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Juul Labs Canada Ltd. submission to Health Canada's Consultation on the proposed Vaping Products Reporting Regulations

For the attention of:
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1. Introduction

1.1. Introduction

Juul Labs Canada[1]'s mission is to transition the millions of Canadian adult smokers away from combustible cigarettes, eliminate their use, and combat underage usage of our products.

We support the Government of Canada in its goal to reduce tobacco use to less than 5% prevalence by 2035 and share the Tobacco and Vaping Products Act[2] (TVPA)'s goals of protecting young persons and non-users from tobacco products. We do not want any non-nicotine users, especially those underage, to try our products, as they exist only to help transition the world's one billion adult smokers away from combustible cigarettes.

We are committed to combating underage use of vaping products, including JUUL products, today and in the future. We believe industry has a key role to play in that effort and are focused on listening and building constructive relationships with regulators, policymakers and other stakeholders as we strive to reset the vaping products category and earn a license to operate in society. We are committed to working with all stakeholders to develop a risk-proportionate regulatory framework that encourages current adult smokers to migrate away from combustible cigarettes to potentially less harmful alternatives while

[1] Juul Labs Canada Ltd. (JLC) is a subsidiary of Juul Labs, Inc (JLI). In this text, "Juul Labs" refers to both entities collectively or individually. These terms are used for convenience and do not precisely describe any of the separate companies, each of which manages its own affairs. Altria, a US-based tobacco manufacturer, is a minority investor in JLI.
[2] Tobacco and Vaping Products Act (TVPA), 2018. Link.

simultaneously combating underage use of these products.

Juul Labs Canada Ltd. (JLC) is pleased to make this submission to Health Canada's consultation on the proposed Vaping Product Reporting Regulations[3]. We continue to express our full support for Health Canada as the appropriate regulatory body that will determine which vaping products will be available in the Canadian marketplace now and in the future.

Through the TVPA and subsequent regulations, Canada has developed a robust framework for the regulation of vaping products. We believe that this framework will be enhanced by the implementation of robust reporting requirements to ensure that Health Canada is better equipped to regulate the category.

JLC strongly supports the proposal (Option 3) for mandatory reporting obligations to be placed on the manufacturers of vaping products and believes that these obligations should be further extended beyond the scope proposed in the current regulations. This would allow Health Canada to better meet its objectives, as well as provide the opportunity for Health Canada to vet new products *before* they come to market.

In particular, we recommend that:

- The content of reporting obligations on manufacturers is expanded to include additional information about the ingredients, emissions, product specifications, and manufacturer plans to combat underage use. This would better allow Health Canada to achieve its stated goals.
- The process for reporting is amended to:
    - Require product notifications *prior* to market entry of new products;
    - Introduce fees for product notifications, updates, and sales reports - to better fund Health Canada's analysis and enforcement capabilities;
    - Protect commercial confidentiality, allowing manufacturers to specify certain information as trade secrets; and
    - Introduce penalties and mechanisms for enforcement.

In this submission, we set out our perspective on the challenges facing the sector and detail our recommendations for further regulatory change on reporting obligations.

1.2. The challenge

We believe that vaping products can offer adult smokers an alternative to combustible cigarettes and potentially reduce the harm associated with smoking. But we fully recognize that vaping products are not risk-free. Those who are underage should never use vaping products. Nor should non-smoking adults be encouraged to start vaping. In the fight to reduce the harm from combustible cigarettes, we should all be

[3] Canada Gazette, Part 1, Volume 156, Number 25: Vaping Product Reporting Regulations, 18 June 2022. Link,

clear in our message: those who don't use nicotine should never start - nicotine is addictive and can cause certain harms to health.

To deliver against the government's long-term public health goals, the regulatory and policy landscape for vaping needs to evolve towards a more responsible framework. The opportunity for vaping products to significantly contribute to tobacco harm reduction for adult smokers is undermined by the risk of underage use.

JLC is committed to working with governments, regulators, and other stakeholders to create a responsible vaping industry that has strong safeguards in place. Smokers who want to switch should be confident in the quality of products they buy and the regulation that surrounds them, while non-users should be prevented from taking up vaping. We think there is work to do to achieve this goal in Canada, and emerging evidence is already showing a number of potential warning signs.

Underage use

While there is encouraging evidence that underage use in Canada has stabilized, as Health Canada's recent Discussion Paper notes, "*the concerning trend of rising youth vaping rates may be levelling off*"[4], underage use remains too high and is rightly a priority for Health Canada and for all of us in the industry to address.

The government's recent 2021 Canadian Tobacco and Nicotine Survey (CTNS) shows that vaping among youth (15-19) remained stable compared with the previous year. For youth (aged 15-19), current vaping product use (past 30-day use) was reported at 13% in 2021 vs. 14.4% in 2020.[5] In addition, current cigarette use among youth (15-19) was 3.5% from 3% in 2020, and overall 10% of Canadians reported smoking cigarettes on a regular basis.[6]

Though we are encouraged by these signs, we believe the data indicates that more can be done. JLC believes there are several evidence-based policies which could be implemented to help combat underage use, including raising the minimum age to purchase tobacco and vaping products to 21. We believe that Tobacco 21 (T21) is one of the most critical tobacco-control strategies to combat underage use. That is because it directly addresses social sourcing. Given that nearly 65% of underage users of vaping products got their devices through social sources[7], we believe a Tobacco 21 policy could be an effective intervention.

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4 Health Canada, Discussion Paper: Legislative Review of the Tobacco and Vaping Products Act. Link,

5 https://www150.statcan.gc.ca/n1/daily-quotidien/220505/dq220505c-eng.htm

6 https://www150.statcan.gc.ca/n1/daily-quotidien/220505/dq220505c-eng.htm

7 https://www.canada.ca/en/health-canada/services/canadian-student-tobacco-alcohol-drugs-survey/2018-2019-summary.html

We also believe that new reporting obligations provide an opportunity for Health Canada to require manufacturers to share information with the regulator about their plans to combat underage use in advance of bringing new products to market. This could include information, for example, about marketing guidelines, retailer training, "mystery shopping" programs, etc.

Illicit and non-compliant products

There are also concerning signs of illicit and non-compliant vaping products being sold in Canada. These may pose additional safety concerns. In addition to negatively impacting consumer health and safety, illicit vaping products reduce sources of government revenue through tax evasion, facilitate criminal operations that threaten national security, and undercut the rule of law, legal and regulatory frameworks, and public-health policies. Critically, they also undermine underage use-prevention measures given their ease of access and how they are often sold through retail channels without adequate age verification.

As the Discussion Paper notes, non-compliant products remain a serious concern: "*Health Canada inspectors visited more than 3,000 specialty vape shops and convenience stores across the country between July and December 2019. These inspections resulted in the seizure of more than 80,000 units of non-compliant vaping products*."[8] Additionally, Health Canada's Vaping Compliance and Enforcement Report found an unacceptably high rate of non-compliance at 83% of specialty vaping establishments and 14% of convenience stores.[9]

In Nova Scotia, authorities have conducted 25 seizures and confiscated $545,000 worth of illicit products since January 2021. Investigators note that a large portion of the illicit vaping products was flavoured and contained high levels of nicotine.[10]

JLC commissioned Euromonitor, the independent market research firm to conduct a study of the Canadian vaping market, with a focus on disposable vaping products from 2020 through 2021. Researchers found:

- About 30% of Disposable Vaping Product sales were non-compliant in 2020.
- Most non-compliant products had nicotine strengths that exceeded provincial limits.[11]
- Disposable Vaping Products with non-compliant flavours totalled $12 million in 2020, while those for non-compliant nicotine strengths totalled $36 million.

The introduction of robust reporting regulations, if they include the obligation to submit information about the product specifications, ingredients and scientific testing *in advance* of products being brought to market, would provide Health Canada with the ability to better understand the nature of legally marketed

[8] Ibid
[9] Health Canada, Vaping Compliance and Enforcement Report: July to September 2019. Link,
[10] Service Nova Scotia and Internal Services, News Release, Illegal Vape Product Seized in New Waterford. Link,
[11] As of 24 July 2021, the federal government has restricted the maximum nicotine concentration limit to 20 mg/mL.

products, to ensure that products are compliant with the applicable regulations *before they come to market*, and support enforcement efforts against non-compliant products by enabling the creation of a public product registry of compliant products.

Harm misperceptions among adult smokers

Finally, we believe that it is vital to address the worrying misperceptions that adult smokers hold regarding the relative harm of vaping products compared to combustible cigarettes.

Only 22% of current smokers believe that vaping is less harmful than smoking cigarettes,[12] while the majority of adult smokers indicated that vaping products were either as harmful or more harmful than cigarettes (46%) or did not know (31%). Among current smokers who have never used vaping products, the perceptions are more extreme- only 10% believe that vaping is less harmful than smoking cigarettes, with the majority believing vaping products are as harmful or more harmful than cigarettes (46%; 43% indicated they did not know). Such misperceptions have important implications for vaping use among adult smokers. The correct perception that vaping products are less harmful than combustible cigarettes has been found to be predictive of future use of vaping products among smokers and of complete switching away from cigarettes. This is deeply concerning, and misperceptions must be tackled head-on if more adult smokers, particularly in disadvantaged communities, are to switch to potentially less harmful alternatives.

A robust regulatory regime for the introduction of new vaping products to the Canadian market could help give adult smokers confidence in the quality of products, for example, knowing that they had been required to undergo scientific testing before being marketed.

2. Creating robust reporting obligations on manufacturers

2.1. Objectives for reporting obligations

JLC strongly supports the intent of Health Canada's proposed reporting regulations.

The Regulatory Impact Analysis Statement describes the objectives as to allow Health Canada to:

> *"better understand the vaping product market, including product types and designs popular with Canadians, especially youth; monitor vaping product sales trends over time; identify the ingredients in vaping substances that are heated to form the vapour inhaled by users; support internal research efforts regarding vaping products and share information where possible with external stakeholders; interpret the impact of tobacco control measures and to identify emerging*

[12] Statistics Canada, Canadian Tobacco and Nicotine Survey 2019. July 2020. Link.

vaping use trends."[13]

JLC supports each of these objectives. The proposed requirements for manufacturers to submit sales and ingredient data are an important step, but we are concerned that without also requiring additional information from manufacturers, the proposed approach will fall short of achieving Health Canada's goals.

We recognize that Health Canada is proposing to take a *"stepwise approach… designed to avoid increasing the administrative burden on vaping manufacturers all at once and to spread the impact on Health Canada's compliance monitoring activities over time"*. However, we believe that there should be greater obligations placed on manufacturers to equip Health Canada with a fuller picture and to help achieve the objectives more quickly.

2.2. Content of reporting obligations

Vaping products contain nicotine, which is addictive, and other potentially harmful chemicals for inhalation. Additionally, vaping devices are complex electronics that should comply with internationally recognized safety and manufacturing standards.

For example, in the EU, the Tobacco Products Directive[14] requires that manufacturers submit a notification to the competent authority six months before a product is placed on the market. This notification includes details of the e-liquid ingredients, e-liquid emissions when heated, toxicological data, nicotine dose, product components, and production process.[15]

Similarly, in New Zealand, a notification process was recently introduced under the Smokefree Environments and Regulated Products (Vaping) Amendment Bill.[16] This requires manufacturers to submit a description of the product and its parts, including ingredients, and a declaration that the notifier complies with product safety requirements set out in section 61 of the bill.[17]

In both cases, these require more of manufacturers than just sales data and ingredients, including requirements for more granular detail about the product to allow regulators to better assess the products before they come to market.

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13 Canada Gazette, Part 1, Volume 156, Number 25: Vaping Product Reporting Regulations, 18 June 2022, Link.
14 European Union, Directive 2014/40/EU of the European Parliament and Council, on the Approximation of the Laws, Regulations and Administrative Provisions of the Member States Concerning the Manufacture, Presentation and Sale of Tobacco and Related Products and Repealing Directive 2001/37/EC. Link.
15 Ibid.
16 New Zealand Government Smokefree Environments and Regulated Products (Vaping) Amendment Act 2020. Link.
17 Ibid.

JLC recommends that Health Canada consider additional requirements for the contents of product notifications, including:

- **Administrative information.**
  - Contact details for the manufacturer or importer and any contract manufacturing sites.

- **Ingredients.** Manufacturers should include information on e-liquid ingredients, such as:
  - A detailed list of ingredients by weight;
  - Ingredient toxicity status; and
  - Toxicological assessment of ingredients, including testing for Harmful and Potentially Harmful Constituents (HPHCs), in the aerosol. Neutral Red Uptake (NRU) in vitro assays can be conducted to test the cytotoxicity of the aerosol.

- **Emissions.** Manufacturers should be required to conduct emissions testing on e-liquids when heated, and include:
  - Description of the methodology employed to generate the aerosol, including the puff regime, with citation of standards followed; and
  - A list of aerosol constituents evaluated and mean mass (where quantified), and the unit of measurement.

- **Product specifications.** Manufacturers should include information on product design, such as:
  - Details about each vaping device or liquid, including the product name, model number and nicotine concentration. For example, the EU TPD process requires significant details on product design as part of the notification, including the coil composition, wattage and voltage ranges, and battery capacity; and
  - Details about manufacturing processes, including process flows for device production, pod production, pod filling, and e-liquid manufacturing.

- **Underage use prevention plans.** Manufacturers should include information on their underage use prevention plans. This would place the burden on manufacturers to proactively demonstrate their commitment to combating underage use and give Health Canada the opportunity to scrutinize these plans prior to market entry. This could include requirements to include indicative packaging designs, marketing and retailer guidelines, and plans for "mystery shopping" to ensure retailer compliance.

Importance of Applicable Vaping Standards in Product Notifications

Requiring products to conform to internationally recognized standards can aid in the notification process to reduce the amount of time Health Canada needs to review product notifications while improving product quality. International standards-setting bodies have made significant progress in developing

standards to improve product quality and set standardized methods for testing vaping products. For example:

- Internationally recognized testing standards and methods can be used to screen e-liquids and aerosols for ingredients of potential concern. Standards bodies such as BSI in the UK and CEN for the European Union have made significant advances in setting safety standards for e-cigarette products.
- The Cooperation Centre for Scientific Research Relative to Tobacco (CORESTA) develops analytical methods for measuring constituents in ENDS products and emissions. Manufacturers should perform testing that adheres to CORESTA standards on vapour product emissions.
- The International Organization for Standardization (ISO) sets best-in-class standards agreed to by industry experts in order to improve product quality and reduce product failures. ISO standards cover Quality Management, Environmental Management, Health & Safety, Energy Management, Food Safety, and IT Security, among others. For vaping product manufacturers, it is important to adhere to ISO standards in order to prevent physical contamination and/or device malfunction, as well as to prevent bacterial contamination of the e-liquid and pods.

Appendix 1 sets out additional detail on international standards to consider when introducing a premarket notification process.

2.3. Process for reporting obligations

JLC recommends that Health Canada consider additional requirements for the process and enforcement around product notifications, including:

- **A requirement to submit notifications prior to market entry**. We believe it is appropriate that before a vaping product is brought to market that it undergoes scientific testing and that the relevant regulator undertakes a review *prior* to market entry for vaping products. For example, under the EU's Tobacco Products Directive, manufacturers are required to submit notifications to the competent regulatory authorities six months prior to placing a product on the market.

- **Implementing a fee for manufacturers**: Additional funding will be required to ensure Health Canada has the capacity to enforce a robust notification process. JLC believes Health Canada should implement a notification fee to allow appropriate resources to be deployed by Health Canada and in recognition of its expanded mandate. This would mean both an upfront fee for each initial product notification and an annual 'maintenance' fee per published product to cover the costs of enhanced scrutiny. For example, the Italian regulator charges[18] manufacturers €327.85 for every new e-cigarette product notification and €108.23 for every substantial modification. Additionally, importers and manufacturers will have to pay an annual fee of €293.53 for the market data notification.

[18] Italian Government, Ministry of Health Decree, 7 March 2022. Link.

- **A process for providing updates.** As with the EU's TPD, there should be a requirement that manufacturers provide updated information if their product is substantially modified.

- **Regulations to protect trade secrets.** While it is right that Health Canada, as the regulator, should receive full information about all vaping products on the Canadian market, it is also important to protect the commercial confidentiality of product details. Ingredient formulations, in particular, are proprietary to each manufacturer and considered commercially sensitive.

  The EU for example, allows that[19] "In their submission, manufacturers and importers shall mark all information which they consider to be a trade secret or otherwise confidential and shall, upon request, duly justify their claims." They exclude from this provision "ingredients used in quantities above 0.1 % of the final formulation of the liquid."

- **Introducing penalties and mechanisms for enforcement.** Health Canada should consider introducing penalties and fines for manufacturers who breach these regulations, including making false statements or failing to provide the required information.

3. Conclusion

Through the TVPA and subsequent regulations, Canada has developed a robust framework for the regulation of vaping products. We believe that this framework will be enhanced by the implementation of robust reporting requirements to ensure that Health Canada is equipped to regulate the category.

JLC strongly supports the proposal (Option 3) for mandatory reporting obligations to be placed on the manufacturers of vaping products and believes that these obligations should be further extended beyond the scope proposed in the current regulations.

[19] Commission Implementing Decision (EU) 2015/2183 of 24 November 2015 establishing a common format for the notification of electronic cigarettes and refill containers. Link.

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Appendix 1 - International standards to consider when regulating vaping products

Applicable standards could include:

- For Manufacturing Facilities and Processes for Pods and E-liquids:
    - Manufacturers should have a quality management system with facilities subject to ongoing inspection.
    - Ingredients should be produced in controlled manufacturing facilities that can adequately exclude or control for potential contaminants. All e-liquids and pods should be manufactured in ISO Class 8 clean rooms.
    - Nicotine content of e-liquids must be verified by a validated method such as *ISO 20714:2019 E-liquid - Determination of nicotine, propylene glycol and glycerol in liquids used in electronic nicotine delivery devices — Gas chromatographic method.*

- For Manufacturing Facilities and Processes for Devices:
    - Vaping products should be developed to resist alteration, tampering, or unintended use.
    - Devices should be designed and manufactured using quality standards that minimize any potential risks or unintended consequences to users by controlling the introduction of contaminants.
    - Device temperature control is an important safeguard to minimize the generation of harmful by-products in the aerosol produced because higher temperatures can generate harmful by-products such as carbonyls. An ISO standard for the determination of selected carbonyls in emissions is currently in development (ISO/FDIS 24199), and a CORESTA Recommended Method for the determination of formaldehyde and acetaldehyde in E-Vapour product aerosol is available.
    - Device batteries should be designed and manufactured to internationally recognized safety standards such as IEC 62133 to prevent overheating or ignition. Batteries should be tested at multiple stages and under varying conditions to reduce concerns of malfunction. Battery malfunctioning controls should be subject to third-party inspections.

- For Ingredients:
    - Internationally recognized testing standards should be developed to screen e-liquids and aerosols for ingredients of potential concern. Due to the contact between liquid and metal parts of the device, the presence of metals in aerosol should be evaluated; an ISO method for the determination of metals in e-vapour product emissions is currently in development (ISO/AWI 24198).
    - Only nicotine, propylene glycol, glycerol and acids are added for the purpose of generating nicotine salts meeting recognized pharmaceutical specifications such as those specified in the European Pharmacopoeia (EP) or the United States Pharmacopeia (USP) Nicotine Monograph shall be used.

- Ingredients should be produced in manufacturing facilities that can adequately exclude or control potential contaminants, aligned to international standards, such as ISO 9001.