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Juul Labs Canada Ltd. submission to Health Canada's Consultation on the Legislative Review of the Tobacco and Vaping Products Act

For the attention of: Manager, Legislative Review Office of Policy and Strategic Planning Tobacco Control Directorate Controlled Substances and Cannabis Branch, Health Canada 0301A-150 Tunney's Pasture Driveway Ottawa, ON K1A 0K9

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1. Introduction

1.1. Introduction

Juul Labs Canada¹'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 Act² (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 simultaneously combating underage use of these products.

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.

Juul Labs Canada Ltd. (JLC) is pleased to make this submission to Health Canada's consultation on the legislative review of the Tobacco and Vaping Products Act³. 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.

To date, Canada has taken an approach that recognizes the significant harm reduction potential in encouraging adult smokers to switch to potentially less harmful alternatives like vaping products. We welcome the Discussion Paper's recognition that "*while not harmless, vaping products were a less harmful source of nicotine for an individual who smokes and quits smoking completely*"⁴.

Through the TVPA and subsequent regulations, Canada has developed a robust framework for the regulation of vaping products. We believe that there are several areas where regulations can be further developed in order to continue to combat underage use, while supporting adult smokers to switch to a potentially less harmful alternative.

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

- creating a process for pre-market review of vaping products before they can be sold,
- raising the age of sale of tobacco and vaping products to 21 years old,
- ensuring appropriate age verification on e-commerce,
- increasing enforcement activities, supported by more funding
- addressing harm misperceptions among adult smokers.

Canada has a unique opportunity to lead the way in responsible and evidence-based vaping regulation that acknowledges the role vaping products can play in helping smokers switch, but also discourages uptake by young people and non-smokers. The legislative review of the TVPA, and forthcoming regulations on the forward regulatory plan, present a key opportunity for Health Canada to create a sustainable regulatory framework that helps achieve Canada's goals on reducing tobacco use and protecting young people.

1.2. The opportunity

Smoking tobacco remains Canada's single leading cause of preventable disease and premature death. Canada has made significant strides in reducing smoking prevalence but 3.7 million (12%) Canadians still smoke⁵. Half of them will die from a smoking-related disease, resulting in nearly 48,000 deaths per year.⁶ Ruan et al, estimated that smoking-related cancer will cost Canada \$44.4 billion CAD between 2032 and 2044.⁷

Smoking and Social Inequalities

³ Health Canada, Consultation on the Legislative Review of the Tobacco and Vaping Products Act. Link

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

⁵ Statistics Canada, Canadian Tobacco and Nicotine Survey 2019. July 2020. Link

⁶ Canadian Lung Association. Smoking and Tobacco Statistics. 2020. Link

⁷ Ruan, Yibing, et al. "Estimating the future cancer management costs attributable to modifiable risk factors in Canada." *Canadian Journal of Public Health* (2021): 1-10. Link

While smoking rates in Canada have fallen significantly over the last 50 years – from 49.5 percent in 1965 to 15.1 percent in 2017^8 – smoking is concentrated among certain demographics and often linked with health and social inequalities.

- The prevalence of smoking among Indigenous Peoples is about two to five times higher than non-Indigenous Canadians.
- Smoking rates are also high among LGBTQ+ persons, ranging from 24 percent to 45 percent across different groups.⁹

A majority of Canadians who smoke want to quit, and about half of Canadian smokers will make a quit attempt each year¹⁰. Yet, one year after a quit attempt only 12.3% of people remained smokefree¹¹. The best way for people who smoke to reduce their risk of disease would be to quit all tobacco and nicotine. Many, however, will not. We believe adult smokers who do not quit should have access to potentially less harmful alternative nicotine products.

JLC fully supports Health Canada's Tobacco Strategy to reduce smoking prevalence to less than 5% by 2035 and its recognition of "... the potential of harm reduction – helping those who can't or won't quit using nicotine to identify less harmful options – while continuing to protect young people and non-smokers from inducements to use nicotine and tobacco"¹². Ensuring that those smokers who do not quit using nicotine have access to potentially less harmful non-combustible alternatives to cigarettes will help contribute to the 2035 goal.

The opportunity for tobacco harm reduction

Harm reduction is a well-established public health concept that seeks pragmatic ways to minimize the impact of an inherently risky activity for those who do not wish to stop. Tobacco harm reduction recognizes that nicotine products fall onto a continuum of risk with products that deliver nicotine through combustion as the most harmful source of nicotine. For those who do not stop using nicotine, switching completely to a non-combustible alternative can reduce their exposure to harmful constituents in smoke and their risk of smoking-related disease.

In 2018, the US FDA indicated that this continuum of risk may play an important role in their roadmap for tobacco regulation.

"While it's the addiction to nicotine that keeps people smoking, it's primarily the combustion, which releases thousands of harmful constituents into the body at dangerous levels, that kills

⁸ Reid, Jessica and David Hammond. *Tobacco Use in Canada: Patterns and Trends*. 2019 Edition. Propel Centre for Population Health Impact, University of Waterloo." <u>Link</u>

⁹ Health Canada. Canada's Tobacco Strategy. 2020. Link

¹⁰Reid JL, Hammond D, Tariq U, Burkhalter R, Rynard VL, Douglas O. *Tobacco Use in Canada: Patterns and Trends, 2019 Edition*. Waterloo, ON: Propel Centre for Population Health Impact, University of Waterloo. Link ¹¹ Ibid.

¹² Health Canada. Canada's Tobacco Strategy. 2020. Link

people. This fact represents both the biggest challenge to curtailing cigarette addiction—and also holds the seeds of an opportunity that's a central construct for our actions."¹³

The role of vaping products in tobacco harm reduction

Along the risk continuum, Health Canada recognizes "*Vaping is less harmful than smoking. Many of the toxic and cancer-causing chemicals in tobacco and the tobacco smoke form when tobacco is burned.*"¹⁴ Non-combustible alternatives to cigarettes, such as e-cigarettes, deliver nicotine without burning tobacco and have the potential to present less risk of harm than continued exposure to toxicants through smoking. The opportunity of harm reduction in individual smokers can translate to a massive public health gain if smokers who will not quit using nicotine switch completely to a non-combustible alternative.

The Discussion Paper also recognises the public health potential for adult smokers of switching to vaping products:

"While scientific knowledge continues to evolve, there is a general consensus in the scientific community that for people who smoke, switching completely to vaping is less harmful than smoking conventional cigarettes. In that context, potential public health benefits associated with reducing tobacco-related disease and death might be realized if adult tobacco users either quit or switched completely to vaping as a less harmful source of nicotine."¹⁵

The harm reduction potential of vaping products in Canada is already evident, with the vast majority of adult consumers in Canada either current or former smokers. As the Discussion Paper recognizes, "*With respect to adult use, there is some evidence that adults who smoke are using vaping products as a less harmful source of nicotine*"¹⁶.

Currently, among Canadians (aged 25+) who used a vaping product in the past 30 days, 45.9% are current smokers and 47.7% are former smokers¹⁷. Statistics Canada's analysis of the 2020 data showed, "... *older Canadians aged 25 and older were more likely to report vaping to reduce or quit smoking (53%)*"¹⁸. These smokers especially need harm reduction strategies tailored to them, i.e., a well populated category of well regulated, alternative nicotine products to help in their transition away from cigarettes.

We are encouraged by the growing body of third-party evidence regarding the health impacts of using vaping products relative to smoking combustible cigarettes as well as evidence regarding the effectiveness of vaping products in helping adult smokers transition completely away from combustibles. The Discussion Paper asked for recent examples of relevant research to the category - some of the notable studies include:

¹³ U.S. Food and Drug Administration. FDA announces comprehensive regulatory plan to shift trajectory of tobacco-related disease, death. July 27, 2017. <u>Link</u>

¹⁴ Health Canada. Canada's Tobacco Strategy. 2020. Link

¹⁵ Health Canada, Discussion Paper: Legislative Review of the Tobacco and Vaping Products Act. <u>Link</u> ¹⁶ Ibid.

¹⁷ Statistics Canada. Canadian tobacco and nicotine survey (CTNS), 2021. Link

¹⁸ Statistics Canada. Canadian tobacco and nicotine survey (CTNS), 2020. Link

- A randomized trial conducted by researchers from Lady Davis Institute, McGill University and at sites across Canada showed nicotine e-cigarettes plus counseling significantly increased smoking abstinence at 12 weeks versus counseling alone.¹⁹
- A randomized trial conducted by Brown University researchers (and others), funded in part by the National Institutes of Health, found that compared to continued cigarette smoking, switching completely to electronic nicotine delivery systems (ENDS) led to over 90% reductions in a major pulmonary carcinogen, approximately 80% reductions in carbon monoxide levels, and significantly fewer reports of respiratory symptoms among adult smokers.²⁰
- A randomized controlled trial conducted by Penn State School of Medicine and Virginia Commonwealth University researchers found that "use of an ENDS with cigarette-like nicotine delivery can reduce exposure to a major pulmonary carcinogen, NNAL, even with concurrent smoking."²¹
- A large analysis of the US Population Assessment of Tobacco and Health Study showed not only did combustible cigarette users who switched to vaping products show significant decreases in biomarkers of exposure to important toxicants, individuals who switched to dual use of vaping products and decreased their consumption of combustible tobacco by 50% or more also showed significant decreases in several important biomarkers of toxicant exposure.²²
- A systematic review of the literature on e-cigarettes published by The Cochrane Library found that "we are moderately confident that nicotine e-cigarettes help more people to stop smoking than nicotine replacement therapy or nicotine-free e-cigarettes." ²³
- A study from the University of Waterloo which included Canadian respondents showed smokers perceptions of the harmfulness of Nicotine replacement therapies and nicotine vaping products relative to cigarettes predicted the likelihood of that respective product use in attempting to quit cigarettes.²⁴ Another study using the same survey indicated individuals using non-tobacco flavoured products were more likely to report stopping smoking than people who indicated they used tobacco flavoured vaping products.²⁵

¹⁹ Eisenberg MJ, Hébert-Losier A, Windle SB, et al. Effect of e-Cigarettes Plus Counseling vs Counseling Alone on Smoking Cessation: A Randomized Clinical Trial. JAMA. 2020;324(18):1844–1854. Link

²⁰ Pulvers et al, Effect of Pod e-Cigarettes vs Cigarettes on Carcinogen Exposure Among African American and Latinx Smokers, 2020, Link

²¹ Cobb et al, Effect of an electronic nicotine delivery system with 0, 8, or 36 mg/mL liquid nicotine versus a cigarette substitute on tobacco-related toxicant exposure: a four-arm, parallel-group, randomised, controlled trial, 2021, Link

²² Anic GM, Rostron BL, Hammad HT, van Bemmel DM, Del Valle-Pinero AY, Christensen CH, Erives G, Faulcon LM, Blount BC, Wang Y, Wang L, Bhandari D, Calafat AM, Kimmel HL, Everard CD, Compton WM, Edwards KC, Goniewicz ML, Wei B, Hyland A, Hatsukami DK, Hecht SS, Niaura RS, Borek N, Ambrose BK, Chang CM. Changes in Biomarkers of Tobacco Exposure among Cigarette Smokers Transitioning to ENDS Use: The Population Assessment of Tobacco and Health Study, 2013-2015. Int J Environ Res Public Health. 2022 Link

²³ Cochrane Database of Systematic Reviews, Electronic cigarettes for smoking cessation, October 2020, Link ²⁴ Hua-Hie Yong, PhD, Shannon Gravely, PhD, Ron Borland, PhD, Coral Gartner, PhD, K Michael Cummings, PhD, Katherine East, PhD, Scott Tagliaferri, MClinExPhys, Tara Elton-Marshall, PhD, Andrew Hyland, PhD, Maansi Bansal-Travers, PhD, Geoffrey T Fong, PhD, Do smokers' perceptions of the harmfulness of nicotine replacement therapy and nicotine vaping products as compared to cigarettes influence their use as an aid for smoking cessation? Findings from the ITC Four Country Smoking and Vaping Surveys, Nicotine & Tobacco Research, 2022 Link

²⁵ Li, Lin, Borland, Ron, Cummings, K Michael, Fong, Geoffrey T, Gravely, Shannon, Smith, Danielle M, Goniewicz, Maciej L, O'Connor, Richard J, Thompson, Mary E, McNeill, Ann (2021). How does the use of

• A study from the University of Toronto, in which adult smokers who reported successfully quitting smoking using vaping products indicated positive experiences in several dimensions including sensory functions (for example "ability to taste again") and side effects (for example "Breathing is easy") were associated with higher odds self-reported success in cessation. ²⁶

1.3. The challenge

JLC welcomes the legislative review of the TVPA as an opportunity to continue to build a responsible regulatory framework that helps achieve Canada's goals on reducing tobacco use and protecting young people.

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 recognise 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 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 that want to switch should be confident in the quality of products that 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 reached an inflection point, as the Discussion Paper notes "*the concerning trend of rising youth vaping rates may be levelling off*"²⁷, underage use remains too high and is rightly a priority for Health Canada and for all of us in the industry.

The latest Canadian Tobacco and Nicotine Survey (CTNS) from 2020 shows that there has been a decrease in cigarette smoking and levelling off of the previous increases in vaping product use among youth. For youth aged 15-19, current vaping product use (past 30 day use) was reported at 14.4% in 2020

flavored nicotine vaping products relate to progression towards quitting smoking? Findings from the 2016 and 2018 ITC 4CV Surveys. Nicotine & Tobacco Research. Link

²⁶ Fu, Rui, O'Connor, Shawn, Diemert, Lori, Pelletier, Hayley, Eissenberg, Thomas, Cohen, Joanna, Schwartz, Robert (2021). Real-world vaping experiences and smoking cessation among cigarette smoking adults. Addictive Behaviors.116 106814. <u>Link</u>

²⁷ Health Canada, Discussion Paper: Legislative Review of the Tobacco and Vaping Products Act. Link

vs. 15.0% in 2019²⁸. Current cigarette use among youth (15-19) decreased to 3% from 5% in 2019, and daily smoking was reported at 0.8%, down from 2.1% in 2019.²⁹

As the Discussion Paper also notes, concerns about a potential 'gateway effect' from vaping to smoking are not supported by population level trends: "Smoking rates, for both youth and adults, continue to decline and are at an all-time low. The prevalence of daily smoking among youth aged 15 to 19 years was so low (small sample size) that it was considered to be 'unreportable' in 2020."³⁰

Though we are encouraged by these signs, we believe the data indicate that more can be done - and this submission sets out our proposals to further combat underage use through updates to the TVPA and future regulations. See Appendix 1 for the actions that JLC is already taking to combat underage use.

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- 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*."³¹ 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.³²

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 product was flavoured and contained high levels of nicotine.³³

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.³⁴

²⁸ Statistics Canada, Canadian Tobacco and Nicotine Survey 2020, March 2021. Link

²⁹ Ibid.

³⁰ Health Canada, Discussion Paper: Legislative Review of the Tobacco and Vaping Products Act. Link ³¹ Ibid

³² Health Canada, Vaping Compliance and Enforcement Report: July to September 2019. Link

³³ Service Nova Scotia and Internal Services, News Release, Illegal Vape Product Seized in New Waterford. Link

³⁴ As of July 24, 2021, the federal government has restricted the maximum nicotine concentration limit to 20 mg/mL.

• Disposable Vaping Products with non-compliant flavours totalled \$12 million in 2020, while those for non-compliant nicotine strengths totalled \$36 million

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 cigarettes³⁵ 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.

Adult smokers must have access to accurate, science-based information about the risks, including relative risks, of all tobacco and nicotine-containing products. Data from around the world show that smokers that understand the relative risk of non-combustible products are more likely to switch completely away from cigarettes³⁶.

2. Five policy perspectives for a more responsible vaping category (See infographic on next page)

³⁵ Statistics Canada, Canadian Tobacco and Nicotine Survey 2019. July 2020. Link

³⁶ Persoskie A, O'Brien EK, Poonai K. Perceived relative harm of using e-cigarettes predicts future product switching among US adult cigarette and e-cigarette dual users. Addiction. 2019; <u>https://doi.org/10.1111/add.14730</u>; Hua-Hie Yong, PhD, Shannon Gravely, PhD, Ron Borland, PhD, Coral Gartner, PhD, K Michael Cummings, PhD, Katherine East, PhD, Scott Tagliaferri, MClinExPhys, Tara Elton-Marshall, PhD, Andrew Hyland, PhD, Maansi Bansal-Travers, PhD, Geoffrey T Fong, PhD, Do smokers' perceptions of the harmfulness of nicotine replacement therapy and nicotine vaping products as compared to cigarettes influence their use as an aid for smoking cessation? Findings from the ITC Four Country Smoking and Vaping Surveys, Nicotine & Tobacco Research, 2022 Link

Five policy perspectives for a more responsible vaping category



4. Enhancing enforcement

- There should be increased enforcement activities, supported by more funding and tough penalties for retailers who sell to those who are underage.
- We encourage Health Canada to ban at retail the sale of fruit flavours, as well as any other non-tobacco, menthol or mint flavours after 30 days from publication of final regulations.

5. Addressing harm misperceptions

- Misperceptions must be tackled head on if more adult smokers, particularly in disadvantaged communities, are to switch to potentially less harmful alternatives.
- Adopt policies that ensure adult smokers have access to accurate, scientific, evidence-based information, building on best-practice international examples.
- Ensure future tax changes increase the price differential between combustible and non-combustible products.

3. Building a responsible vaping category in Canada

There is a risk that these issues - underage use, illicit products and harm misperceptions - if not robustly tackled today, could reduce public confidence in the use of vaping products and undermine the government's ability to use them as a tool for achieving public health goals.

To tackle these issues, and to build a mature, strongly regulated sector, we are setting out our roadmap for change, from when a product is brought to market, through its marketing and retail, to the enforcement regime.

3.1. Enhanced review prior to market entry for vaping products

JLC supports science-based and risk-proportionate regulations of vaping products around the world. We respect the role of regulators in determining the appropriate framework for a particular jurisdiction and 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.

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. 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, in the EU, the Tobacco Products Directive³⁷ 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.³⁸

Similarly, in New Zealand, a notification process was recently introduced under the Smokefree Environments and Regulated Products (Vaping) Amendment Bill.³⁹ This requires manufacturers to submit a description of the product and its parts, including ingredients, and a declaration that the notfier complies with product safety requirements set out in section 61 of the bill.⁴⁰ Additionally, emissions testing requirements must be conducted by an ISO/IEC 17025 accredited laboratory.

As the Discussion Paper notes: "the TVPA provides the authority to make regulations to collect information from industry about vaping products, their emissions and any research and development (e.g.,

³⁷ 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 ³⁸ Ibid

³⁹ New Zealand Government Smokefree Environments and Regulated Products (Vaping) Amendment Act 2020. Link

⁴⁰ Ibid

sales data and information on market research, product composition, ingredients, materials, health effects, hazardous properties and brand elements)."

We also note that Health Canada has included Amendments to the Tobacco Reporting Regulations in the Forward Regulatory Plan⁴¹. We believe that in addition to ongoing reporting obligations being placed on the manufacturers of vaping products that there should also be a requirement to submit information prior to market entry.

This should be designed to give Health Canada the opportunity to scrutinize all new vaping products to ensure they comply with regulations *before* they are allowed to be sold. The Proposals for the regulation of vaping products document for consultation⁴² called for basic requirements for manufacturers to report upon market entry. We believe that Health Canada should adopt those requirements and go further to require additional information from manufacturers. The TVPA should be updated to include a set of required information, and Health Canada should set out guidance regarding the detailed requirements and applicable standards, which could include:

• Administrative information.

- Contact details for the manufacturer 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
 - Toxicological assessment of ingredients including testing for Harmful and Potentially Harmful Constituents (HPHCs), in both the e-liquid and aerosol. Neutral Red Uptake (NRU) in vitro assays can be conducted to test the cytotoxicity of both the e-liquid and 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
 - 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
 - Details about manufacturing processes including process flows for device production, pod production, pod filling, and e-liquid manufacturing

⁴¹ Health Canada. Forward Regulatory Plan 2021-2023: Amendments to the Tobacco Reporting Regulations. Link

⁴² Health Canada, Document for Consultation, Proposals for the regulation of vaping products. Link

- 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.
- **Implementing a fee for manufacturers**: Additional funding will be required to ensure Health Canada has the capacity to enforce a robust notification process. Juul Labs 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 a more substantial upfront fee for each initial product notification and an annual 'maintenance' fee per published product to cover the costs of enhanced scrutiny.

As with the EU's TPD, there should be a requirement that manufacturers provide updated information if their product is substantially modified. Similarly there should be requirements for ongoing post-market reporting, including of sales figures and adverse events, to allow Health Canada to monitor trends in the marketplace and respond quickly to any unsafe products.

Importance of Applicable Vaping Standards in Premarket Review

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 at the European Union level have made significant advances in setting safety standards for e-cigarette products.
- 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 vapor 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 2 sets out additional detail on international standards to consider when introducing a premarket review process.

3.2. Tackling the appeal of vaping online

JLC wants to see a responsibly branded sector that is focussed solely on targeting adult smokers, and is explicit that it will restrict appeal to those underage through packaging and marketing. We welcome Health Canada's steps to regulate the marketing and packaging of vaping products through the Vaping Products Promotion Regulations (VPPR)⁴³ and Vaping Products Labelling and Packaging Regulations (VPLPR)⁴⁴.

We believe that Health Canada could take additional steps to reduce the potential exposure of those underage to vaping products online - both by brands themselves, and in terms of exposure to user generated content.

Prohibiting promotion on social media by manufacturers and retailers

We are concerned by the use of owned digital channels, such as social media accounts operated by manufacturers, retailers and other third parties, to conduct promotional activities in a way that could be seen by those underage. The discussion paper highlighted an unacceptably high rate of non-compliance among retailer social media accounts related to promotions aimed at youth.⁴⁵ JLC does not operate any social media channels in Canada and does not engage in any social media promotions or advertising. JLI maintains a single social media account for corporate communications use only. We believe that manufacturers and retailers should be prohibited from using public social media accounts to promote their products.

Tackling user-generated content

JLC also remains concerned about the impact of user-generated vaping content on social media which may appeal to those underage. Research published last year found that close to two-thirds of TikTok videos with the most popular vaping-related hashtags portrayed e-cigarette use positively, and the final sample of 808 videos had been collectively viewed over 1.5 billion times.⁴⁶ JLI actively monitors social media platforms for inappropriate content, including content that depicts or encourages underage use, and seeks its removal. However, social media companies must take more action to ensure that vaping content that is not appropriate to their age. We encourage Health Canada to explore options to place greater obligations on social platforms to ensure that those underage are not exposed to inappropriate content about vaping products, including through Canadian Heritage's work looking at Online Safety⁴⁷.

3.3. Restricting underage access at retail - offline and online

JLC believes those underage should not have access to or use any tobacco product.

⁴³ Government of Canada. Vaping Products Promotion Regulations (SOR/2020-143). Link

⁴⁴ Government of Canada. Vaping Products Labelling and Packaging Regulations (SOR/2019-353). Link.

⁴⁵ Health Canada, Discussion Paper: Legislative Review of the Tobacco and Vaping Products Act. Link

⁴⁶ Tobacco Control, Vaping on TikTok: a systematic analysis, July 2021. Link

⁴⁷ Government of Canada. The Government's commitment to address online safety. Link

Tobacco 21

JLC strongly supports 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, the largest contributor to underage access of vaping products throughout the country.

A leading contributor of underage use of tobacco and vaping products has been social sourcing — when a purchaser of legal age provides a nicotine product to an underage user. Recent data from the Canadian Student Tobacco Alcohol and Drug Survey found that 84% of students who smoked in the past 30 days obtained their cigarettes from social sources, and 65% of underage users of vape products got their device from social sources⁴⁸.

T21 policy could be an effective intervention as these friend or peer sources are themselves likely under the age 21. A study conducted by the Institute of Medicine (IOM) in the United States found that a minimum purchasing age of 21 will reduce tobacco initiation in those aged 15-17 likely because this age group isn't in the same social circles as those who are over 21 (IOM). According to the Ontario Tobacco Research Unit, increasing the minimum legal purchase age to 21 would be expected to reduce smoking prevalence by an additional 2.7% by 2035⁴⁹.

Recent data out of the U.S. suggests that, although significant work remains, progress is being made to combat underage use of vaping products, demonstrating the importance of evidence-based interventions such as Tobacco 21. The CDC stated that "*These declines [in underage vaping rates] were likely attributable to multiple factors at the national, state, and local level. For example, in December 2019, the federal minimum age of sale of all tobacco product types increased from 18 to 21 years.*"⁵⁰

Canadian Public Health Support for T21

Council of Chief Medical Officers of Health in Canada

"Consider making the age of 21 the minimum sales age for both tobacco and vaping products, knowing that establishing the legal minimum sales age requires balancing policy objectives to minimize an illegal market while delaying the onset of youth use through limiting access through social sources"⁵¹

Canadian Cancer Society

"We're trying to remove the legal purchaser from the high school setting, and increasing the age to 21

⁴⁸ Government of Canada, Summary of results for the Canadian Student Tobacco, Alcohol and Drugs Survey 2018-19. <u>Link</u>

 ⁴⁹ Chaiton, M., Dubray, J., Guindon, G. E., & Schwartz, R. (2021). Tobacco Endgame Simulation Modelling: Assessing the Impact of Policy Changes on Smoking Prevalence in 2035. *Forecasting*, *3*(2), 267-275. Link
 ⁵⁰ United States Center for Disease Control and Prevention. Tobacco Product Use Among Middle and High School Students — United States, 2020. Link

⁵¹ Public Health Agency of Canada. Statement from the Council of Chief Medical Officers of Health on Nicotine Vaping in Canada. 2020. Link

would really accomplish that."52

Heart and Stroke Foundation of Canada

"Heart & Stroke is pleased to see momentum internationally to increase the minimum age of purchase for tobacco products to 21 years of age."⁵³

JLC believes a national Tobacco 21 policy approach could serve as a centerpiece of what can become a comprehensive implementation of evidence-based tobacco-control strategies to address underage use. Additionally, we believe that in order to reach Canada's Tobacco Strategy goal of 5% tobacco use by 2035, Tobacco 21 laws would be an effective regulatory tool to help accelerate a decline in prevalence, achieving that goal. In March 2020, Prince Edward Island increased their age of purchase for tobacco and vaping products to from 19 to 21 years old. We are encouraged by P.E.I and encourage Canada to adopt Tobacco 21 nationally.

Mandatory ID checks at retail

No one underage should be able to purchase vaping products in Canada. In 2020, an unreasonably high percentage of underage users were able to access vaping products from a convenience store/ gas station (15.2%) or a specialty vape shop (31.5%). These access issues must be tackled now. JLC believes that retailers are a key part of the solution – robust age verification at the point of sale and strong understanding of the products they sell can make a huge difference.

We believe there should be mandatory **introduction of a 'no ID, no sale'** policy for physical retailers for both tobacco and vaping along with other age-gated products like alcohol, lottery tickets, and cannabis.

Exploring enhanced age verification technology at point-of-sale

In order to enhance retail age verification compliance, additional point-of-sale technology could be a potential solution. We were encouraged by the initiative of Liquid Avatar Technologies and Ontario Convenience Stores Association which recently unveiled its new digital age verification solution for retailers. The technology is able to provide retailers with a verifiable, digital credential of a government issued ID card along with biometrics to help combat underage sales and protect a user's personal information.⁵⁴ They aim to have a 100% success rate in restricting access to age-gated products. Enhanced point-of-sale technology could be required at retail and could drastically reduce underage sales.

Robust age verification online

Health Canada should require mandatory upfront age verification processes for any online retailer, ensuring the online world is as safe as the offline world.

⁵² CBC. Cancer society wants legal age for buying tobacco, vaping products raised to 21. 2019. Link

⁵³ Heart and Stroke Foundation of Canada. A Tobacco Endgame for Canada: Creating a future free of commercial tobacco use. 2019. Link

⁵⁴Access Wire. Liquid Avatar Technologies and Ontario Convenience Stores Association (OSCA) Deliver Successful Pilot of Digital Age-Verification Solutions to Reach over 8,000 Retail Locations. 2022. Link

We note that Health Canada's Forward Regulatory Plan includes Amendments to the Tobacco Access Regulations (Age Verification for Online Sales)⁵⁵. We believe that this should include regulations mandating retailers of vaping products online to require upfront age and identity verification before a sale is made online.

For example, visitors to any page on JUUL.ca will be required to be logged-in with an age verified account in order to access the website or make a purchase on www.juul.ca, which includes a scan of a photo ID and a 'selfie' photograph to confirm age and identity, which is validated by a third party⁵⁶. Too many retailers rely solely on ID checks for delivery, or may not implement age verification at all. The government should set out clear requirements for the entire sector, and provide support to make age verification easier, bringing tobacco and vaping product sales into efforts to enable digital age verification for age restricted products.

3.4. Enhanced enforcement

Illegally marketed and illicit products evade legal and regulatory frameworks and may present additional health and safety risks to adult consumers and undermine underage-prevention measures. Active enforcement at the provincial level remains critical to ensure a responsible marketplace. We applaud local governments for their efforts to remove illicit products from the marketplace but we believe that more can be done.

Juul Labs as a partner in tackling illicit products

Juul Labs works with law-enforcement authorities and other stakeholders around the world to cut production, disrupt distribution, and seek cooperation from involved retailers. This work is part of a broader effort to ensure a more responsible marketplace for vaping products.

As with other illicit goods, criminal enterprises operating in China continue to be the main source of supply for black market vaping products. Over the past years, JLI has conducted numerous investigations and enforcement campaigns, including several that led to:

- 565,000+ counterfeit products seized
- 18 illicit production facilities disrupted
- 13 illicit manufacturers/distributors shut down

In our efforts to earn trust and be a responsible steward of our products, Juul Labs strongly supports enforcement against illicit products as we strive to reset the vaping category and earn a license to operate in society.

A Published List of Compliant Products

⁵⁵ Health Canada. Forward Regulatory Plan 2021-2023: Amendments to the Tobacco Reporting Regulations. Link

⁵⁶ This will be effective as of May 31, 2022

Health Canada should compile a publicly available list of compliant products to help retailers and consumers identify non-compliant products. Such a list could aid in enforcement efforts by identifying retailers or distributors who sell non-compliant products.

Increased enforcement with tougher penalties

JLC applauds Health Canada for its rigorous compliance and enforcement program but we believe that more can be done at the retail level to address underage and non-compliant product sales. We believe there needs to be increased investment towards enforcement at retail and continued compliance checks along with tough penalties for retailers who sell to underage individuals. Additional funding for enforcement could be generated from the new federal excise tax, provincial retailer licensing schemes, and any new fees as part of a pre-market review process. Sales bans, or the revocations of retail licenses, should be implemented for retailers who repeatedly sell to those underage.

Removing non-tobacco and non-mint/menthol based flavours 30 days from publication of final regulations

JLC believes, and evidence demonstrates, that flavours in vaping products play an important role in helping adult smokers transition away from cigarettes. There is a growing body of international evidence⁵⁷ that shows that flavoured vaping products can offer adult smokers a potentially less harmful alternative to combustible cigarettes and, in so doing, reduce the death and disease associated with tobacco use. There is also evidence that adult consumers of flavoured vaping products are more likely to subsequently fully transition off cigarettes^{58,59}, less likely to be dual-users⁶⁰, and are less likely to relapse to smoking.⁶¹

With regard to the proposed Order Amending Schedules 2 and 3 to the Tobacco and Vaping Products Act (Flavours) and the proposed Standards for Vaping Products' Sensory Attributes Regulations we wish to make clear that JLC supports Health Canada's efforts to combat underage usage while leaving flavour options - such as tobacco, mint and menthol - available for adult smokers that want to transition to potentially less harmful nicotine alternatives, like vaping products⁶².

 ⁵⁷ Russell, C., McKeganey, N., Dickson, T. *et al.* Changing patterns of first e-cigarette flavor used and current flavors used by 20,836 adult frequent e-cigarette users in the USA. *Harm Reduct J* 15, 33 (2018). Link
 ⁵⁸ Friedman AS, Xu S. Associations of Flavored e-Cigarette Uptake With Subsequent Smoking Initiation and

Cessation. JAMA Netw Open. 2020;3(6):e203826. Published 2020 Jun 1. Link

⁵⁹ Lin Li, PhD, Ron Borland, PhD, Kenneth Michael Cummings, PhD, Geoffrey T Fong, PhD, Shannon Gravely, PhD, Danielle M Smith, MPH, Maciej L Goniewicz, PhD, Richard J O'Connor, PhD, Mary E Thompson, PhD, Ann McNeill, PhD, How Does the Use of Flavored Nicotine Vaping Products Relate to Progression Toward Quitting Smoking? Findings From the 2016 and 2018 ITC 4CV Surveys, *Nicotine & Tobacco Research*, Volume 23, Issue 9, September 2021, Pages 1490–1497, Link

⁶⁰ Jones DM, Ashley DL, Weaver SR, Eriksen MP. Flavored ENDS Use among Adults Who Have Used Cigarettes and ENDS, 2016-2017. *Tob Regul Sci.* 2019;5(6):518-531. Link

⁶¹ Ibid.

⁶² JLC's submission of 1 September 2021 to Health Canada's consultation on the proposals provides additional detail

That said, we continue to encourage Health Canada to implement its ban at retail the sale of fruit flavours, as well as any other non-tobacco, menthol or mint flavours after 30 days from publication of final regulations, with a longer implementation timeline for the introduction of the ingredient restrictions.⁶³

Supporting adult smokers who could benefit from switching to a potentially less harmful alternative

3.5. Addressing harm misperceptions

As the Discussion Paper notes:

"For adults who smoke, there appears to be a lack of awareness that vaping products are a less harmful source of nicotine for those who currently smoke and switch completely to vaping. A 2020 survey found that only 22 percent of current smokers recognized that vaping is less harmful than smoking cigarettes."⁶⁴

Approved switching messaging

Adult smokers as well as healthcare professionals should have access to accurate, science-based information about the risks, including relative risks, of all tobacco and nicotine-containing products enabling them to make informed decisions for their health.

Additionally, targeted communication with age-verified adult smokers is an effective means to limit the reach of communication to targeted audiences and to enable clear communication with the population that would benefit from switching completely to vaping. Only appropriate marketing channels should be used to promote awareness of e-cigarettes among adult smokers, and it is vital that any communications e.g. online, or social media are narrowly targeted at adult smokers, with robust safeguards in place to protect underage exposure.

To specifically target information at adult smokers, the government could take steps to allow physical and online retailers to provide switching messaging at the point of sale of cigarettes. For example New Zealand allows retailers to have signage saying "If you smoke, switching completely to vaping is a much less harmful option".

As the Discussion Paper notes the TVPA included provisions which would "allow manufacturers and retailers to use prescribed statements regarding the potential health benefits and comparison statements that align with evolving scientific knowledge." However, Health Canada has yet to set out any such approved statements.

Targeted information for smokers - pack inserts/onserts

Cigarette packs and tobacco products could also be used to deliver targeted messaging about switching directly to adult smokers, through inserts or onserts, as explored in Health Canada's prior work on New Health Information Messages. Health Canada research testing relative risk messages concluded that *"Findings suggest that most of the risk statements tested are suitable to alert consumers of the health risks*

⁶³ In Canada Gazette Part II

⁶⁴ Health Canada, Discussion Paper: Legislative Review of the Tobacco and Vaping Products Act. Link

of vaping in comparison to smoking, while not inducing interest in those types of products among non-users."⁶⁵.

Public information campaigns

Health Canada could launch a 'Vaping Facts' website, like that set up last year by the New Zealand Ministry of Health,⁶⁶ to provide accurate, scientific evidence-based and up-to-date information on the vaping category.

Health Canada could also commission and fund a new nation-wide, targeted media campaign aimed at adult smokers. In the UK the Royal College of Physicians (RCP) has called for something similar, and argues it would be an 'effective and relatively inexpensive' way to redress false perceptions and 'provide balanced information'.⁶⁷ A recent vaping information campaign developed by the New Zealand Health Ministry offers a good example⁶⁸.

Case study: New Zealand

New Zealand is a global leader in proportionate e-cigarette regulation that supports harm reduction. The Health Ministry has publicly endorsed e-cigarettes as playing a key role in reaching its 2025 smoke-free goal.

Its Health Ministry has set up a website called 'Vaping Facts'⁶⁹ to provide a trusted source of information for smokers wanting to switch to a less harmful product consumers and run alongside the new programme for youth. The website includes information on the facts of vaping, how vaping can help quit smoking, vapefree schools, and vaping vs smoking.

The New Zealand government has also developed a public education campaign to support smokers to successfully switch to vaping and stop smoking completely, reduce inequalities in smoking prevalence, and enable health practitioners, smokers and the broader community to better understand that vaping is significantly less harmful than smoking (though not risk-free, which is why it is not for non-smokers).

Its Smokefree Environments and Regulated Products (Vaping) Amendment Act 2020 aims to strike a balance between ensuring vaping products are available for smokers who want to switch to a less harmful alternative and ensuring these products aren't marketed or sold to young people. This legislation governs e-cigarette safety standards, safety messages and options for retailers to display harm reduction messages.

In 2016, 14.5% of NZ used tobacco whilst 0.9% used e-cigarettes. In 2021, the number of smokers had decreased to 9.4% whilst the number of vapers had increased to 6.2%. The New Zealand Ministry of Health notes "While smoking rates have been declining for many years, the decrease over the last year was larger than usual."

⁶⁵ Health Canada, Testing of Relative Risk Statements for Vaping Products, September 2018. Link

⁶⁶ New Zealand Ministry of Health. Vaping Facts Website. Link

⁶⁷ Royal College of Physicians UK, Smoking and health 2021: A coming of age for tobacco control?, April 2021. Link

⁶⁸ NZ Health Ministry, Business Case for a Public Education Campaign on Vaping, June 2019. Link

⁶⁹ New Zealand Ministry of Health. Vaping Facts Website. Link

Risk proportionate taxation

JLC believes in a risk-proportionate regulatory framework to advance the harm-reduction potential for non-combustible alternatives for adult smokers. Tax policy is a critical component of a risk-proportionate framework, applying higher taxes to the riskiest products (combustibles) and encouraging adult smokers to transition and completely switch to less risky products (non-combustibles) with proportionately lower rates.

The recent passage of Budget 2022 included a commitment that "the overall tax burden on vaping products will be regularly reviewed to ensure that important public health objectives are being met." We believe that as these reviews take place, Health Canada should ensure that tax is being used as a lever to encourage smokers to switch to a potentially less harmful alternative.

Price is a key factor in encouraging smokers to try alternatives like vaping products, and it can be a powerful tool for pushing adult smokers away from combustible cigarettes. Fiscal policies that create price differentials are powerful tools that can help push adult smokers away from cigarettes and pull them to non-combustible products.

Several economic studies conclude that excessive taxes on vaping products can have the unintended consequence of discouraging switching and, as a result, increasing cigarette smoking:

- A US study analyzed the effects of the vaping tax in Minnesota, which equalized vaping products and combustible cigarettes. Researchers estimated that taxing vaping products at the same rate as cigarettes nationwide in the US would deter approximately 2.75 million smokers from transitioning away from cigarettes in a ten-year period⁷⁰
- Researchers from the US used two nationally representative public health surveys, the Behavioral Risk Factor Surveillance System and National Health Interview Survey to estimate that a national tax on vaping products equivalent to \$1.65 per milliliter of vaping liquid would raise the proportion of adults who smoke cigarettes daily by approximately 1 percentage point, translating to 2.5 million additional adult daily smokers.⁷¹ The authors concluded, "results suggest caution in regulating e-cigarettes because e-cigarette regulations may have a harmful, unintended consequence: increased smoking of traditional cigarettes."
- 4. Conclusion

JLC supports the Government of Canada in its goal to reduce tobacco use to less than 5% by 2035 and shares Canada's Tobacco Strategy goal to "protect the health of young people and non-smokers from the dangers of tobacco use."⁷² JLC believes this can be accomplished by a robust and appropriate regulatory framework for vaping products from notification to enforcement to combat underage users while facilitating adult smokers' transition to less harmful products. We now urge both the Government and vaping product manufacturers to build a more responsible industry – together we can help seize the prize of a smoke-free 2035. JLC would welcome a conversation with policymakers and other interested stakeholders about our ideas.

⁷⁰ Saffer, H. et al. E-cigarettes and adult smoking: Evidence from Minnesota. J Risk Uncertain 60, 207–228 (2020). Link

⁷¹ Pesko M. et al. The effects of traditional cigarette and e-cigarette tax rates on adult tobacco product use. J Risk Uncertainty J Risk Uncertain 60, 229–258 (2020). Link

⁷² Health Canada. Canada's Tobacco Strategy. 2020. Link

Appendix 1 - Juul Labs Canada actions to combat underage use

JLC is committed to resetting the company and earning trust as we advance the harm reduction potential for adult smokers while combating underage use, including taking the following data-driven actions::

- JLC strongly supports raising the minimum age to purchase tobacco and vaping products to 21. We believe that a T21 policy is one of the most critical tobacco-control strategies to combat underage use. That is because it directly addresses social sourcing, the largest contributor to underage access of vaping products throughout the country. As social sourcing remained the main source by which youth from aged 15-19 obtained vaping products (devices 57.5%, liquids 57.1%) in 2019⁷³, a Tobacco 21 policy could be an effective intervention as these friend or peer sources are themselves likely under the age 21.⁷⁴ To further demonstrate our commitment and support for T21, in November 2021, JLC raised the minimum age on JUUL.ca to purchase JUUL products to 21+.
- In January 2020, we halted the import of all non-tobacco, non-mint-based products in Canada.
- In January 2020, all mass market product advertising was halted in Canada, several months before regulations were introduced.
- JLC has a product quantity limit policy at retail and on JUUL.ca designed to reduce the risk of bulk purchase for resale limiting the amount of JUUL products that can be purchased at one time (retail) or per calendar month (e-commerce).
- Enhanced Access Controls offer the entire retail industry an effective tool to reach our shared goal of 100 percent compliance for age-verification and quantity-purchase limits. We have proposed that Health Canada consider mandating Enhanced Access Controls, including advanced age verification and product quantity limits, at retail and online.
- We continue to expand the body of scientific knowledge and research around vaping products in Canada with the goal of publishing and presenting this research in peer-reviewed journals at major international conferences.

⁷³ Statistics Canada, Canadian Tobacco and Nicotine Survey 2019. July 2020. Link

⁷⁴ Institute of Medicine. *Public health implications of raising the minimum age of legal access to tobacco products*. National Academies Press Washington, DC; 2015. Link

Appendix 2 - 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, 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 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.