM report examined the exhaled air of a number of volunteers, ranging from samples of 3 volunteers for metal analyses, 4 volunteers for aldehyde analyses, 9 volunteers for TSNA analyses and 17 volunteers for nicotine and humectants analyses for each chemical. It performed risk assessment by setting a car scenario and an office scenario with the following conditions:

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<sup>5</sup> Based on the comparison of 9 harmful constituents, recommended for reduction by the World Health Organization in Cigarette Smoke, measured in the smoke of a standard reference cigarette (3R4F) versus the vapor from Logic Compact. Use of this product does not mean it is necessarily safer than smoking regular cigarettes.

<sup>6</sup> See page 15 of the report by the Science and Technology Committee of the UK House of Commons (August 2018) and available at: <https://publications.parliament.uk/pa/cm201719/cmselect/cmsctech/505/505.pdf>.

<sup>7</sup> See page 20 of the report commissioned by Public Health England (February 2018) and available at: [https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment\\_data/file/684963/Evidence\\_review\\_of\\_e-cigarettes\\_and\\_heated\\_tobacco\\_products\\_2018.pdf](https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/684963/Evidence_review_of_e-cigarettes_and_heated_tobacco_products_2018.pdf)

<sup>8</sup> See *"Impact Statement: Supporting smokers to switch to significantly less harmful alternatives"* (January 2019), page 7. available at: [https://www.health.govt.nz/system/files/documents/pages/ris-support-smokers-to\\_switch-to-alternatives-jan-2019.pdf](https://www.health.govt.nz/system/files/documents/pages/ris-support-smokers-to_switch-to-alternatives-jan-2019.pdf).

<sup>9</sup> See page 2 of Proposal for the Regulation of Vaping Products, a document for Consultation (August 2017) and available at: <https://www.canada.ca/content/dam/hc-sc/documents/programs/consultation-regulation-vaping-products/pub1-eng.pdf>

<sup>10</sup> See the RIVM Letter Report titled *'The health risks of e-cigarettes for bystanders, 2016'* by Visser et al. and available at: <https://www.rivm.nl/bibliotheek/rapporten/2016-0036.pdf>

Table 1 Parameter settings of the two predefined scenarios used for risk assessment used in the study in the RIVM Report

Parameter	Scenario 1 - Car	Scenario 2 - Office
Number of persons vaping	2	1
Puffing frequency	0.5 min <sup>-1</sup>	2 min <sup>-1</sup>
Total vaping time *	1 h	4 h
Volume of car / office space	2 m <sup>3</sup>	30 m <sup>3</sup>
Ventilation	No	Yes; 0.5 h <sup>-1</sup>

\* exposure duration of the bystander is considered similar to total vaping time

3.11 The RIVM report stated that only the highest amount was selected for risk assessment to consider worst-case scenario and also stated in terms of propylene glycol in page 76 that it *“could not be detected in the exhaled air of 13 of the 17 volunteers”*. The RIVM report also acknowledged that *“In order to identify possible health risks of e-cigarettes to bystanders, two scenarios were defined in which relatively high levels of exposure to bystanders occur but that are not unrealistic”*. It concluded in page 86 that, for car scenario, *“it cannot be excluded that local effects on the respiratory tract and eyes upon exposure to propylene glycol will occur for the bystander. However, it is expected that effects, if they occur, are mild”*. Even in extreme scenario, the effect of exposure of propylene glycol to bystanders was not clearly identified.

3.12 The RIVM report also concluded in page 84 that *“Bystander exposure to nicotine might result in adverse health effects such as increased heart rate and increased systolic blood pressure for the child in scenario 1. The increase in heart rate is expected to be smaller than 10 beats/min and the increase in systolic blood pressure might be similar to that induced by caffeine when drinking two to three cups of coffee in these scenarios”*.

3.13 However, as described in page 69 in the RIVM report, *“The available toxicological (inhalation) data for nicotine are very limited”*. Indeed, although nicotine is a toxic compound, nicotine intoxications are rare<sup>11</sup>. Evidence from nicotine replacement therapy help us to understand the effects of nicotine<sup>12,13</sup>. At commonly used dose levels, short-term nicotine use does not result in clinically significant harm. The available scientific evidence on the use of nicotine does not indicate long-term adverse effects on health<sup>14</sup>. In addition, no scientific evidence supports the notion that the levels of nicotine absorbed from “passive vaping” produce any biological effect. An abundance of literature dating back some 20 years does not indicate any harmful effect of nicotine when given in its pure form by inhalation<sup>15</sup>.

3.14 The RIVM report also referred to tobacco-specific nitrosamines (TSNA), concluding in page 84 that *“For e-liquids containing significant amounts of TSNAs, increased incidences of tumors in the respiratory tract upon exposure to tobacco-specific nitrosamines cannot be excluded for the child in scenario 1”*.

3.15 As described in page 82, *“e-liquids were selected that we previously found to yield relatively high vapor concentrations of aldehydes, TSNAs, metals and nicotine”* to ensure a worst-case assessment. The RIVM also acknowledged in page 83 that *“TSNAs may occur as impurities in ingredients used by manufacturers of e-liquids, most notably in nicotine”* and that *“Most e-liquids currently available on the Dutch market do not contain significant amounts of TSNAs”*, since the new European Tobacco Product Directive does not permit the presence of compounds that are harmful to human health in e-liquids if this can be avoided.

3.16 There is a possibility that the e-liquid with high amount of TSNAs did not fully comply with European Tobacco Product Directive or had a low quality without passing rigorous product standards conducted voluntarily by manufacturers. This matter should be addressed by enforcing that e-liquids may not contain

<sup>11</sup> See ‘How much nicotine kills a human? Tracing back the generally accepted lethal dose to dubious self-experiments in the nineteenth century’ by Mayer, B., pages 5-7, Archives of Toxicology 88 (2014).

<sup>12</sup> See ‘A systematic review of possible serious adverse health effects of nicotine replacement therapy’ by a Lee, P.N., and Fariss, M.W., pages 1565-1594, Arch Toxicol 91 (2017).

<sup>13</sup> See ‘Cardiovascular toxicity of nicotine: Implications for electronic cigarette use’ by Benowitz, N. L., & Burbank, A. D., pages 515–523, Trends in Cardiovascular Medicine, 26(6) (2016).

<sup>14</sup> See ‘Long-term nicotine replacement therapy: cancer risk in context’ by Shields PG., pages 1719–23, Cancer Prev Res 2011;4.

<sup>15</sup> See ‘Comprehensive review of epidemiological and animal studies on the potential carcinogenic effects of nicotine per se.’ by Hausmann, H.J., and Fariss, M.W., pages 701-734, Critical reviews in toxicology 2016 Sep;46(8). The authors conclude that *“[o]verall, taking the human and animal studies into consideration, there appears to be inadequate evidence to conclude that nicotine per se does or does not cause or modulate carcinogenesis in humans. This conclusion is in agreement with the recent US Surgeon General’s 2014 report on the health consequences of nicotine exposure.”*

detectable amounts of TSNAs, in accordance with the European Tobacco Product Directive, instead of simply expanding the scope of products to be prohibited for use in public places to include electronic cigarettes.

3.17 In a test conducted by JTI to assess the indoor air quality after the use of Logic Compact in comparison to ambient air in an environmentally controlled chamber, all of the four TSNAs remained at background levels when measurements were taken in the empty chamber, in any of the air samples when 2, 4 and 8 volunteers vaped inside the chamber<sup>16</sup>.

3.18 In addition, the Science and Technology Committee of the UK House of Commons stated in the report on e-cigarettes published in August 2018 that *“Researchers have found it almost impossible to measure the risks from ‘second-hand’ e-cigarette vapour because any potentially harmful compounds released into the surrounding area are so negligible”* and concluded that *“second-hand vapour does not cause harm”*<sup>17</sup>.

3.19 JTI is of the view that the MoH does not provide enough evidence to justify proposed regulations to ban vaping in public places in the same manner as smoking.

### **Assertion that “See smoking, do smoking”**

3.20 The Notes state in the 2nd paragraph of the Section 3 that *“there is evidence from various perspectives for the assertion “See smoking, do smoking”. The assertion is supported by several behavioural theories”*. The Notes suggest that vaping should be prohibited in public places to prevent young people from initiating use of electronic cigarettes. However, it cannot justify ban on vaping in facilities intended for use by adults such as workplaces, bars and pubs.

3.21 JTI fully agrees that minors should not use electronic cigarettes. This could be achieved by a mechanism with appropriate enforcement system to prevent minors from purchasing and having access to electronic cigarettes, instead of simply expanding the scope of the current smoking ban.

### **Gateway effect of electronic cigarettes leading to smoking**

3.22 The Notes state in the 2nd paragraph of the Section 3 that *“More and more international research indicates that the use of an e-cigarette can be a stepping-stone towards smoking tobacco cigarettes”*.

3.23 However, available evidence that denies the existence of a gateway effect of electronic cigarettes to traditional cigarettes. For example, the Royal College of Physicians in the UK is of the view that *“E-cigarettes are not a gateway to smoking”*<sup>18</sup>. In its report published in April 2016, it was also stated that *“E-cigarettes are used almost exclusively by smokers who are trying to cut down or quit smoking, or who have quit smoking. Among adults, use by non-smokers is extremely rare. A higher proportion of non-smoking children than adults have experimented with e-cigarettes, but most of those who do have smoked in the past, or are current smokers”*<sup>19</sup>.

3.24 In addition, in a written evidence submitted by Public Health England and the Medicines and Healthcare products Regulatory Agency in December 2017, they concluded that *“British youth experiment with e-cigarettes but regular use is rare and very largely confined to young people who have smoked. There is some evidence that young people who have vaped but never smoked are more likely subsequently to smoke but there is no evidence that this relationship is causal. The UK has good data on this issue from surveys”*<sup>20</sup>.

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<sup>16</sup> See the test result conducted by JTI published on our science web page at [JT-Science.com](https://www.jti-science.com/sites/default/files/2019-04/2019-p1.pdf) and available at: <https://www.jti-science.com/sites/default/files/2019-04/2019-p1.pdf>

<sup>17</sup> See pages 15 and 26 of the report by the Science and Technology Committee of the UK House of Commons (August 2018) and available at: <https://publications.parliament.uk/pa/cm201719/cmselect/cmsctech/505/505.pdf>.

<sup>18</sup> See the website of Royal College of Physicians at: <https://www.rcplondon.ac.uk/news/promote-e-cigarettes-widely-substitute-smoking-says-new-rcp-report>

<sup>19</sup> See page 186 of *‘Nicotine without smoke – Tobacco harm reduction’* by the Tobacco Advisory Group of the Royal College of Physicians (April 2016) and available at: <https://www.rcplondon.ac.uk/projects/outputs/nicotine-without-smoke-tobacco-harm-reduction-0>

<sup>20</sup> See Written evidence submitted by Public Health England and the Medicines and Healthcare products Regulatory Agency (ECG0081) and available at: <http://data.parliament.uk/writtenevidence/committeeevidence.svc/evidencedocument/science-and-technology-committee/ecigarettes/written/75386.html>



### ***Maintained addiction when non-combustible products with nicotine are allowed for use***

3.25 The Notes also propose to bring tobacco for oral use and snus under the current smoking ban, stating in the 5th paragraph that *“these products can be used in places where smoking is prohibited, in order to maintain the addiction. In this way, these products can contribute to reducing the motivation to stop smoking”*.

3.26 This inclusion of oral tobacco products demonstrates that the main goal of this text is not to protect bystanders but to really forbid the use of nicotine products in public place. It is difficult to understand how such a ban could be enforced. In addition, this logic would undermine years of public health policy promoting nicotine replacement therapy (**NRT**). Nicotine such as gums could be also covered under the current ban. Some literature show that many people quit smoking using alternative ways to get nicotine<sup>21</sup>. It could be through the well-established use of NRT or by using electronic cigarettes, heated tobacco products or oral tobacco. Preventing those people from having access to those products in public place is probably not the best way to help them quit smoking.

## **4. A better way forward**

4.1 As mentioned above, evidence included in the Notes do not support measures to ban use of electronic cigarettes and heated tobacco products in all governmental and public institutions and services, hotels, restaurants, cafes, workplaces, public transport as well as subsidized institutions, such as those in the fields of health, charity, education, arts, culture and sports without considering the purpose and nature of different facilities.

4.2 JTI believes that vaping should be differentiated from smoking in regulatory treatments including use of those products in public places, since there is a significant difference between smoking and vaping, and electronic cigarettes and heated tobacco products have the potential to reduce the risk associated with smoking. Ban on vaping in the same manner as smoking would prevent users from trying products with this potential and minimize a possible benefit provided by e-cigarettes and heated tobacco products.

4.3 Considering the difference between smoking and vaping, the manager or owner of the buildings should have a discretion to decide if vaping is permitted in enclosed places at the buildings, depending on the purpose and nature of their buildings.

4.4 For those who could find vapor of electronic cigarettes and heated tobacco products unpleasant, it is important to inform people in the facility about use of those products. Therefore, regulations should require the manager or owner of the buildings to take appropriate measures to inform people at the building if vaping is or is not permitted. Such measures could include posting a statement at the primary entrance point: "USE OF ELECTRONIC CIGARETTES AND HEATED TOBACCO PRODUCTS IS PERMITTED INSIDE" or "USE OF ELECTRONIC CIGARETTES AND HEATED TOBACCO PRODUCTS IS NOT PERMITTED INSIDE".

4.5 JTI believes that minors should not smoke and should not have access to tobacco products or any other related products including electronic cigarettes and heated tobacco products. Therefore, we are committed to prevent youth smoking in the Netherlands and elsewhere.

4.6 JTI is of the view that youth access prevention could not be achieved by simply expanding current scope of smoking ban. Better enforcement of measures to prevent minors from purchasing and having access to RRP would be more effective. Such measures could include: (i) establishment of rigorous age verification system; (ii) establishment of an effective licensing and registration system for anyone selling e-cigarettes;(iii) setting or increasing the penalties against suppliers or retailers that have been found to conduct illegal sales; and (iv) restricting the sale of electronic cigarettes via internet to manufacturers only to ensure clear responsibility in the effectiveness of age verification systems.

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<sup>21</sup> See *‘Different doses, durations and modes of delivery of nicotine replacement therapy for smoking cessation’* by Nicola Lindson et al, Cochrane Database of Systematic Reviews (April 2019)

4.7 JTI would be happy to elaborate these proposals in more detail and to provide information on how tobacco control legislation could be improved in the Netherlands to benefit public health, based on our long-standing experience.

**25 May 2019**