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VAPING INDUSTRY TRADE ASSOCIATION
ASSOCIATION DES REPRÉSENTANTS DE L'INDUSTRIE DU VAPOTAGE

Consultation Response to *proposed* Order Amending Schedules 2 and 3 to the Tobacco and Vaping Products Act

Submitted on Thursday September 2nd 2021

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Ms Gingras,

The Vaping Industry Trade Association of Canada (VITA) is pleased to submit our response to the proposed *Order Amending Schedules 2 and 3 to the Tobacco and Vaping Products Act (Flavours)* as presented in the Canada Gazette 1 on *June 19th, 2021.*

VITA is deeply concerned that the proposed restrictions will have a devastating impact on our sector, foster the expansion of an illicit market that does not age-gate or properly provide quality control and increase the number of smokers in Canada.

Best Regards,

Daniel David,

President,

Vaping Industry Trade Association (VITA)

Declaration of Interests and Right to Submit

"Transparency and international obligations"
“Any perceived or actual conflicts of interest with the tobacco industry must be declared when providing input to this consultation." "Members of the vaping and/or pharmaceutical industry, an affiliated organization or an individual acting on their behalf are asked to clearly indicate this in their submission." Canada Gazette Part I, Vol. 155, No. 25 – Page 2987

VITA, As the national voice for Canada’s vaping sector includes members who also produce tobacco products. This participation in our Association represents a minority position on our Board of Directors, which is codified within our bylaws to ensure that independent vaping companies can continue to ensure a vibrant, diverse policy development process within our Association and to ensure that our primary focus remains helping adult smokers access a product category that is 95% less harmful than smoking.

VITA believes and contends that this minority participation in our organisation does not create any conflicts. Indeed, the participation of industry participants allows us to develop better viewpoints with an eye towards helping Canada’s 4.5 million smokers reduce their risk.

Should there be dispute about our submission or perceived conflicts, VITA stands ready to supply a copy of our bylaws which validate the independence of our organisation. We expect our views to be considered, as one of the primary impacted stakeholders.

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VITA Consultation Submission

About VITA:

Canada's largest trade association (by market share) representing the vaping industry's manufacturers, importers, distributors and retailers, VITA is committed to working with stakeholders and governments to set and uphold regulations for vaping products in Canada. Our approach is based on credible evidence, science, facts, and logic. In our efforts to responsibly grow and defend the category, the Association is committed to collaborating with Health Canada and other regulatory bodies to identify best practices and to inform the development of evidenced-based regulations.

Introduction to This Submission

There are many flawed assumptions and problems related to the impact of this proposal that despite having 75 days and teams of experts working on this, we still couldn't cover everything. Instead, we decided to focus our response to areas that we are uniquely qualified for while leaving certain issues to other expert submissions.

VITA's submission will focus primarily on three broad topics:

1. The technical issues & challenges presented by the proposed restrictions
2. The illicit market impact caused by similar restrictions (Attached as Appendix 1)
3. Alternative options.

Canada's Vaping Industry: The Legislative Path to Regulation:

On May 23rd, 2018, the Act to amend the Tobacco Act and the Non-smokers' Health Act and make consequential amendments to other Acts received royal assent, bringing the Tobacco and Vaping Products Act (TVPA) into force. This created a policy framework which allowed the legal and highly regulated sale of nicotine vaping products in Canada.

This was an outflow of Vaping: Toward a Regulatory Framework for E-Cigarettes in 2015, which found broad support from witnesses for the regulation of the category as a reduced risk consumer product.

Various other regulations under the TVPA have been made since this time, including restrictions on public facing advertising and product labelling at a federal level.

All provinces have enacted additional legislative/regulatory regimes intended to restrict access to youth.
These recent legislative and regulatory steps have ensured that in no part of Canada is it legal for:

- Youth to buy or consume nicotine vaping products.
- Youth to be exposed to marketing materials related to vaping products.

Since the recent creation of a highly regulated framework to legally access vaping products, a significant and diverse industry has emerged including a range of different access points. These access points include:

- 1400 dedicated specialty vape shops which are predominantly small independently owned businesses.
- Over 30,000 convenience stores and gas stations.
- 200 domestic manufacturers of E-liquid.

- Approximately 10-15 large distributors.

While the convenience store and gas station channels are the largest access point for vaping products, the direct economic/employment footprint is difficult to fully quantify because they provide a range of other goods.

However, when one considers only the specialty vape channel, manufacturers, and distributors, of which the vast majority would fall under the definition of small business, VITA can estimate, based on the average number of employees within these respective operations, that:

- Approximately 7000 - 7500 Canadians are directly employed within the specialty vape channel and ancillary areas such as e-liquid manufacturing and distribution.

Vaping as a Harm Reduction Product:

Vaping is not harm-free and should never be presented as an absolutely safe, or harmless product. It is however significantly less harmful than smoking combustible cigarettes.

According to Health Canada:

- Vaping products deliver nicotine in a less harmful way than smoking cigarettes.
- Vaping products may reduce health risks for smokers who cannot or will not quit using other methods.
- Vaping products contain a very small fraction of the 7,000 chemicals found in tobacco smoke, and where present, they are at significantly reduced levels.[1]

This view is informed and supported by the majority opinion in the global scientific community that vaping is significantly less harmful than smoking. For example:

- Public Health England's 2015 evidence report found that, in their "While vaping may not be 100% safe, most of the chemicals causing smoking-related disease are absent and the chemicals which are present pose limited danger."[2]
- In 2018 the US National Academies of Sciences, Engineering and Medicine (NASEM) found that the available evidence suggests e-cigarettes are far less harmful than combustible cigarettes.[3]
- According to the Royal College of Physicians (UK), the available data suggests that vaping products "are unlikely to exceed 5% of those [risks] associated with smoked tobacco products and may well be substantially lower than this figure.[4]

Due to this significant disparity in harm, vaping has become an effective tool for many adult smokers seeking to reduce their risk associated with the consumption of nicotine.

The Canadian Tobacco and Nicotine Survey (CTNS) data indicates that over 1 million adult Canadians have used a vaping product in the last 30 days, compared with an estimated 4.5 million adult smokers.[5]

This is positive, as increasingly, evidence is emerging that demonstrates that vaping is one of the best ways, if not the best way, to transition smokers away from combustible cigarettes.

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[1] https://www.canada.ca/en/health-canada/services/smoking-tobacco/vaping/smokers.html

[2] https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/733022/Ecigarettes_an_evidence_update_A_report_commissioned_by_Public_Health_England_FINAL.pdf

[3] https://www.nap.edu/catalog/24952/public-health-consequences-of-e-cigarettes

[4] https://www.rcplondon.ac.uk/projects/outputs/nicotine-without-smoke-tobacco-harm-reduction

[5] https://gazette.gc.ca/rp-pr/p1/2020/2020-12-19/html/reg3-eng.html

For example, a 2021 comparison of the efficacy of vaping vs nicotine replacement therapy (NRT) in England found that vaping was approximately twice as effective in encouraging quitting smoking.[6]

Vaping is Not for Youth or Non-Smokers:

As detailed, vaping's purpose is linked to the category's efficacy as a tool for adult smokers to reduce risk. Vaping is not intended for youth, non-smokers and in no case should its usage by minors be allowed or encouraged.

In each Canadian province, and at the federal level, it is illegal to sell vaping products to minors and evidence demonstrates that the primary youth access points are predominantly through social sharing and online access from unregulated international suppliers.

VITA believes that enhanced enforcement of current restrictions, coupled with robust youth education around the potential harms of vaping is the best targeted approach to minimize youth uptake.

To this end, VITA has actively been working with member companies and service providers such as Patronscan and Equifax to ensure that beyond physical age verification, sophisticated ID scanning technology is available and in the field in as many locations as possible.

Nova Scotia: The Unintended Consequences of Prohibition:

In April of 2020 Nova Scotia implemented a comprehensive flavour ban and nicotine cap of 20mg/ml. The stated purpose of this proposal was to combat youth vaping rates by ensuring that vaping products are not appealing to youth.

However, the primary outcome appears to have made the product less effective for adults trying to reduce risk, shutting down much of the legal and regulated vaping sector, leaving unregulated and illegal youth access points largely unaffected.

Since the implementation of these restrictions:

- The Atlantic Convenience Store Association President, Mike Hammond, indicated that local retailers saw a significant spike in the purchase of legal tobacco cigarettes for the first time in years.[7]
- Neilsen Data showed an immediate near-term increase of the sale of legal tobacco cigarettes of over 25% following the implementation of a nicotine cap and flavour ban.[8]
- Abacus polling data showed that 30% of vapers were at risk of migrating back to smoking after successfully switching to vaping.

The transition of adult vapers returning to smoking has had a devastating impact on the specialty vape market, resulting in the immediate closure of 50% of local vape shops. Without a successful conclusion to the ongoing legal challenges in the province, VITA expects the permanent closure rate to grow to at least 85% of the Nova Scotia vape shop sector.

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[6] https://www.gov.uk/government/publications/vaping-in-england-evidence-update-february-2021/vaping-in-england-2021-evidence-update-summary

[7] https://www.halifaxtoday.ca/local-news/cigarette-sales-in-nova-scotia-increasing-atlantic-convenience-stores-association-2792516

[8] Neilsen Data, "Cigarette sales from Nielsen Canada, 2017-2020", September 24th, 2020

Despite this immediate increase in cigarette sales and the rapid contraction of the legal vape market, VITA is unaware of any evidence to demonstrate a reduction in youth consumption on any significant scale. This appears to validate industry's long-standing position that the legal market is not the primary access point for youth and that reducing the efficacy of vaping products for adult smokers is not an appropriate or effective policy to address youth vaping.

Compliance and Enforcement

Enforcement Issues - Federal Communication and actions:

Since the passing of Bill S-5 [TVPA] in May 2018 the industry has faced a plethora of regulatory changes at both a provincial and federal level. In a regulatory and legislative environment that is in constant flux, a lack of guidance and consistent enforcement is challenging for any business, and even more so during mandatory lockdowns due to COVID-19.

To add further context, while Health Canada has been active on the enforcement front, much of this work, while important, is not focused on the primary issue of youth access to vaping products. Instead, it seems disproportionately focussed on technical issues, for example font size or consumer written testimonials.

When regulations are proposed with the express purpose of protecting youth, as an industry, we expect regulators to provide detailed expectations to all new regulations. Since 2019 Health Canada has released three compliance and enforcement reports. All three reports include a column citing what actions Health Canada took with respect to products they deemed to be noncompliant. While these found 1232 infractions, not one led to penalization under the law. Warnings are a good first measure, but they must be promptly followed up on, so that penalties can be applied where appropriate.

VITA believes that if youth access is the core issue, then instead of prioritizing minor technical issues, Health Canada should develop a coordinated approach with provincial governments to significantly increase enforcement in the key area of youth access. Any company found to be providing vaping products to youth or seeking to develop youth as customers should face significant consequences. We believe this approach would result in a tangible reduction in youth vaping; as opposed to the proposed regulations, which would increase the number of smokers in Canada and have an undetermined impact on youth vaping rates.

Industry Action on Compliance

In April of 2021, Health Canada notified vaping industry associations about some of the issues they were finding during their compliance inspections on websites and social media pages. The industry took these findings very seriously and committed to take corrective action.

In May 2021, VITA responded to Health Canada's call for online compliance by creating an online compliance program with the full support and participation of CVA. This program called for vape companies to submit their online websites, Instagram, Facebook, and Twitter IDs for review through an online portal system.

VITA then established a compliance review team comprised of 11 highly trained and experienced individuals from across the industry who would comb through each page searching for items that were non-compliant under the current regulatory framework. Upon completion of the first review, a letter of findings was sent to the corresponding business with examples of their non-compliant items

and suggested corrective measures. Additional support was offered by providing tools and one on one assistance to ensure appropriate changes were made. The compliance teams checked every registered company page at least twice or until the business owner was comfortable with the compliance level of their website. The second review was also designed to continuously track the number of compliance improvements over time.

Less than eight weeks later, VITA was able to present the compliance program and results to Health Canada. We also presented various challenges identified throughout this process, including the various interpretations of what would be considered “appealing to youth” and consumer testimonials. Unfortunately, Health Canada was not able to provide any clarifying answers to these questions that would allow us to strengthen industry compliance efforts.

Despite the lack of clarity from regulators we are proud to report that our compliance program was extremely successful. Upon the Health Canada publication (Aug 5) of non-compliant Instagram account content for Canadian vaping companies, we were able to compare their audit results against our reviews and are proud to see that a vast majority of reported companies had already corrected their issues well before the report was released. A high-level summary of industry driven compliance efforts and improvements include:

- Designed, promoted, and executed from April 15 to June 3 2021
- First Review - Total Websites & Social Media pages reviewed: 701
- Total Number of Companies reviewed: 254
- Compliance Notice Letters Sent: 254
- Second Review – Websites & Social Media pages reviewed: 701
- Tracked Compliance Improvements (Promotions/testimonials removed, warnings added): 336+
- Social Media accounts closed: 30+

VITA and the vaping industry take compliance seriously and will continue to engage with Canadian companies to ensure compliance targets are met. In saying this, we must note that since the implementation of the TVPA, VPPR, and VPLPR, through quarterly meetings with Health Canada, and written correspondence through their inspectorate program, little clarity has been provided to the industry on what ‘compliance’ or ‘non-compliance’ looks like in specific situations. Through legal consultation we are met with the same vague answers.

One of the hardships the industry is currently undergoing is the lack of guidance from Health Canada regarding compliance issues. After a very in-depth second review, Health Canada contacted a member company stating a compliance issue; however, they would not identify what the issue was. We engaged with Health Canada alongside the business owner and were told to simply contact a lawyer as they could not state what the non-compliant item was. We overviewed the site and could not find an issue under the regulation stated and question what their compliance measures are and whether they were unable to identify the issue. Our compliance program was made to be rigorous and tracked by each step, allowing us to see the steps taken from start to finish. The second review of each company is done fine tooth to identify any or all notable issues. If we are unable to identify the issues, we should be able to rely on regulators to provide the proper information if compliance is their goal. Without guidance from our regulators the vaping industry is left asking questions and facing scrutiny for issues that are simply not detectable.

Technical Committee Review

VITA Established a technical review panel comprised of chemists, researchers, and qualified experts who analyzed the proposed legislative and regulatory changes outlined in the Canada Gazette Part I, Vol. 155, No. 25 – Page 2987. Their research was divided into 5 specific topics: Reformulation, Methodology, Ingredients, Sensory Attributes, and Industry Impact.

Reformulations

> Based on a preliminary scan of a representative sample of e-liquids, Health Canada assessed the extent to which reformulation may be required. It was found that approximately 20% of tobacco-flavoured vaping products and 15% of mint/menthol-flavoured products would not require reformulation. The remaining tobacco- and mint/menthol-flavoured products (about 80% to 85%) may require reformulation and impose related costs on industry. Thus, this analysis assumes that 82.5% of tobacco- and mint/menthol-flavoured vaping products remaining on the market would be reformulated.

Our research indicates that a minimum of 95% of currently available tobacco-flavoured or mint/menthol-flavoured vaping products will require completely new formulations rather than reformulations. All currently available flavouring bases used in the vaping market will be disallowed based on the 40 ingredients approved for use in tobacco-flavoured products and 42 ingredients for mint/menthol-flavoured products. This will result in international flavour houses having to newly formulate their solutions to cater to the specific requirements of the Canadian market (which is unlikely), or will result in the closure of small businesses as they will be unable to procure and produce flavourings in a non-standardized format.

Implementation Lead Time

For the businesses that are able to pivot and accommodate these new flavouring requirements, the implementation timeframe is inadequate. Based on the current proposal, there would be 180 days following royal assent until enforcement of the new regulations. Standard product development, testing, and validation practices can take up to 18 months; and must be completed prior to the start of production. Limiting product development, testing, validation, and production to 180 days after royal assent is unachievable for mid-to-large scale manufacturers.

Production Practices

In addition to the 18-month lead-time on new vapour product development, the Canadian vaping industry will be largely impacted by the lead-time on new product development from the flavour houses that supply e-substances to manufacturers. Aside from the production practices of the large, tobacco-affiliated vape companies, all Canadian e-substance manufacturers procure their flavouring ingredients from flavour houses. These flavour house suppliers offer pre-blended flavour bases in various profiles. Canadian manufacturers procure these ingredients to use in their final-product blends – these final products could contain anywhere up to 25 different flavour base ingredients. Due to the size of the Canadian vaping industry, it is very unlikely that these international flavour houses will reformulate their flavour bases to cater to these newly-proposed Canadian regulations. If they did opt to reformulate products for the Canadian marketplace, we should expect a lead-time on new offerings of at least 6 months. Factoring the flavour house lead-time and the 18-month lead-

time for new vapour product development, the implementation timeframe would need to be modified to accommodate these elements. If these, or similar regulations are enacted, a minimum lead time from royal assent to enforcement should be 24 months at minimum.

Impact

The Technical Committee was surprised that Health Canada assumed that 17.5% of products on the Canadian market would not require reformulation or new formulation. Our preliminary findings indicate that at most, 5% of products in the Canadian market would meet compliance under these newly proposed regulations. While there are a vast selection of tobacco, mint, and menthol flavoured products on the market, many of the flavour bases being used contain sweeteners or other ingredients that would not be allowed. We've come to our assumption of 5% products currently existing in the market by conducting analysis of the compounds used in tobacco, mint, and menthol flavouring bases from international flavour houses. Aside from one tobacco flavour base (information below), all existing tobacco flavourings would require reformulation to meet the proposed regulations. Additionally, aside from menthol-only flavour bases there are an extremely limited selection of mint flavourings that do not contain sweeteners, or other mint-profile flavourings that are not contained in the exemption list.

As stated in the proposed regulations, unflavoured vaping products are not popular, but would require no reformulation. Since they represent less than 1% of the vaping market, this number is included in the 5% assumption. We have also determined through our research that approximately 1% of currently-existing tobacco-flavoured vaping products would be compliant under the proposed regulations, this number is also included in the 5% assumption. Our research of the available mint/menthol flavour bases currently being used in the Canadian vaping market indicate that approximately 3% of these products would not require reformulation, this number is also included in the 5% assumption.

In addition to the burden resulting from the lead time on preparing these new flavour bases by large, international flavour houses, the newly proposed regulations could also pose an unforeseen burden on manufacturers in having to validate the flavour bases via gas chromatography prior to production to ensure that there is no prohibited ingredients at the supplier level. Since the banned ingredients would be readily utilized in these flavour house environments, the potential for a non-exempt ingredient being evident in a flavour base is relatively high. This would therefore result in a significant impact on the e-liquid manufacturing sector by either having to bring in-house testing (very high cost) or outsourcing the validation of flavours prior to production (costly and excess burden on the supply chain).

The revised estimation of 95% of products requiring new formulation (reformulation) has a direct impact on the cost estimate. Based on the revised data, the estimated cost would be $33.7 million PV over 30 years. Additional costing elements should be considered – recruiting highly-skilled employees to facilitate the new formulation requirements, additional testing requirements to ensure production compliance, and disposal of dead inventory resulting from manufacturers' non-approved flavouring stock levels. In addition, as a result of the sensory panel not being enacted until 2-5 years post-regulation, there will likely be additional formulation costs required of manufacturers to accommodate the uncertainty regarding products that are using only-approved ingredients that do not pass the sensory panel approval.

From another frame of reference, based on Health Canada's assumption on the costs of $25,000-$75,000 per formulation, this will result in a cost ranging from $375,000-$1,125,000 per

manufacturer. When multiplying this by the 200 vaping liquid manufacturers in Canada (as indicated by Health Canada), this would result in a forced cost to the vaping industry of $75,000,000-$225,000,000. This is far-and-above the Cost Benefit Analysis' figure of $28,488,750 PV in Reformulation costs that is utilized for the Cost Benefit Analysis. As we can see, this creates an even further out-weighing of the costs under the proposed regulations when compared to the benefits.

New Formulations

Another large challenge in addressing the new formulations (reformulations) arises from the uncertainty regarding the sensory attributes panel. A consumer product must be manufactured in such a manner to be appealing to the target consumer (adult vapers / smokers). With the lack of information regarding the proposed restrictions on sensory attributes, how are manufacturers best-suited to accommodate this? How "good" can we make our tobacco and mint/menthol products before they "cross the line" into a banned product? Are we limiting the target audience (adult vapers / smokers) to a sub-par product to accommodate the proposed regulations and further exacerbating the likelihood of current vapers returning to smoking in addition to less current smokers completely switching to vaping as a less-harmful alternative?

These newly proposed regulations will ensure the closure of many small-to-mid scale companies. In light of global circumstances resulting from COVID-19, the Canadian economy has a lot of hard work ahead to restore to pre-pandemic strength. These same companies that will be forced to close support local small businesses, provide above-standard living wages for numerous employees and families, generate tax revenue for the governments, and have helped to bolster the Canadian image of excellence through developing a globally respected, self-regulating industry; in spite of the lack of governmental oversight from 2008 through 2018 until the first vaping product regulations were enacted. The abounding impact on the economy as a result must be quantified and included in the Cost Benefit Analysis to adequately consider the regulatory impacts of this proposal.

Upon review of the tobacco flavouring blends available to purchase form the Canadian vaping industry's primary flavour house suppliers, there only exists 1 tobacco flavouring base that would be permitted for use under the proposed regulations:

1) RY4 Asian Flavour (The Flavorists Apprentice)

Upon consultative review of the Canadian e-substance manufacturing sector, we have determined that less than 1% of products on the market contain this RY4 Asian Flavour. More importantly it can be estimated that, currently, there would be less than 1% of tobacco-flavoured vaping products on the market containing ingredients that have known CMR properties.

In addition, most mint/menthol flavouring bases will have to be reformulated to fall within the requirements under these proposed regulations. Again, we must highlight that these are international flavouring suppliers and the likelihood of products being reformulated to satisfy the relatively small Canadian demand is low. The impact on many small businesses (that make up a substantial portion of the Canadian vaping industry) as a result of these changes will be detrimental – resulting in many business closures, job losses, reduced taxation for governments, and countless vapers returning to smoking with its detrimental health issues.

Summary

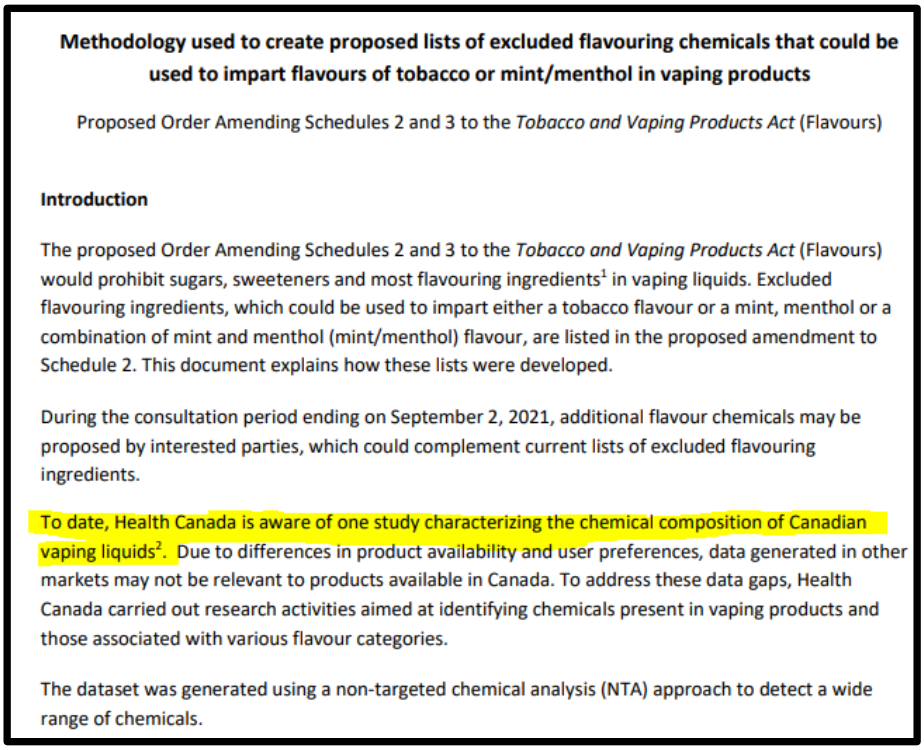
In summary, when considering the potential impacts resulting from these proposed regulations, if they were to proceed, a minimum of 24-months for implementation would be necessary. As illustrated above, the flavouring supplier lead time, vaping product manufacturer lead time, and

excessive burdens associated would make it virtually impossible for the industry to align within the proposed 180-day lead time for implementation after royal assent. We also highly recommend additional review into the potential impacts that these regulations would have – creating excessive cost, extended raw material validation lead times, and unsurety for the manufacturing sector fostering the potential for non-compliance and increased cost of enforcement for Health Canada.

Methodology

The Technical Committee has many unanswered questions and grave concerns about the methodology applied by Health Canada in their current study on the chemicals found in vape e-liquid, but without Health Canada's full disclosure of the research, the committee is unable to resolve these concerns. The following report highlights areas of question and concern brought forth by the committee.

A. Health Canada Report - *Introduction*



Methodology used to create proposed lists of excluded flavouring chemicals that could be used to impart flavours of tobacco or mint/menthol in vaping products

Proposed Order Amending Schedules 2 and 3 to the *Tobacco and Vaping Products Act* (Flavours)

Introduction

The proposed Order Amending Schedules 2 and 3 to the *Tobacco and Vaping Products Act* (Flavours) would prohibit sugars, sweeteners and most flavouring ingredients[1] in vaping liquids. Excluded flavouring ingredients, which could be used to impart either a tobacco flavour or a mint, menthol or a combination of mint and menthol (mint/menthol) flavour, are listed in the proposed amendment to Schedule 2. This document explains how these lists were developed.

During the consultation period ending on September 2, 2021, additional flavour chemicals may be proposed by interested parties, which could complement current lists of excluded flavouring ingredients.

To date, Health Canada is aware of one study characterizing the chemical composition of Canadian vaping liquids[2]. Due to differences in product availability and user preferences, data generated in other markets may not be relevant to products available in Canada. To address these data gaps, Health Canada carried out research activities aimed at identifying chemicals present in vaping products and those associated with various flavour categories.

The dataset was generated using a non-targeted chemical analysis (NTA) approach to detect a wide range of chemicals.

The single study that is referred to above by Health Canada had the main objective to identify flavouring chemicals and potential toxicants in e-cigarette products in Ontario, Canada. [9]

The study stated that it "*systematically purchased at 80 retail outlets across 4 cities in Ontario, Canada, in January–February 2015. Product constituents were identified using gas chromatography and mass spectrometry. Additionally, tobacco-specific nitrosamines (TSNAs) were quantified in tested products using liquid chromatography with tandem mass spectrometry.*"

Notes related to Study:

[9] https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6964474/

Although Health Canada does not make clear how much they relied on this study, it is worth noting the following points regarding the referenced study:

1. The study was performed in early 2015 and is out of date because e-liquid manufacturers have become more sophisticated and the market more regulated since 2015.

2. The 2015 study's (recent Health Canada study only states "diverse") selected samples were "systematically" purchased versus a random sampling.
    - There are many reports available discussing the advantages and disadvantages of systematic sampling versus random sampling. The key points are:
        - Systematic sampling is used when on a tight budget or a short timeline due to the method being simpler, faster and cheaper. This method is at risk for data manipulation if researchers reorder or restructure a data set posing a threat to running an informative and clear study.

3. The 2015 study (similar to the recent Health Canada study) does not make clear the chain of custody of the samples: (a) how long product may have sat on retailers' shelves or whether it was expired? (b) who, how or where was it manufactured and if it was made in Canada or outside Canada? and (c) how did the retailer store the product with respect to heat/light?
    - The concern is whether the samples represented the population of good quality products to make up the data set and that could have been a risk of chemical changes caused by environmental factors and/or time on the shelves/expired products.

4. The 2015 study results were published in 2019, indicating that it took years to finalize the results, including references to other studies from 2017.
    - It is not understood by the Committee why the 2015 study took so long to finalize results and our concern is whether time had an outcome on the results.

5. The 2015 study (similar to the recent Health Canada study) used *gas chromatography and mass spectrometry* which is highly accurate, except when there is a thermally labile[10] compound being tested.
    - The WFO FCTC sets out in their REGULATION OF THE CONTENTS OF TOBACCO PRODUCTS AND OF TOBACCO PRODUCT DISCLOSURES[11] on page 17 Appendix 3 (d) & (e) that Headspace-Gas Chromatography[12] or Solid-Phase Microextraction should be used, specifically for flavouring agents which have a low boiling point and the vapor is being tested. The Technical Committee's concern is that the method used may not have been appropriate to test e-liquid because of the temperatures used and could have resulted in skewed tests. And that Headspace-Gas Chromatography would have been a more appropriate and valid testing method to use.

6. The 2015 study tested 166 products that were systematically collected from 80 retail outlets across 4 cities in Ontario from vape shops, convenience stores and gas stations. Out of the 166 products, 55 were tobacco and 36 were menthol with the balance being classified as

[10] https://www.phenomenex.com/Info/Page/labilecompounds
[11] https://www.who.int/fctc/guidelines/Guideliness_Articles_9_10_rev_240613.pdf?ua=1
[12] https://en.wikipedia.org/wiki/Headspace_gas_chromatography_for_dissolved_gas_measurement

fruit, drinks, non-fruit sweets and other. Tobacco and menthol made up 55% of their sample size. Their findings resulted in 19 different chemicals found. However, only 2 of the chemicals (Trimethylpyrazine - CAS 14667-55-1 and Menthol - CAS 2216-51-5) detected in the 2015 study is on Health Canada's list of excluded chemicals.

- Both studies were attempting to determine common chemicals found in Tobacco and Mint flavoured e-liquid, and the 2015 study samples consisted of 55% combined of these 2 categories, while the Health Canada study samples consisted of 28% Tobacco and Mint. The Technical Committee would have expected more chemical overlap than 2 chemicals.

Table 2

Flavouring chemicals commonly detected in e-cigarette products ($n = 166$)

Chemical name	CAS no.	Odour type	Flavour and odour description	Potential inhalation toxicity (Y/ND)*	Frequency of detection % (*n*)	
1-Methyl naphthalene	90-12-0	Naphthyl	Naphthyl, chemical, medicinal, camphoreous	ND	69.3	(115)
2-Methyl naphthalene	91-57-6	Floral	Sweet, floral, woody, oily, aromatic	ND	62.7	(104)
Isoquinoline	119-65-3	Balsamic	Sweet, balsamic, herbal, almond, bitter almond, anise	ND	41.6	(69)
Menthol	2216-51-5	Mentholic	Peppermint, cooling, mentholic, minty, camphoreous, clean, spicy	ND	24.7	(41)
Ethyl vanillin	121-32-4	Vanilla	Sweet, creamy, vanilla, caramellic, smooth	ND	22.3	(37)
Benzyl alcohol	100-51-6	Floral	Floral, rose, phenolic, balsamic	Y	19.9	(33)
Benzaldehyde	100-52-7	Fruity	Strong, sharp, sweet, bitter, almond, cherry, oily, nutty, woody	Y	21.7	(36)
Vanillin	121-33-5	Vanilla	Sweet, vanilla, creamy, chocolate, creamy, spicy, phenolic, milky	Y	21.7	(36)
Ethyl maltol	4940-11-8	Caramellic	Sweet, caramel, jam, strawberry, cotton candy	ND	18.7	(31)
Terpineol	8000-41-7	Herbal	Fresh, clean, woody, pine, floral, lime	ND	15.7	(26)
Triacetin	102-76-1	Fruity	Clean, tropical fruit, creamy, oily	ND	7.8	(13)
Anisaldehyde	123-11-5	Anisic	Sweet, powdery, mimosa, floral, hawthorn, balsamic, creamy, vanilla, marshmallow	ND	6.6	(11)
Valeric anhydride	2082-59-9	N/A	N/A	ND	6.6	(11)
Gamma-decalactone	706-14-9	Fruity	Fresh, oily, waxy, peach, apricot, coconut, buttery, sweet, fruity, creamy	ND	6.0	(10)
Methyl, 3-hydroxy-hexanoate	21188-58-9	Fruity	Sweet, woody, ripe, fruity, pineapple, tropical, juicy, oily	ND	6.0	(10)
Cyclotene (3-methyl-1,2-cyclopentanedione)	765-70-8	Caramellic	Sweet, caramel, maple, sugar, coffee, woody	ND	6.0	(10)
Creosol	93-51-6	Spicy	Spice, clove, vanilla, phenolic, medicinal, leathery	ND	6.0	(10)
Trimethylpyrazine	14667-55-1	Nutty	Nutty, musty, earthy, powdery, cocoa, roasted peanut	ND	5.4	(9)
Rheosmin	5471-51-2	Fruity	Sweet, berry, jam, raspberry, ripe, floral	ND	5.4	(9)

CAS, Chemical Abstract Service; *Y*, yes; *ND*, not determined

Chemicals presented are those that were detected in a minimum of 5% of all tested products

*Inhalation toxicity determined using a flavourings database, available at: http://www.thegoodscentscompany.com/search2.html

7. The 2015 study outlines its limitations, highlighting that their sample of products was not necessarily representative of the Ontario or Canadian market. It further notes that direct inhalation exposures were not examined in the current study.

B. Health Canada Report - *Introduction Cont'd*

Methodology used to create proposed lists of excluded flavouring chemicals that could be used to impart flavours of tobacco or mint/menthol in vaping products

Proposed Order Amending Schedules 2 and 3 to the *Tobacco and Vaping Products Act* (Flavours)

Introduction

The proposed Order Amending Schedules 2 and 3 to the *Tobacco and Vaping Products Act* (Flavours) would prohibit sugars, sweeteners and most flavouring ingredients[1] in vaping liquids. Excluded flavouring ingredients, which could be used to impart either a tobacco flavour or a mint, menthol or a combination of mint and menthol (mint/menthol) flavour, are listed in the proposed amendment to Schedule 2. This document explains how these lists were developed.

During the consultation period ending on September 2, 2021, additional flavour chemicals may be proposed by interested parties, which could complement current lists of excluded flavouring ingredients.

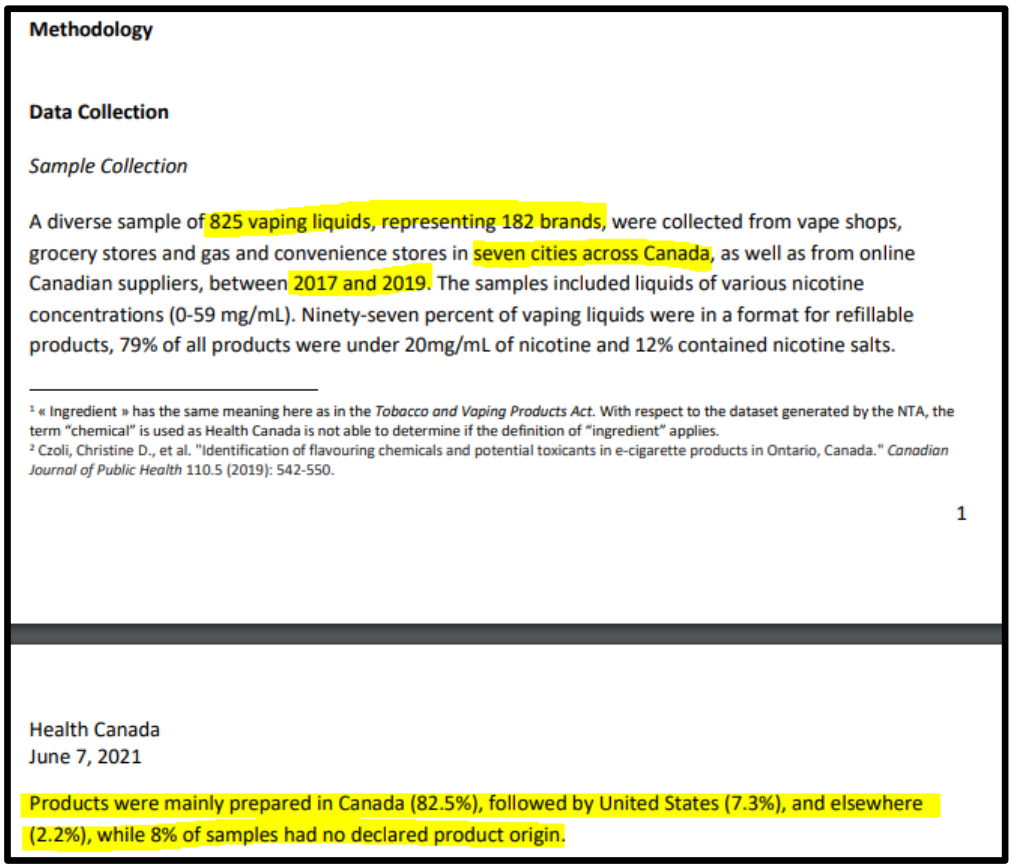
To date, Health Canada is aware of one study characterizing the chemical composition of Canadian vaping liquids[2]. Due to differences in product availability and user preferences, data generated in other markets may not be relevant to products available in Canada. To address these data gaps, Health Canada carried out research activities aimed at identifying chemicals present in vaping products and those associated with various flavour categories.

The dataset was generated using a non-targeted chemical analysis (NTA) approach to detect a wide range of chemicals.

1. Health Canada stated that the dataset was generated using a non-targeted chemical analysis.
    - The USA EPA states that "NTA approaches largely produce qualitative results and don't estimate chemical concentrations, which limits their use in risk assessment. Chemical concentration is necessary to assess potential exposure, which looks at how much of a chemical was present and the source of exposure to determine potential health risks."[13] The Technical Committee's concern is that NTA was not an appropriate approach and may not have estimated the chemical concentrations found in the samples thereby skewing the results.

C. Health Canada Report - *Data Collection*

[13] https://www.epa.gov/sciencematters/epa-scientists-test-non-targeted-analysis-methods-using-drinking-water-filters



Methodology

Data Collection

Sample Collection

A diverse sample of 825 vaping liquids, representing 182 brands, were collected from vape shops, grocery stores and gas and convenience stores in seven cities across Canada, as well as from online Canadian suppliers, between 2017 and 2019. The samples included liquids of various nicotine concentrations (0-59 mg/mL). Ninety-seven percent of vaping liquids were in a format for refillable products, 79% of all products were under 20mg/mL of nicotine and 12% contained nicotine salts.

[1] « Ingredient » has the same meaning here as in the *Tobacco and Vaping Products Act*. With respect to the dataset generated by the NTA, the term "chemical" is used as Health Canada is not able to determine if the definition of "ingredient" applies.
[2] Czoli, Christine D., et al. "Identification of flavouring chemicals and potential toxicants in e-cigarette products in Ontario, Canada." *Canadian Journal of Public Health* 110.5 (2019): 542-550.

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Health Canada
June 7, 2021

Products were mainly prepared in Canada (82.5%), followed by United States (7.3%), and elsewhere (2.2%), while 8% of samples had no declared product origin.

***Some of the Technical Committee concerns listed below are based on assumptions due to the lack of information provided in the Methodology report, such as the use of non-probability sampling and exclusion criteria. Further disclosure by Health Canada may resolve these concerns.**

1. The data collection represented e-liquid purchased over a 2-year span from 2017-2019, which could have been manufactured at a time earlier than 2017. Which brands were used? Those made by reputable manufactures in ISO standard labs or the back rooms of vape shops?
    - E-liquid manufacturers have become more sophisticated (established laboratories) and the market has become more regulated since that time, including the addition of made-on and expiry dates. The Technical Committee's concern is that Health Canada could have tested e-liquid that was manufactured as early as 2015 which would not be comparable to current standards in the market.
    - The Technical Committee's concern is that the samples may not have been manufactured under current ISO standards that most reputable manufacturers use and therefore not be representative of current e-liquid on the market.

2. The Health Canada study does not make clear the chain of custody of the samples: (a) how long product may have sat on retailers' shelves or whether sample was expired? (b) who, how or where it was manufactured? (c) how did the retailer store the product with respect to heat/light exposure? (d) what steps did Health Canada take to preserve the samples in their lab so as not to contaminate the liquid prior to analysis?
    - The Technical Committee's concern is whether the samples represented quality products to make up the data set. Including whether there was risk of chemical

degradation caused by environmental factors and/or time on the shelves/expired. And if the chain of custody standards were not followed, what the impact of that would be on the related findings?

3. Health Canada states that it collected a "diverse" sample of 825 vaping liquids, but does not specifically state the method used.
    - Was it a random/probability or non-probability/systematic sample? Probability sampling involves random selection, allowing you to make strong statistical inferences about the whole group. Non-probability sampling involves non-random selection based on convenience and therefore risking the integrity of the results. HC states, a "diverse sample", but not a "random" sample which may mean that it was "non-probability"[14] sampling. Government of Canada Standards[15] for sample size (though related to surveys, it does address probability or random sampling vs non-probability), state that "non-probability" selection should be used with caution. This is further stated by Health Canada standards on Food[16] sampling which states that the sampling should be randomly selected.

4. Health Canada stated that their samples were 97% vaping liquids for refillable products, leaving 3% for non-refillable or pre-filled pods systems. Additionally, the sample only include 12% nicotine salts.
    - This sample data set is not representative of the current market where nicotine salts and pre-filled disposables are dominate sellers. This is another example of how old the study is, by not representing the liquids that are most commonly sold. The Technical Committee's concern is that the study results are out of date and pre-dates the current standards in the marketplace.

5. Were the inclusion/exclusion criteria[17] dearly identified? Health Canada states that 9.5% of the sample was manufactured outside Canada, while 8.0% had unknown origins. However, under Vaping Liquid Flavor Classification section of this report, they classified the entire 825 samples collected.
    - The Technical Committee's concern is that because all of the samples (825) were classified, Health Canada used 17.5% or 144 bottles of liquid manufactured outside of Canada in their testing. And of the 17.5%, 8% were of "unknown" origin leading the Committee to doubt the quality of the samples and therefore the results.

D. Health Canada Report – *Chemical Analysis*

[14] https://conjointly.com/kb/nonprobability-sampling/
[15] https://www.tpsgc-pwgsc.gc.ca/rop-por/rapports-reports/comiteenligne-panelonline/page-03-eng.html
[16] https://inspection.canada.ca/preventive-controls/sampling-procedures/eng/1518033335104/1528203403149
[17] https://assessment-module.yale.edu/human-subjects-protection/protocol-design-inclusion-and-exclusion-criteria

Chemical Analysis

Vaping liquids were analyzed in a Health Canada laboratory. Individual chemicals making up vaping liquid samples were separated using gas chromatography and qualitatively identified using non-targeted tandem mass spectrometry analysis (GC MS/MS). Immediately following the sample analysis, the data was processed and the spectrum of an individual unknown chemical was compared with reference spectra from mass spectral libraries[4]. An in-house database of chemicals in vaping liquids, compiled from previously reported peer-reviewed studies (available upon request), was used to create a list of expected chemicals in vaping products and increase confidence in the chemicals identified in the non-targeted analysis. Chemical name and CAS number (where available) were tabulated for each detected chemical resulting in the creation of an extensive dataset.

1. Health Canada applied GC MS/MS to identify chemicals in the vape liquid, which is a thermally liable substance.
    - The Technical Committee's concern is that the method used may not have been appropriate to test vape liquid because of the temperatures used and could have resulted in skewed test results. For most vape e-liquid studies using GC-MS a limitation in their findings is that samples examined constituents in e-liquids, not in e-cigarette aerosol, which is the end product being used by the consumers. As participants inhale the aerosol instead of ingesting the liquid, there may be different physiological effects from one another, and different risks/thresholds associated. We believe that Headspace-Gas Chromatography would have been a more appropriate method to use for testing e-liquid.
    - The WFO FCTC sets out in their REGULATION OF THE CONTENTS OF TOBACCO PRODUCTS AND OF TOBACCO PRODUCT DISCLOSURES[18] on page 17 Appendix 3 (d) & (e) that Headspace-Gas Chromatography[19] or Solid-Phase Microextraction should be used, specifically for flavouring agents which have a low boiling point and the vapor is being tested.
    - There is a study on the "Identification of flavour additives in tobacco products to develop a flavour library"[20] by Erna Krusemann (same researcher listed in Health Canada's footnote for the flavour wheel), which states, "Since headspace GC-MS focuses on volatile compounds, this technique is highly suitable and commonly used in flavour research.", but also states that "Since chemical analysis does not provide information concerning human perception of flavours, for regulation purposes chemical analysis should be complemented with knowledge obtained from sensory analysis." And further states, "In the future, the identification of flavour components should be confirmed using analytical standards, because absolute certainty regarding the identity of components is necessary for regulatory purposes. Similarly, their amount is of importance, in order to be able to determine whether the component is present in sufficient amounts to be perceived by consumers (for this, the human detection threshold must be known)." And "Flavours are complex due to the fact that they consist of complex mixtures of multiple flavour compounds. In addition, a defined universal combination of flavour components that causes a

[18] https://www.who.int/fctc/guidelines/Guideliness_Articles_9_10_rev_240613.pdf?ua=1
[19] https://en.wikipedia.org/wiki/Headspace_gas_chromatography_for_dissolved_gas_measurement
[20] https://tobaccocontrol.bmj.com/content/27/1/105#T2

certain flavour does not exist. Two products with similar perceived flavours may contain different combinations of flavour components. For instance, our chemical analysis has shown that two different mango-flavoured cigarette brands also have a different chemical composition. Furthermore, many flavour components are chiral molecules, that is, they are present in two different spatial forms that are mirror images of each other that cannot be superimposed, but are otherwise chemically identical. However, the two mirror images (enantiomers) often have quite different biological properties, such as their perceived flavour. Therefore, an analytical method aimed at predicting the flavour of a mixture as perceived by humans must be able to discriminate enantiomers, for example, by using chiral columns.8" and "The different types of flavour additives in cigarettes, and the complexity of their flavour description is not well characterised yet. Neither are the differences between products expected to have a characterising flavour, and those not expected to have such a flavour."

2. Health Canada relied on reported peer-reviewed studies to compile an in-house database of chemicals expected.
    - Upon requesting and reviewing (30%) of the peer-reviewed studies, the Technical Committee's concern is that the studies were outdated ranging from 1984 to 2015 and were not related to chemicals in e-cigarettes. A large percentage of the studies were related to testing Propylene Glycol, Nicotine and Tobacco. And many of the studies, which did test e-cigarettes had no chemicals in vape liquids referenced. Steps in a typical chemical analysis report should include not only (1) sampling, but (2) field sample pre-treatment (3) laboratory treatment (4) calculations and most importantly missing is (5) results presentation such as Tables, Figures, Schemes and Chemical Structures. The committee needs Health Canada to disclose the actual "confidence level" along with all the supporting research.

E. Health Canada Report – *Data Analyses*

Tobacco and Mint/Menthol- Associated Flavour Chemicals - Canadian Vaping Liquids

(The method described here is also applicable to mint/menthol vaping liquids.)

In order to determine tobacco flavour-associated chemicals in vaping liquids, flavour chemicals detected in vaping liquids labelled as tobacco flavour were compared to chemicals from other flavour categories. As several of the flavour chemicals were detected across all flavour categories, a relative detection frequency ratios (RDFR) algorithm was developed to generate a list of chemicals that are more associated with tobacco-flavoured vaping liquids compared to all other flavour categories.

Two ratios were generated based on the frequency of occurrence of each flavour chemical detected in tobacco-flavoured vaping liquids. The frequency of occurrence refers to the number of samples a chemical is detected in, relative to the total number of samples analyzed in a particular flavour category multiplied by 100 %.

1. Health Canada states they were relying on e-liquid “labelled” tobacco flavour.
    - The Technical Committee’s concern is that this method seems to lack scientific steps and may result in skewed results for tobacco flavors that are combination flavours, such as Vanilla Caramel, Pistachio or Mocha for example.

2. Health Canada states, “several of the flavour chemicals were detected across all flavours”.
    - Several, by definition means “not many”. The Technical Committee needs the details of Health Canada’s data table to better analyze what they actual found.

3. Health Canada states that they used RDFR.
    - Once again, the Technical Committee needs the data to review this adequately. The RDFR states that when they found a commonly used chemical, they “thought” it could indicate a function role, but no more is said about what that was or how they confirmed their thoughts.

4. Health Canada does not provide the data value and outcomes to see how the number of each sample category (Tobacco, Confectionary, Fruit) affect the analysis.
    - The Technical Committee is concerned that not having the same number of Fruit samples as Tobacco samples may affect the outcome. Health Canada does state that RDRF2 takes this factor into account, but the committee needs to review the data tables to verify the math.

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Why Appropriate Procedures, Protocols and Methodology Matters

Throughout any research study there is an importance to follow a structured protocol that is documented. This allows for other researchers to extrapolate your findings and generate similar results. Further allowing your data to hold up to a stringent review by your peers. These procedures start with following a documented protocol which includes information on the handling of samples from field to lab. This documentation includes data on samples acquired (date/time/location), age and storage conditions prior/post to you handling. This may also include things such as how samples were taken (randomly, selective, or location found {top shelf, dark cabinet}). Storage information and pre-handling conditions is especially important for thermally liable or light sensitive samples. Improper storage or transport can change the results of a study, by altering the chemical makeup of the sample you are looking at before it can make it to a controlled environment. A well-documented Chain of Custody will allow individuals to find any irregular sources of error from external forces. These can occur before testing but after sampling was acquired.

A study should also include clearly presented tables and figures which display the findings and results. With a well-documented research procedure and expected results, other researchers can run the experiment and find similar results which increases the validity of a study. Validity is important because it means that it can be replicated consistently and is probably true. This allows for the expansion of knowledge on the topic with further research building on the topic.

Another important section of a research paper is the limitations and sources of errors. Here authors state the issues observed while running the study and problems they had. These

limitations are important to place findings into context and interpret the validity of the scientific work. This helps in further ascribing a level of credibility to the published research.[21]

In conclusion, the Technical Committee has grave concerns about the methodology applied by Health Canada in their recent study and believe that Health Canada should therefore disclose their research in detail and allow the time for proper review by other researchers, including this Technical Committee.

The contributing factors for those concerns include, but are not limited to:

1. reliance on outdated studies, such as peer-review studies that were not focused on outcomes that provided a list of chemicals in vape liquid, published between 1984 to 2015 in order to compile an in-house database of expected chemicals and the 2015 cited study on identify flavouring chemicals and potential toxicants in e-cigarette products in Ontario, Canada, of which their methodology is also questioned by this committee;
2. problematic data collection methods over the period of 2017-2019, which likely represented vape liquid manufactured one to two years prior to the collection date and could be expired, as well as dubious samples resulting from possible poor conditioning and handling of the vape e-liquid in convenience stores and vape shops;
3. lack of consideration that more recent government regulations may have increased the standards for Canadian manufacturers and that some of the samples may have been manufactured by now defunct/out of business manufacturers;
4. a dataset generated by using non-targeted chemical analysis;
5. Health Canada's use of GS/MS in their chemical analysis despite clear evidence that headspace GS/MS should be used for these type of samples as recommended by the WHO;
6. Health Canada's decision to allow the inclusion of 17.5% of samples manufactured outside of Canada, with 8% being from "unknown origins".

Based on the serious concerns expressed by the Technical Committee and the impact on human life, we request that Health Canada review their applied methodology and reconsider their reliance on the outcomes. We reiterate that Health Canada should disclose their research in detail and allow the time for proper review by other researchers before implementing new regulations.

Exempt/Approved Ingredient List (CAS #)

There are 9 ingredients contained in the 82 exempted flavouring ingredients that have been identified as having CMR (***Carcinogenic, Mutagenic and Reprotoxic***) properties from various international scientific bodies (See Table 1). Out of the 40 tobacco flavouring compounds allowed under the proposed regulations, **10%** have CMR properties. The EU and UK (among others) have banned ingredients that have CMR properties from use in vaping products.

The tobacco flavouring ingredients in question are:

[21] https://linkinghub.elsevier.com/retrieve/pii/S0895435606003970

1) Estragole (CAS # 140-67-0): **may cause cancer and is suspected of causing genetic defects**.
2) Furfuryl Alcohol (CAS # 98-00-0): **may cause cancer**
3) Pyridine (CAS # 110-86-1): **may cause cancer**
4) Isophorone (CAS # 78-59-1): **may cause cancer**

In addition, there are **5** menthol/mint flavouring compounds that are known to have **CMR** properties:

1) Alpha-Terpinene (CAS # 99-86-5): **Suspected of damaging fertility or the unborn child**.
2) Methyl Salicylate / Wintergreen Oil (CAS # 119-36-8): May damage fertility or the unborn child.
3) Para-Cymene (CAS # 99-87-6): **Suspected of damaging fertility or the unborn child**.
4) Pulegone (CAS # 89-82-7): **may cause cancer**
5) Menthofuran (CAS 494-90-6): **may cause cancer**

Flavour ingredients that are not food-grade (**unsuitable for vaping**):

1. 4-ethylanisole (CAS 1515-95-3)
2. methyleneisophorone (CAS 20548-00-9)

CMR Prevalence in E-liquid Currently Available on the Canadian Market.

By reviewing the Material Safety Data Sheets (MSDS) documentation from flavour concentrate manufacturers, which represent the large majority of flavour ingredients used in Canadian e-liquid, we can estimate the prevalence of CMR ingredients currently on the Canadian market.

- 9 ingredients on the proposed Tobacco/Mint/Menthol list are on the CMR (carcinogenic/mutagenic/reprotoxic) list
- After reviewing the MSDS produced by the most prominent flavour companies used in e-liquid, we found only 1 flavour concentrate that contained a CMR ingredient (Furfuryl Alcohol).
- The concentrate containing the CMR chemical was a flavour called Asian RY4 (tobacco).
- Estimated prevalence of **1%** (likely far less) of <u>current tobacco flavours on the Canadian market</u> use this flavouring.

We find it disturbing that Health Canada would limit (instruct) the vaping industry to using these compounds as some of the only 82 flavouring ingredients allowed under these proposed regulations. While we appreciate that these ingredients were validated in products from the sampling process, there should have been a greater focus when preparing this exemption list to ensure the utmost safety of the end consumer.

In the marketplace currently, a rough estimation is that there are 400,000 unique flavouring compounds being utilized in the manufacture of the various flavour bases being used in e-substance manufacture in Canada. With the proposed list of 82 exempted ingredients, this represents over a 99% reduction in the available varieties for flavourings able to be used. While those 99% non-exempted ingredients may contain ingredients contained on various CMR-property lists around the world, all reputable manufacturers procure food-grade, water-soluble formulations for their manufacturing requirements. We appreciate the focus of these regulations in limiting flavour

selection to reduce the impact on youth uptake, but at what point do we consider the protection of adult consumers? Vaping is a tobacco-harm reduction product and as such, we should be focused on removing as much harm as possible from these products. The fact that >10% of the exempted ingredients exist on CMR-property lists is shocking and affirms our belief that this list of exemptions was rushed and not properly analyzed.

Table 1.

Abbreviations: Carc = carcinogenic, Muta = mutagenic, Repr = reprotoxic classifications

List of Ingredients	CAS	Flavour Characteristic	EU/UK Harmonised classification	EU intentions to classify	California Prop 65	IFRA classification	IARC	Others
alpha-terpinene	99-86-5	Menthol/Mint		Repr. 2, H361				
estragole	140-67-0	Tobacco			cancer	Muta. 2;H341 Carc. 2;H351		
furfuryl alcohol	98-00-0	Tobacco	Carc. 2		cancer	Carc. 2;H351	2B	
isophorone	78-59-1	Tobacco	Carc. 2			Carc. 2;H351		
methyl salicylate or wintergreen oil	119-36-8	Menthol/Mint	Repr. 1B, H360D			Repr. 2;H361		
para-cymene	99-87-6	Menthol/Mint				Repr. 2;H361		
pulegone	89-82-7	Menthol/Mint			cancer		2B	
pyridine	110-86-1	Tobacco			cancer		2B	
Menthofuran	494-90-6	Menthol/Mint						Carc 2 (Australia HCIS)

US FDA:

As per section 910(b) of the Federal Food, Drug, and Cosmetic (FD&C) Act[22], a Premarket Tobacco Product Application must be submitted for any new tobacco products seeking an FDA marketing order. In 2016, FDA finalized a rule extending CTP's regulatory authority to cover all tobacco products, including electronic nicotine delivery systems (ENDS) that meet the definition of a tobacco product. FDA regulates the manufacture, import, packaging, labeling, advertising, promotion, sale, and distribution of ENDS, including components and parts of ENDS but excluding accessories. A

[22] https://www.fda.gov/tobacco-products/rules-regulations-and-guidance/section-910-federal-food-drug-and-cosmetic-act-application-review-certain-tobacco-products

PMTA must provide scientific data that demonstrates a product is appropriate for the protection of public health.

As per section 910(b)(1) of the FD&C Act and the Draft Guidance: Premarket Tobacco Product Applications for Electronic Nicotine Delivery Systems (ENDS) (2016), FDA has established requirements and recommendations for ENDS including ingredients to evaluate whether a specific product would be APPH:

- Under section 910(b)(1), a full statement of the components, ingredients, additives, and properties, and of the principle or principles of operation, of such tobacco product; (FDA interprets this requirement to mean that the manufacturer should provide a complete list of uniquely identified components, ingredients, and additives by quantity in the new product, as well as the applicable specifications and a description of the intended function for each.)
- A thorough literature review is recommended to provide **valuable information on the toxicity of each of the ingredients in the e-liquid**; exposure kinetics, metabolism, and deposition and elimination profile of the ingredients, when available.

In addition, the FDA also established a list of harmful and potentially harmful constituents in tobacco products and smoke as required by the Federal Food, Drug, and Cosmetic Act (the FD&C Act). The HPHC list includes 93 chemicals (see appendix 1) and focuses on chemicals that are linked to the five most serious health effects of tobacco use (cancer, cardiovascular disease, respiratory effects, reproductive problems, and addiction.)

EU:

As per TITLE III, article 20 of DIRECTIVE 2014/40/EU[23], manufacturers and importers of electronic cigarettes and refill containers shall submit a notification to the competent authorities of the Member States of any such products which they intend to place on the market. The notification needs to include the following ingredient information:

- a list of all ingredients contained in, and emissions resulting from the use of, the product, by brand name and type, including quantities thereof;
- toxicological data regarding the product's ingredients and emissions, including when heated, referring in particular to their effects on the health of consumers when inhaled and taking into account, inter alia, any addictive effect;

As per article 7(6) and 20 (3), a list of additives are prohibited in vaping products:

1. vitamins or other additives that create the impression that a tobacco product has a health benefit or presents reduced health risks.
2. caffeine or taurine or other additives and stimulant compounds that are associated with energy and vitality.
3. additives having colouring properties for emissions.
4. for tobacco products for smoking, additives that facilitate inhalation or nicotine uptake; and
5. additives that have CMR (carcinogenic, mutagenic or reprotoxic) properties in unburnt form

Beside the similar ingredient prohibition as TVPA to reduce the appealing effect to youth and non-users of tobacco, the Tobacco Product Directive (TPD) also considered the health risk of consumers

[23] https://ec.europa.eu/health/sites/default/files/tobacco/docs/dir_201440_en.pdf

by prohibiting ingredients that may facilitate inhalation or nicotine uptake and CMR compounds. As per article 20 (3), in addition to the list of prohibited substances, further ingredient requirements have been established to ensure the quality and safety of vaping products in the EU:

- Only ingredients of high purity are used in the manufacture of the nicotine-containing liquid.
- Except for nicotine, only ingredients are used in the nicotine-containing liquid that do not pose a risk to human health in heated or unheated form.

Comparing with US and Europe, Canada is the only country has a vaping regulation developed without considering consumers of vaping products. Beside the problem whether such regulation can effectively address the problem of youth vaping, it is unlikely that such regulation and the current proposal can bring net benefit to the entire population.

Summary

In summary, we recommend that Health Canada take a similar approach to the UK, New Zealand, and various other countries in their efforts to ensure success of vaping as a tobacco harm reduction product by identifying known-harm ingredients and banning them from use in e-substance manufacturing. We feel it is a narrow-sighted approach that was applied when developing the list of exempted ingredients and more focus should have been applied to reducing the potentially harmful ingredients, rather than focusing on how to make the product unappealing as the overarching theme. If the regulations were to proceed as written, we should anticipate less public health benefits by two avenues: 1) forcing countless vapers back to smoking as the products will no longer be appealing and 2) potentially resulting in harms for vapers who choose to continue their tobacco abstinence, but with a greater likelihood of potentially harmful ingredients being used.

Sensory Attribute Regulations

The simplicity of the proposed sensory attribute regulations, along with their unprecedented nature meant that we had limited information to draw upon. While we were able to identify a sensory panel and associated information from the European Union, it is exclusively applied to tobacco products, making it largely irrelevant. This is due to the substantial difference between e-liquid, which is a manufactured product with no inherent flavour, compared to tobacco leaf used in cigarettes, which does have an inherent flavour.

With minimal information to go by, the committee has determined that the best approach to articulate the complexity and concerns of the proposed sensory panel was to present questions that would require answers before the proposal could be implemented.

Sensory Attribute Review Panel – Proposed Regulations

Questions:

1. How is the sensory committee being composed and what are the participation requirements?
2. If chemicals were chosen analytically, how can the flavours be subjectively allowed?
3. Every person has different senses, how will this discrepancy be compensated for?
4. Are the members of the sensory committee only smelling or will they be vaping the product?
5. How will committee members be trained, and by whom?
6. How will sense perception thresholds for determining compliance be established?
7. As an integral part of options 4 & 5 under the proposal, when would sensory perception guidelines for manufacturers that are required to reformulate, products be provided?

8. Was the impact of a scenario where an otherwise compliant tobacco/mint/menthol product that is determined (by sensory committee) to be non-compliant based on sensory perception considered in the cost benefit analysis as it relates to impact on manufacturers?
9. Will all panelists be undergoing neurological assessment to ensure there are no lesions, or symptoms that may alter their sensory perceptions?

Summary

In summary, there are numerous and important unanswered questions regarding the use of sensory attribute regulations which need to be considered before appropriate feedback can be provided. The unprecedented nature of the proposed sensory panel, combined with the significant uncertainty imposed on manufacturers leads to the conclusion that the sensory panel is not ready to be considered for inclusion in Vaping Product Regulations.

Impact Considerations

Technical Committee's Review of Impacts of the Proposed Ban

Impacts considered by the Technical Committee include the impacts that Health Canada recognized in the Regulatory Impact Analysis Statement (RIAS)[24], along with additional relevant impacts that were not considered by Health Canada. In some cases, the Technical Committee quantified the impacts differently than Health Canada for reasons that were either not taken into account by the cost benefit analysis or were materially different than believed to be accurate. In other cases, impacts that Health Canada considered to only be measured qualitatively, were assessed quantitatively by the Technical Committee.

Health Canada stated that the impacts of the proposal were estimated using quantitative, qualitative and break-even analysis and claimed that the cost analysis incorporated information from the vaping industry. They determined that the small business lens applied and that there would be no administrative burden on business related to the one-for-one rule.

> The small business lens applies. There is no administrative burden on businesses that would result from the proposal; therefore, the one-for-one rule does not apply.[25]

Impacts Outlined by Health Canada in the RIAS

1. Health Canada outlined their **quantitative** impacts to be comprised of disposal of non-compliant products, potential industry profit losses, reformulation costs and Health Canada's incremental costs for compliance and enforcement. This document addresses each one of those costs, with the exception of Health Canada's incremental costs, and provides a summary of Health Canada's assumptions based on the RIAS, together with pertinent comments and important information provided by the Technical Committee for serious consideration by Health Canada.

[24] https://gazette.gc.ca/rp-pr/p1/2021/2021-06-19/html/reg2-eng.html
[25] https://gazette.gc.ca/rp-pr/p1/2021/2021-06-19/html/reg2-eng.html

> The proposal would result in total incremental costs estimated at $569.3 million expressed as present value (PV) over 30 years (or about $45.9 million in annualized value). The monetized costs to the vaping industry include the disposal of stocks of non-compliant flavoured vaping products, which could no longer be sold or distributed, potential industry profit losses and reformulation costs. Implementation of the proposal would result in incremental costs to Health Canada from performing compliance and enforcement activities.

(ibid)

- **Disposal of non-compliant stock** – Health Canada assumed that retailers will not be affected because Health Canada expects manufacturers to gather and dispose of non-compliant products and that multi-national importers (99% of pod market) of pods would collect unsold pods and redistribute to other markets.

  Health Canada estimates the one-time costs to domestic manufactures to be $72.2M PV over 30 years and that the cost will be borne in 2022. Their estimate is based on $13.70 per bottle, plus the cost of disposing of products. They do not provide an estimate for the cost of disposal of non-compliant pods and disposable e-cigarettes manufactured either domestically or internationally.

Technical Committee comments:

- Although it is possible that large multi-national importers, such as those owned by Tobacco affiliated companies may be able to redistribute their pods to other markets, there has been no commitment by manufacturers to retailers to accept back non-compliant product for disposal.

- Health Canada acknowledges in the RIAS that bottled liquid outsold pod liquid 7 to 1 in 2019 making it the main source of non-compliant products. They also note that there are 200 vaping liquid manufacturers in Canada with only 7%-10% being large distributors and that they are responsible for the exclusive manufacturing of bottled liquid. The Technical Committee asserts that these micro to large domestic manufacturers will not be able or willing to collect from or reimburse the many small businesses, many of which are vape stores. These same domestic manufacturers will be anticipating other burden costs of attempting reformulation, disposal of their own non-compliant products and more importantly facing the reality of losing their primary market of vape shops, risking their very existence. Therefore, the disposal costs for micro to small business vape shops will be directly borne by them as they need to dispose of an estimated 99% of their non-compliant vape liquid bottles. The Technical Committee recognizes that this unfair burden may cause many small businesses facing financial ruin to not follow safe disposal procedures.

- Health Canada estimates that 99% of the pod market is manufactured by multi-national importers, which is skewed based on Tobacco owned vape brands dominating the G&C market. It should be noted that vape shops carry domestically manufactured pods and disposable e-cigarettes at an estimated rate of about 50%-70% of their pod/disposable

inventory. Therefore, the impact of disposal for vape shop retailers for non-compliant pod & disposable inventories is the same as the above point that addresses the risk that domestic manufacturers will not be willing or able to collect, reimburse or dispose of their pods.

The Technical Committee asserts that these critical oversights and inaccuracies of the actual market data cast doubt on the accuracy of Health Canada's estimates and consequently underestimate the true cost of disposal of non-compliant products that Health Canada relied on for their cost benefit analysis. Consideration of the impact to the small business vape shops is absolutely ignored by Health Canada.

- **Potential industry profit losses** - anticipates manufacturers, importers and all retail channels would carry potential profit loss of $461.4M PV over 30 years due to the loss in sales. They estimate the potential profit loss for manufacturers and importers to be $262.4M PV over 30 years. The potential profit loss for all retailers is estimated at $199.0M PV over 30 years.

Health Canada:

- estimates that 100% of domestic manufacturers would remain in the market to continue producing tobacco- and mint/ menthol-flavoured vaping if they "choose to".

- acknowledges that the domestic vaping liquids manufacturing industry focuses on the production of flavoured, vaping liquid refills and is heavily reliant on the vape shop retail channel. While acknowledging that flavour restrictions could undermine this business model and result in business closures and job losses due to expected vape shops closures

- states vape shops rely heavily on offering vaping liquid refills with a wide selection of flavours; flavour restrictions could potentially lead to closures of these establishments, as well as job losses.

- acknowledges the risk that some people who vape could procure non-compliant vaping products (illicit market). Health Canada does not acknowledge or address the serious health risk that some people who vape could procure do-it-yourself products (DIY market).

- anticipates that retailers (vape shops and G&C stores in Canada, except those in NS and PEI) would also experience profit losses because they would no longer be able to sell vaping products with flavours that are prohibited. And again state, small businesses would also experience potential profit loss because of reduction in adult customers' demand of vaping products.

- states that vaping products are sold in three main categories of stores: vape shops, G&C stores, and online retailers with the market breakdown by channel based on value is as follows: 49% in vape stores, 30% in G&C stores, 21% online. There are 1 400 vape stores, 25% of which are chain retailers, as well as 27 240 G&C stores, 37% of which are chain retailers, and about 1 500 websites, most of which are the online retail component of brick-and-mortar stores. They conclude the majority of these businesses, including manufacturers, are considered to be small under the Treasury Board of Canada Secretariat definition.

- estimates that the proposal would affect 28 087 small businesses, which are composed mostly of small manufacturers (200), importers (20), vape shops (1 358) and G&C stores (26 509). Providing additional time for small businesses to comply with the proposal was considered. However, a delayed implementation period for small businesses was deemed counter-effective in addressing the youth vaping problem. Therefore, a flexible option was not developed.
- Health Canada only included the sales to adult consumers in the analysis. They estimated that adults represent approximately 83% of the Canadian vaping product market.

- states it is difficult to forecast how the sum effect of the ban will impact the vaping products market.

- states their proposal generally aligns with flavour restrictions in Denmark that came into effect in April 2021.

- acknowledges the overall vaping products market in Canada was estimated at $1.36 billion in 2019. However, they assume zero growth rate of the vaping product market in the absence of Health Canada's flavour ban, citing the reason is that existing forecasts fail to recognize the mounting concern over flavoured products and the various provincial efforts to reduce access to them. Overall, they claim it is too difficult to forecast market growth (or contraction) with any certainty.

- estimated a reduction in consumer demand for vaping products ranging from 10% to 14.3%.

- relied on the Nova Scotia case to estimate the potential effect of flavour restrictions on consumer demand for vaping products. Their information is that Nova Scotia experienced a 14.3% reduction in pod sales (<u>only</u>) following implementation of its "tobacco flavour-only" requirement (mint/menthol-flavoured vaping products are prohibited in NS). They then assumed a lower bound estimated rate of 10% and upper bound of 14.3% for the rate of decline in consumer demand for vaping products as a result of this proposal. Their reasoning for using a lower bound rate of 10% was because Nova Scotia doesn't permit menthol and their proposal will. The mid-range of 12.15% was the factor used in the analysis.

The Small Business Lens

The Small Business Lens[26] requires Health Canada to demonstrate that due consideration was given to reduce the burden on small business and if a less burdensome option was available, they must justify when they don't adopt it. The Small Business Lens requires Health Canada to consider <u>flexible regulatory options that reduce costs to small businesses</u> without compromising the health of Canadians. Health Canada had by their own words, less burdensome options that they didn't choose.

<u>Technical Committee comments:</u>

[26] https://www.canada.ca/en/government/system/laws/developing-improving-federal-regulations/requirements-developing-managing-reviewing-regulations/guidelines-tools/policy-limiting-regulatory-burden-business.html

- The Technical Committee comments related to the "potential industry profit losses" are expanded to include other costs that were not considered by Health Canada in their cost benefit analysis and should have been, such as the cost of business closures and job losses and the rise of the black and DIY markets. The committee does so in this section because Health Canada has failed to quantify these loss segments in their cost benefit analysis and the Technical Committee deems them so important that they would materially alter the breakeven analysis and directly impact the outcome of the consideration under the Small Business Lens.

- As it relates to the Small Business Lens, options to restrict Youth access were plentiful and Health Canada had already implemented some regulations already. The blame for not protecting Youth against large vape companies, such as JUUL and British Imperial Tobacco's Vype causing the rise in Youth vaping falls squarely with Health Canada. These large manufacturers were allowed to promote aggressively before Health Canada finally implemented regulations to limit promotion and access that prohibited the sale of flavours in G&C's where JUUL and Vype had established revenue channels and marketing of billboards and social media. And these Health Canada regulations have led to a plateau of youth vaping as noted by Health Canada. The Technical Committee asserts that Health Canada's cost benefit analysis is critically flawed and therefore this proposed regulation costs far more than it benefits, which should be considered under the Small Business Lens.

- The Technical Committee finds it absurd for Health Canada to estimate that 100% of domestic manufacturers would remain in the market to continue producing tobacco- and mint/ menthol-flavoured vaping if they "chose to". While at the same time admitting they know that these same small domestic manufacturers rely heavily on the vape shop retail channel which Health Canada understands will close as a direct result of this ban. The Technical Committee asserts that Health Canada knows with certainty that CHOICE will not play a role into the survival of these small domestic manufacturers and that their cost benefit analysis should reflect the closures and lost jobs instead of only "profit losses" by decreased demand.

- The Technical Committee challenges Health Canada, who fully expects vape shop closures as a direct result of the ban, as well as job losses to quantify these closures and lost jobs in their cost benefit analysis. By Health Canada only anticipating that retailers (vape shops and G&C stores in Canada, except those in NS and PEI) would also <u>experience profit losses</u> because they would no longer be able to sell vaping products with flavours that are prohibited and not recognizing the true cost of closures and job losses for small vape shops and small domestic manufactures it is a material quantifiable oversight in their analysis. The Technical Committee asserts that Health Canada chose to ignore these costs by classifying them as "qualitative" because it would alter the breakeven analysis that would then cause them to reconsider one of the less burdensome options under the Small Business Lens.

- The Technical Committee challenges Health Canada as to why their cost benefit analysis did not quantify the serious health risks that some people who vape could procure non-compliant vaping products (illicit market) or products in the do-it-yourself (DIY) market.

- The Technical Committee advises Health Canada when they assess the 3 main channels where products are sold: 49% in vape stores, 30% in G&C stores, 21% online, they are not

sensitive in their analysis to the different business structure between vape stores and G&C stores. The vape shops rely 100% on flavoured products and the G&C's do not, representing that the G&C's will only incur potential profit losses, while vape shops will incur complete closures. Health Canada also ignores the 1 500 websites in their cost benefit analysis because most are the online retail component of brick-and-mortar stores and therefore when they estimate the 28 087 small business that would be affected, they leave the websites out. The Technical Committee challenges Health Canada who acknowledges in the RIAS that the majority of these businesses, including manufacturers, are considered to be small under the Treasury Board of Canada Secretariat definition, why their cost benefit analysis didn't include the cost of these closures.

- The Technical Committee questions that if Health Canada is aware of the overall vaping products market in Canada to be $1.36 billion in 2019, then why did they assume zero growth rate of the vaping product market in the absence of Health Canada's flavour ban? Health Canada's claims that overall, it is too difficult to forecast market growth (or contraction) with any certainty and their feelings that it is too difficult to forecast how the sum effect of the ban will impact the vaping products market, the Technical Committee would happily offer their assistance in calculating the true costs of these closures and job losses to assist them in a revised more accurate cost benefit analysis.

- The Technical Committee notices that Health Canada compares their proposal with flavour restrictions in Denmark that came into effect in April 2021. They also cite a UK study that claims that youth perceive non-tobacco-flavoured vaping products as less harmful than tobacco-flavoured vaping products. However, they ignore that Denmark allowed for 365 days implementation[27] and the UK base their restrictions on safety and only exclude compounds that are potential harmful. If they look to these countries for guidance, then the Technical Committee questions why they don't consider other aspects of their decisions.

- The Technical Committee asserts that Health Canada's estimate of 12.15% based on their assessment that Nova Scotia experienced a reduction in pod sales (only) to be deeply flawed and not be representative of the true reduction that all the other provinces will experience. Health Canada's first error was to use the pod sales as the sole indicator for consumer reduction for several reasons:
    - Consumers were aware of the ban and would have stocked up on their favorite flavours as they did in other provinces before the nicotine cap thereby decreasing any immediate post sales.
    - As Health Canada has stated, bottled liquid outsold pod liquid 7 to 1 in 2019 and so the experienced decrease in only pod sales distorts the real decline in vape shop sales because it focuses on G&C's channel.
    - Did Health Canada measure the sales made by residents in Nova Scotia to other online websites that were located outside of the province?

- The Technical Committee reiterates the impact on small business vape shops and small domestic manufacturers is being largely overshadowed by G&C stores and completely ignored by Health Canada to ensure the breakeven analysis suits their desired outcome. The

[27] http://www.smoke-free.ca/SUAP/2020/vaping-regs-timeline.pdf

Technical Committee has done their own analysis of the Nova Scotia market and found the following picture to be more accurate and relevant:

- Prior to April 1st 2020, there were 55 active specialty vape shops
- After implementation on April 1st 2020, 24 specialty vape shops closed within 60 days, citing the flavour ban as the primary reason.
- Two specialty vape shops are in the process of closing and are clearing out remaining inventory.
- 14 specialty vape shops indicated their intent to close if a legal challenge on flavours and tax is unsuccessful.
- Vape shops have indicated that they intend on remaining open, even if the injunction fails, however, even these shops could not be certain that they could remain open long term.
- 5 vape shops were unwilling or unable to respond.
- On average, 80% to 90% of e-liquid sales in vape shops came from non-tobacco flavours prior to the ban. On average, 3 out of 5 top selling tobacco flavours sold in vape shops were tobacco/fruit and tobacco/dessert blends prior to the ban.

To summarize the Technical Committee's findings in Nova Scotia, during the early phases of tracking, 40 out of 55 of vape shops that indicated they were in the process of preparing to close. 14 of the remaining 29 vape shops have halted the process of shutting down until the outcome of the legal challenge is known.

Since April when the flavour ban went into effect, cigarette sales began to rise significantly (25%), and far more than what other Atlantic provinces experienced (7%). The rise in cigarette sales due (in part) to new vape regulations is likely; however, it should be noted that this is speculative at this time. The loss of so many vape shops leaves consumers with few choices (purchase pod devices from tobacco retailers, drive hours to the closest vape shop, order online, or return to smoking). Nova Scotia should serve as a stark warning to policy makers that the unintended consequences of flavour bans and excessive restrictions will have a negative public health outcome.

The Technical Committee asserts that Health Canada's gross failure to include the many small business vape shops and domestic manufacturers likely closures and job losses and their understatement of the impacts in Nova Scotia, along with all the other points addressed above, created an inaccurate breakeven analysis that far underestimated the costs to the Vaping Industry. We implore Health Canada to consider the <u>true businesses losses</u> and offer our sincere assistance in determining these losses in a new cost benefit analysis.

- **Reformulation Costs** – Health Canada's proposal would prohibit the use of sugars and sweeteners and restrict the use of most flavours in vaping products. Only 40 flavouring ingredients would be allowed in tobacco-flavoured vaping liquids, and 42 in mint/ menthol-flavoured ones.

Health Canada:

- estimates that approximately 20% of tobacco-flavoured vaping products and 15% of mint/menthol-flavoured products would not require reformulation and therefore, assumes

that 82.5% of tobacco- and mint/menthol-flavoured vaping products remaining on the market would be reformulated.

- acknowledges that their reformulation cost estimate is subject to several uncertainties. These uncertainties include the share of products that would need to be reformulated, the share of manufacturers and importers remaining in the Canadian market, and the cost of reformulation per variant. It is noted in the RIAS that no sources report the specific number of tobacco or mint/menthol SKUs on the Canadian market, so that assumption represents a major source of uncertainty.

- acknowledges that smaller domestic manufacturers producing vaping liquid refills generally purchase pre-blended flavouring ingredients from flavour houses in the United States and that due to this fact, they may encounter logistical barriers or carry additional costs in acquiring compliant flavour blends.

- footnotes in the RIAS that the exclusion of these ingredients from the prohibition on flavouring ingredients should not be understood to mean they are safe for use. Manufacturers and importers are responsible for ensuring the safety of their vaping products, including their ingredients, taking into account their normal or foreseeable use.

- cites a UK study that claims that youth perceive non-tobacco-flavoured vaping products as less harmful than tobacco-flavoured vaping products.

- proposes that the regulations will come into force on the 180th day after they are registered. They state that, providing additional time for small business to comply with the proposal was considered. However, a delayed implementation period for small businesses was deemed counter-effective in addressing the youth vaping problem. Therefore, a flexible option was not developed, and the ban will come into effect 180 days after it is registered.

- estimates the cost of reformulation of one variant will range from $25K to $70K for small manufacturers with a total industry impact of $29.3M PV over 30 years.

- The Small Business Lens requires Health Canada to demonstrate that due consideration was given to reduce the burden on small business and if a less burdensome option was available, they must justify when they don't adopt it. The Small Business Lens requires Health Canada to consider <u>flexible regulatory options that reduce costs to small businesses</u> without compromising the health of Canadians. Health Canada provided 5 options, of which 4 options were considered less burdensome to small business, and they chose to reject them.

<u>Technical Committee comments:</u>

- The Technical Committee does not agree with Health Canada estimates that 20% of tobacco and 15% of mint/menthol products would not require reformulation and that only 82.5% would need reformulation. This assumption may only hold true for large multi-national importers, such as Tobacco affiliated vape brands who manufacture pods. However, Health Canada acknowledges that bottled liquid outsold pod liquid 7 to 1 in 2019 and that bottled liquid is exclusive manufacturing in Canada. And the Technical Committee in this document informs Health Canada that the pod and growing disposable e-cigarette market is not 99%

dominated by multi-nationals with the exception of perhaps the Gas & Convenience store channels where multi-national corporations are well established. The Technical Committee asserts that the percentage of products that would not require some type of reformulation is 5% for domestic manufactures of bottled liquid, disposables and pods. Therefore, reformulation would affect 95% of existing product and not the 82.5% Health Canada estimates.

- Health Canada admits that they recognize the smaller domestic manufacturers (90%-93% of all Canadian manufacturers) will likely incur additional costs because they rely on purchasing pre-blended flavouring ingredients from flavour houses in the United States. The Technical Committee suggests that all currently available flavouring bases used in the vaping market will be disallowed based on the 40 approved ingredients permitted for use in tobacco-flavoured products and 42 proposed ingredients for mint/menthol-flavoured products. The barrier may more likely to be that these international 3rd party flavour houses will not produce specific products for only the Canadian market because it is not economical to do so.

- Another major cost Health Canada did not consider is the cost of time. Even if the international 3rd party flavour houses did agree to do so, their implementation lead time alone would be a minimum of 6 months. The Technical Committee informs Health Canada that current standard product development, testing, and validation practices can take up to 18 months; and must be completed prior to the start of production. It is the Technical Committee's assertion that a 6 month lead time is impossible and that a combined 24 months is more conceivable.

- Additional costing elements should be considered – recruiting highly-skilled employees to facilitate the new formulation requirements, additional testing requirements to ensure production compliance, and disposal of dead inventory resulting from manufacturers' non-approved flavouring stock levels.

- Separately, costs (time and money) as a result of the sensory panel not being enacted until 2-5 years post-regulation, risk the likelihood that there will be additional formulation costs required of manufacturers to accommodate the uncertainty regarding products that are using only-approved ingredients that do not pass the sensory panel approval.

- Health Canada studied and specifically selected the 82 chemicals or ingredients, yet they also stated in a footnote that manufacturers and importers are responsible for ensuring the safety of their vaping products, including their ingredients. The Technical Committee questions why this cost burden is pushed to the small business manufacturers and not Health Canada when they had the resources employed in their efforts to "reduce exposure to harmful chemicals" to fully test out these chemicals. The impact risk could be that once a variant is approved using Health Canada's list of 82 chemicals that the variant will be deemed unsafe and the small manufacturer would incur sunk costs of the formulation and incur new formulation costs to replace it.
  It is important to note that the Technical Committee has already uncovered that 9 of Health Canada's approved 82 ingredients are on the CMR (carcinogenic/mutagenic/reprotoxic) list, along with identifying others that are not food-grade.

- The study[28] that Health Canada cites where it is claimed that youth perceive non-tobacco flavoured vaping products as less harmful than tobacco-flavoured vaping products, also states that they perceive flavours including fruit, candy and menthol flavours to be less harmful. The implication is that Health Canada is citing this study as support for limiting flavours to tobacco and menthol, but menthol was also perceived to be less harmful. The impact risk is that small business manufacturers could invest in many formulations of menthol and mint and Health Canada could decide to ban them.

- As it relates to the Small Business Lens, the Technical Committee asserts that Health Canada did not demonstrate due consideration or show flexibility to reduce the burden on small business when they "deemed" a flexible option of extending the 180 day implementation not needed for 28,087 small businesses.

- As it relates to the Small Business Lens, the Technical Committee asserts that Health Canada did not demonstrate due consideration or show flexibility to reduce the burden on small business when they "rejected" the 4 less burdensome options for 28,087 small businesses.

The Technical Committee asserts that Health Canada's self-admitted critical uncertainties, inaccurate estimate of existing variants that would not require reformulation, lack of proper estimation of all the elements involved and the risk of the sensory panel rejection cast serious doubt on the accuracy of Health Canada's estimate and consequently underestimates the true cost of reformulation that Health Canada relied on for their cost benefit analysis.

Technical Committee Comments on Impacts Health Canada Deemed Qualitative:

The Technical Committee has commented on some of the critical impacts that Health Canada deemed qualitative instead of quantifying them in their cost benefit analysis. Below is a list of other impacts that the Technical Committee asserts that Health Canada should make a serious effort to quantify prior to implementing this massive burden on small businesses and the public in general.

2. Health Canada outlined their **qualitative** impacts to be:
   (1) **consumer surplus loss** – because addictive products negate self-control in rational framework
   (2) relabeling costs to manufactures and importers – VPLPR states that flavouring ingredients must be described as "flavours" and therefore no relabeling will be required
   (3) **costs impacts on retailers** – although Health Canada recognizes that the flavour ban will "potentially" lead to vape shops closures and lost jobs, they believe G&C stores may disproportionately benefit from consumers switching to closed pod systems
   (4) **Cost impacts on domestic manufacturers and importers** - it is noted by Health Canada that any product development costs carried to comply with the proposal would not impact the large manufacturers. In contrast, smaller domestic laboratories producing vaping liquid refills generally purchase pre-blended flavouring ingredients from flavour houses in the United States. They may encounter logistical barriers or carry additional costs in acquiring compliant flavour blends.
   (5) **Loss of tax revenue** – although Health Canada recognizes the minor tax loss, the Technical Committee asserts the government is expecting offsetting increases from vaping consumers returning to cigarettes where the excise tax can be collected.

[28] https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5125087/

(6) **Costs to vaping industry as a result of dual users modifying their smoking behaviour** – Health Canada anticipates that after the proposal comes into force, the total profit loss to the vaping industry that also manufactures tobacco products may be mitigated by the substitution of tobacco purchases from dual users who would go back to smoking and adults who smoke who would continue to smoke instead of switching to tobacco- or mint/menthol-flavoured vaping products.

(7) **Costs to adults who smoke and dual users** – Health Canada anticipates that overall, if people who smoke do not completely switch to vaping, long-term benefits would not be realized in terms of avoided tobacco-related mortality and morbidity, including from exposure to second-hand smoke. Health Canada claims that these costs were considered when performing the sensitivity analysis that examined the break-even points where the reduction in vaping initiation rate provides benefits that equal the costs of the proposal.

Illicit Market Report

To understand the scope and nature of the anticipated Illicit market that should be expected to apply across Canada under proposed flavour restrictions, VITA sought the services of a highly credible 3rd party firm (Company details available by request). The firm we chose is highly reputable and conducts similar work for Government, law enforcement, and industry associations across North America.

The findings were clear, when Government enacts regulations that amount to the prohibition of adult only products that have pre-existing demand, combined with insufficient or ineffective enforcement, the prohibition creates the very situation it seeks to prevent, and that's the best-case scenario.

Please see the detailed report attached as Appendix 1

Options & Recommendations

1. **Expand Enforcement and Develop and an Integrated Federal-Provincial Framework to Address Youth Access:**
    a. In place of the proposed blanket flavour restrictions, which will increase the number of smokers and have an undetermined impact on youth vaping rates, VITA recommends that the federal government, in coordination with provincial authorities, develop an integrated and targeted enforcement approach to the specific issue of youth vaping. Under this framework VITA would expect to see increase penalties and a laser like focus on the core issue, access to vaping products by youth.
2. **That Health Canada recognize the logistical complexity of implementing substantial changes requiring longer implementation timeframes:**
    a. While the proposed implementation timeframe is more reasonable than what was instituted related to maximum nicotine concentration, the proposed timeframe for implementation remains insufficient. VITA would propose that for any revisions to current allowable flavours any timeframe for deployment should include industry consultation.
3. **A revised and fully comprehensive cost/benefit analysis & RIAS be conducted prior to the consideration of any final regulations:**

a. As detailed in this submission, VITA believes that Health Canada has significantly underestimated the total cost burden and impact that this proposal will have on the vaping sector. We believe that the proposed cost/benefit analysis, RIAS, and regulatory approach should start over.
b. Health Canada should carefully and fully consider the real world impact of removing more than 85% of vaping product flavours (and changing at least 95%) as it relates to pre-existing demand being fulfilled by the black market.

4. **Health Canada Recognize the Complexity of the Regulatory Pathway Forward and Work with Industry to Find Better Solutions:**
    a. The method of the proposed flavour restriction as articulated by this submission is incredibly problematic and in VITA's opinion, not viable. As noted, more than 10% of flavour chemicals on the approved list are identified as being Carcinogenic, Reprotoxic, or Mutagenic. Harm reduction products should be regulated in a way to encourage innovation in the area of health and safety, and not limited in a way that makes the product less safe than it already is.
    b. In VITA's view, Health Canada must instead call a panel of experts, including industry experts who have experience in flavour formulation and associated activities to provide technical knowledge to Health Canada in determining more effective mechanisms to restrict youth uptake.

Conclusion

The flavour restrictions proposed will not achieve the stated objective of reducing youth vaping rates. Instead, VITA expects based on the experience of other jurisdictions that have implemented lateral policies, that the primary outflow will be an increase in the number of smokers in Canada, the complete devastation of the legal regulated industry, and the establishment of a thriving illicit market.

This is not a positive policy outcome, nor we believe the goal of the government in proposing these regulations.

To achieve what we believe is our shared goal – specifically reducing access of vaping products for youth – we believe we must collectively enhance and deploy an aggressive enforcement regime targeted at the core issue – youth access to vaping products. The proposed regulations and the plethora of issues caused by them also highlight the importance of working with Industry Associations and stakeholders in order to create balanced, effective, and evidence based regulatory frameworks.

Appendix 1: Illicit Market Research

Presentation Report

Illicit Market Report: Impacts of Upcoming Vaping Restrictions

September 2 2021

Impacts of Incoming Vaping Restrictions

VITA·ARIV

The Vaping Industry Trade Association of Canada (VITA) represents vaping industry retailers, distributors, manufacturers, and importers by working with stakeholders and governments to help set and uphold vaping product and sales regulations. VITA is committed to collaborating with Health Canada and other regulatory bodies to promote evidence-based, logical solutions for ensuring that vaping remains available only as a safer alternative to cigarettes for adult smokers.

VITA advocates for fair, science-based solutions that protect consumers while allowing for entrepreneurial success in the vaping industry, and works to ensure members adhere to strict quality control and safety standards. It also works to educate consumers, governments and stakeholders about how to use, sell, and promote vaping products responsibly; as a safer alternative to cigarette smoking for existing adult smokers.

Executive Summary

Considering the recent legislative and regulatory changes being enacted by Health Canada, VITA has undertaken a comprehensive mystery shopping scan, using a reputable investigative agency. We are concerned that these regulations, while well intentioned, may in fact be counterproductive to the stated policy goals and result in many unintended consequences. The scan took place during August 2021, and as a result of the investigation we have discovered the following:

- There is widespread availability in all avenues for the Canadian public to purchase vaping products that are prohibited and noncompliant. There is little to no barrier for average Canadians to acquire these products via online purchases or through retailers both on- and off- reserves throughout Canada. As a result, the stated purpose of the regulations is being undercut and has little to no effect on the actual marketplace and product availability for Canadians.

- Little to no proper oversight, enforcement and regulatory compliance exists in the industry. This lack of enforcement has created an unlevel playing field in the vaping industry with customers seeking to maintain their preferred products and flavors. This leads to companies that are compliant facing a significant competitive disadvantage compared to non-compliant companies.

- Retail shops have begun developing their own inhouse products with non-compliant labelling, at strengths and flavours that are prohibited. This trend will result in a type of circumvention that will be hard to detect as products are made ‘on demand’ without being evident or onsite during inspections.

- This trend is prompting a strong ‘do it yourself’ framework for vapers that can access flavors and easily add them to their own products. There is a major concern in the industry of overly strong concentrations. The potential of mishaps increases and could result in health and safety concerns by those self-manufacturing. Flavors that are being added are often intended for foods and are not suitable for vaping (water soluble) which may present significant negative health impacts.

- Collectively these regulations are pushing the industry from a professional environment with robust quality control and compliance, to an untaxed, unregulated, and unsophisticated DIY industry that is the opposite of the intent of the regulations.

- More restrictive regulations have increased cigarette sales and have been attributable to pushing consumers back into less safe, combustible products.

- Nova Scotia enacted stringent regulations similar to what Health Canada is now proposing. They have resulted in widespread economic hardship and closure of the 73% of surveyed vape stores in the province (44% closed within 60 days). Those remaining have struggled, which has led to widespread noncompliance to maintain any economic activity. These restrictions have been viewed as heavy handed and resulted in ingenious frameworks to effectively circumvent and sell illicit products including black market sales, aliases for flavors, deceptive packaging, and purposeful sale of illicit products by previously compliant retailers “under the counter”.

- Some manufacturers that have been heavily affected by the ban have begun to implement deceptive packaging specifically to circumvent the regulations and avoid detection. This is done specifically in response to the Nova Scotia regulations that will be further amplified when similar regulations are in place nationwide. This pushing of otherwise legitimate leading manufacturers into the illicit space due to what is perceived as over-regulation is a major concern for VITA and the future of the legitimacy of the vaping industry in Canada.

- Excessive regulations are prompting and pushing the industry into making products that in most cases follow rules while finding potentially following the ‘spirit’ of the regulations. Products are being developed to mimic the “harsher throat feel” of product strengths beyond federal regulations without technically going over the line. These products may have significant health and long-term use impacts than current product offerings that are being forced out of the market.

Vaping Regulations: **Pending Changes**

Pending changes:

- No flavours beyond mint, menthol and tobacco, adding to an existing ban on desserts
- 20 mg/ml maximums
- Short sell-off period

Read the full upcoming vape regulation changes at tinyurl.com/VapeRegChanges

Impact of new regulations by the numbers:

Direct cost in lost inventory: $58,254,497 CAD

Collective impact upon the legitimate industry in 2021: $78,830,767 CAD

Health Canada is currently in the process of banning all flavoured vaping products, except mint, menthol, and tobacco-based flavours. These regulations will add to existing restrictions against dessert-themed flavours. Health Canada has also implemented new restrictions that ban the sale of any e-liquid vaping product over 20 mg/ml. These legislative changes are being undertaken quickly with no ability for products to be phased out in a meaningful manner leaving vaping shops with a substantial amount of their stock that cannot be sold legally. The banning of products during the hardships of COVID restrictions have placed an enormous additional burden on the often small- and medium- sized vape stores.

Many customers and retailers have voiced concerns about the heavy-handed approach being undertaken with vaping regulations. These regulations have prompted near universal comments and resistance by users that believe that they are counter-productive and are going to force and lead customers back to combustible tobacco products and are removing a legitimate and useful tool in their smoking cessation activities.

Recent regulatory changes focus on reducing the concentration of nicotine levels substantially (down to 20 mg) from levels three times higher. Additionally, flavors often popular with customers (both adult and youth) are being prohibited in an effort to curb usage. This will prohibit the sale of large volumes of inventory held by the vape industry estimated by the federal government to be worth at least $58,254,497 in 2021 alone. Further, this will result in a further estimated $20,557,588 in loss gross margins. Combined, this represents a collective impact upon the legitimate industry of $78,830,767 in 2021.

Vaping Regulations:
As They Are Now

80-90%

Of sales in Nova Scotia specialty vape shops came from non-tobacco flavours before the flavour ban

44%

Of small, brick-and-mortar vape shops in the province closed within 60 days of the Nova Scotia flavour ban

25%

Increase in provincial cigarette sales after the Nova Scotia flavour ban came into effect

Ontario:

As of September 2021, regulations in Ontario limit where, how, and what can be sold. These regulations dictate packaging and presence on the sales floor, and limit almost all promotion of vape products. Regulations also ban the sale of any products over 20 mg/ml, and restrict the sale of any flavours beyond mint, menthol and tobacco, to specialty vape stores that no one under nineteen may enter.

Nova Scotia:

Nova Scotia was one of a few provinces to have banned flavoured vaping products provincially before the federal flavour ban was coming into play. In April 2020, the flavour ban in Nova Scotia came into effect.

Prior to this, 80-90% of specialty vape shop sales came from non-tobacco flavours, and an average of 60% of best-selling tobacco flavours sold in shops were tobacco/fruit and tobacco/desert. Within sixty days of the flavour ban, 44% of specialty vape shops had closed, citing the flavour ban as the main reason for the decision.

In July of 2020, a new requirement that e-cigarette sellers must have a retail license came into effect. In September, a new tax was applied on vape products, of $0.50 CAD per ml of vaping liquid bought, and 20% on devices (essentially, a minimum of $10.00 per product, which often doubles the price.) Shortly after regulations came into force to restrict nicotine in vape products to 20 mg/ml.

The lack of enforcement of these regulations in Nova Scotia has allowed widespread non-compliance to permeate the marketplace. Retailers have noted that there are two compliance officers whose job it is to ensure that all of the vape market regulations and restrictions are being followed. However, the posting of a compliance officer is difficult and rotates every six months leaving officers with little long-term experience. This lack of sufficient resources has left the market to effectively self-regulate against their interest.

At this point, cigarette sales had risen a worrying 25% since the flavour ban, significantly higher than other Atlantic provinces at 7%, which shouldn't be surprising to regulators, given Health Canada's previous statements on the issue.

Pushing vapers back to cigarettes

Health Canada's Regulatory Analysis Impact Statement, published June 19th, 2021 in the Canada Gazette regarding a potential federal flavour ban has admitted that:

"After the proposal comes into force, it is anticipated that some dual users who currently use flavoured vaping products would not substitute their purchases with tobacco and mint/menthol-flavoured vaping products. They would choose to purchase more cigarettes, hence offsetting the loss of sales of tobacco- and mint/menthol flavoured vaping products."

Health Canada allows very little promotion of vaping products, but under certain circumstances Health Canada statements such as "Vaping products and e-cigarettes deliver nicotine in a less harmful way than smoking cigarettes" may be usable. Unfortunately, Health Canada has yet to release a list of authorized relative risk statements that can be used by companies in the promotion of vaping products. This is even though Health Canada recognizes that vaping is a less harmful option for smokers, and that flavour bans on vaping products will push smokers back to cigarettes.

The point of this regulation is to protect underage kids from getting hooked by vape products, which VITA recognizes as an admirable goal, however consumers still have easy access to flavoured vaping products. If the regulation doesn't prevent kids from accessing vape products, and pushes vapers back to more harmful options like cigarettes, is this truly the best way to achieve the stated policy goals?

The Investigation:
Methodology

Online Sales

Examining online vape stores in Canada for compliance with regulations and availability of products for customers in restricted areas.

Stores on Reserves

Mystery shoppers visited stores on reserves to check the availabilty of regulated products for average Canadians.

Nova Scotia

Visiting stores in a province with existing flavour and strength restrictions to check whether these products continue to be sold “under the table”.

In order to gain a clear understanding of the effects of a flavour ban, VITA sought an environmental scan of products that are non-compliant with existing regulations, to showcase the widespread availability of non-compliant products and how the restriction on legitimate enterprises leads to an uncompetitive environment and pushes customers to illicit products and illicit providers. Understanding the need for professional, above-board research, VITA hired a non-partisan investigative firm with experience examining issues of noncompliance. They undertook a mystery shopping survey in Nova Scotia, Online and larger Indigenous reserves in Ontario and Quebec, to determine if the average Canadian customer can still access prohibited products and banned flavours.

The existing regulations and regulatory compliance in place by governments in Canada do not prevent consumers from accessing flavours, but instead put small, brick-and-mortar businesses on an unfair playing field against stores that do not comply and push consumers to the black market for their needs.

Our mystery shopping focused upon E-liquid, vape pods, and disposable vapes, with emphasis on anything above the federally mandated 20 mg/ml nicotine cap, and any flavours beyond mint and tobacco (the flavours that are not threatened by the upcoming ban).

The Investigation:

Canadian Online Sales

On the behalf of VITA, investigators looked into online sales in Canada with the ability to deliver to Nova Scotia. This mystery shopping and scan was completed to understand whether concentration and flavour bans currently in place achieve their goal of keeping flavours out of customers' reach. There are hundreds of Canadian-focused vaping sites easily accessible through online search engines, with many physical stores having online counterparts. These stores are based across the country, from provinces with and without vaping restrictions in place.

In a sampling of nineteen stores selected at random from the larger lists provided by online search engines, 15 websites sold vape products online. Of that group of 15:

- 93% of stores sold flavoured products beyond mint, menthol and tobacco
- 93% of stores sold confectionary-based flavours, and of that group, 79% advertised products as being dessert-flavoured, which is federally prohibited
- 87% were age-gated, but only 53% had a Health Canada warning visible on their site

Stores often had clever solutions to get around existing regulations, such as using subtle names for dessert flavours (ex: "Polar Bear" instead of Chocolate Thin Mint Cookie), encouraging customers to do an online search for flavour descriptions of products not allowed to be described in Canada, and linking outside reviews (like YouTube videos) where influencers describe the flavours that Canadian store websites cannot, and offer giveaways.

- 93% of stores will ship flavoured products to provinces with flavour bans
- New product lines designed to feel harsher on the throat are emerging in response to strength restrictions
- Pop culture references are being used to promote vaping

Though almost all online stores were compliant with the Canadian 20 mg/ml nicotine cap, brands are finding ways to satisfy consumer demand. New product lines such as “BOLD 35” and “BOLD 50” offer a hybrid nicotine product designed to give a harsher feeling vape that will “make 20 mg/ml feel like 50 mg/ml” without breaking any rules. These product offerings indicate that the current regulations seem to be encouraging manufacturers to create products that are designed to comply with regulations, while attempting to effectively satisfy the pre-existing demand for a product that is no longer legally available.

Some websites just break the rules outright, selling past the 20 mg/ml cap or using popular culture references to promote products, like naming them after famous celebrities and characters, or by choosing a name customers will recognize without appropriate trademark licensing authorizations and advertising compliance. Examples of this include “Black Mamba” and “Queen’s Gambit” salts, “Red Wedding,” “Pinkman,” and “Heisenberg” pods.

Of the stores that offered flavoured products, 93% were willing to ship to provinces with existing flavour bans. From the consumer perspective, it is very quick, easy and convenient to locate, purchase, and have flavoured or illegally strong products shipped to your door. Clearly, flavour bans are failing to restrict certain products from flowing into their impacted areas; the sales have just moved from entrepreneurial businesses within the province to businesses outside of it that might not be as heavily regulated or that lack enforcement. This trend will increase with restrictions nation-wide causing the industry to increasingly go offshore negatively impacting the Canadian vape sector to the benefit of other nations.

The Investigation:
Stores on Reserves

Shopping on Indigenous Reserves is a common activity for Canadians living off-reserves, and is another avenue to access vapour products.

Mystery shopping was undertaken by investigators to determine enforcement or compliance of restrictions and products being sold on Indigenous reserves in Ontario and Quebec. It is important to note that this report does not seek to criticize the treaty rights and ability to conduct trade on reserves by Indigenous peoples. VITA recognizes the importance of existing treaties and alternative regulatory frameworks that govern commerce. This mystery shopping is intended to showcase the potential availability and range of products on reserves.

Indigenous Reserves have long been known to Canadians as a cheap place to stock up on tobacco, gas and cannabis products, due to the lack of taxes charged on reserves and the freedom from restrictions on what can be sold.

As flavor and concentration bans are implemented, it is useful to understand and predict avenues that Canadians might explore to fill the void left by a flavour ban. The reserves visited by VITA were the four of the largest and most populated reserves in Ontario and Quebec, namely; Tyendinaga, Six Nations, Kahnawake, and Kanesatake. All are close to major population centers and major highways.

VITA respects the sovereignty of Indigenous people. However, Indigenous local governance structures and frameworks have diverged from off-reserve regulations. It is important to note that this has resulted in a dual regulatory system that affects most markets in Canada. The implementation of a federal flavour ban will likely exacerbate this divergence.

VITA noted several concerning behaviours during its scan, including selling expired products, incentive programs for buying (such as free gifts with purchase), an abundance of sales and specials, and lower prices than the Canadian average. Products were usually openly displayed in places where they could be visible to underage kids. Strength of products often ranged as high as 50 mg/ml, more than double the federal limit.

0% of stores selling vape products checked ID

80% of stores sold product stronger than the federal nicotine cap of 20 mg/ml

The most common strength of vape products available was 50 mg/ml

95% of stores selling vape products had flavours available beyond mint, menthol and tobacco

The Investigation:
Nova Scotian Stores

During VITA's investigators' secret shopping scan in Nova Scotia vape stores, we found an abundance of products with flavours and potencies beyond those allowed by regulations, which should concern regulators. We found a large variety of products at the 35 mg/ml and 50 mg/ml, that often-included fruit and confectionary flavours.

The source and forms of the products varied from disposables imported from China, to flavoured pods imported from the US and other Canadian provinces, as well as e-liquids which appeared to be manufactured DIY-style in the back of a vape shop. These products are coming in from unregulated markets without any oversight or guaranteed quality control. The unknown factors involved in these products could pose a greater health risk to Canadian consumers compared to regulated products on the Canadian market.

In our investigation, VITA was told repeatedly by vape store employees that they feel the government is unsympathetic to their struggles and have forced them between a rock and a hard place with the regulations banning the sale of flavoured products and the existing stock they were not given the chance to sell off. This situation is pushing legitimate retailers who were compliant and respectful of regulations to sell prohibited products under the counter to survive. Enforcement is not strong enough to prevent these issues; most stores communicated to VITA that they had never been raided.

> One shop owner bragged that they have a foolproof strategy to avoid being investigated: when they see anyone in their parking lot with a clipboard, they lock the door and turn out the lights.

Of even greater concern is an emerging incognito packaging trend. Major Canadian manufacturers of vape pods and e-liquids are purposefully packaging flavoured pods and e-liquids under tobacco flavour names for sale in the Nova Scotia market, in order to allow retailers to hide the flavours from inspectors. Stores we visited were well-aware of the intentional fraud, and often had coding charts to determine which real flavour corresponded with each kind of fake packaging. For example, one popular brand of closed pod systems uses letters in the fraudulent name to identify the actual flavour.

Examples of questionable packaging found in Nova Scotian stores:

Packaged as	Actual Flavour
Tobacco – A	Apple
Tobacco – C	Cherry
Tobacco – G	Grape

Note: Product names/flavours have been changed to avoid singling out any brands. This table is for example only

The restrictions placed on the Nova Scotia market are pushing formerly compliant manufacturers to use fraudulent packaging, and stores have the weighty burden of deciding what is more important; finding a way to continue selling their most popular products or complying with regulations and folding.

Flavoured vapour products are still readily available in Nova Scotia, despite the existing flavour ban. The major changes since the new regulations came into force were an increasingly difficult sales environment for small businesses already struggling through a global pandemic, and the encouragement of various non-compliance strategies by manufacturers and sellers, including fraudulent packaging, do-it-yourself products, selling under the counter, and enforcement dodging.

Conclusion

The bottom line is, when it comes to getting around flavour bans and concentration limits, Canadians have options. The range of options include a variety of methods, both in-person and digital, to purchase products, whether it be under the counter at regulated shops, buying online and having it shipped to your house, shopping on reserves, or trying even riskier options like making their own products.

It is evident that the customer does not face barriers to purchase and use restricted vape products. With the impending federal regulations, only regulatory compliant retail and manufacturers will be affected, with a persistent source and availability of illicit products remaining in the marketplace.

In actuality, the regulations being imposed nation wide will in fact increase the illicit vaping industry, increase unregulated product use by consumers and enhance the untaxed and non-compliant markets. This will push the burgeoning vape industry back underground and its benefits such as stability and quality control for vape customers will be lost.

With no ability to sell off existing stock and a reasonable phase out period, this will force small business owners to take a loss on $58,254,497 of existing product, rendered unsellable by the ban. This large burden will prompt some retailers to maintain selling prohibited stock to recoup their existing investments. The lack of a proper phase out period inherently poses a large ethical challenge to retailers heavily impacted by these changes.

The incoming flavour ban has been recognized by Health Canada as having the potential to push nicotine users back to less safe options like cigarettes, and yet it is being touted as a harm reduction strategy. While these regulations are designed to limit desirability of vape products by youth, the ban will not actually prevent access. By limiting vape products that customers desire, these regulations will in fact push vapers back to cigarettes with the associated health risks and damages.

These regulations from our perspective will not meet its stated policy goals and will in fact hurt small businesses in the middle of on ongoing global pandemic, steer current vape users back into combustible products and provide a sustained boost to the illicit market.

We need to return to regulations that are practical, research-based and collaborative solutions that work for all stakeholders who all seek to improve the health of the Canadian public, and VITA stands ready to assist in that process.

Appendix 2: List of Harmful and Potentially Harmful Constituents

Table 1.--Established List of the Chemicals and Chemical Compounds Identified by FDA as Harmful and Potentially Harmful Constituents in Tobacco Products and Tobacco Smoke	
Constituent	Carcinogen (CA), Respiratory Toxicant (RT), Cardiovascular Toxicant (CT), Reproductive or Developmental Toxicant (RDT), Addictive (AD)
Acetaldehyde	CA, RT, AD
Acetamide	CA
Acetone	RT
Acrolein	RT, CT
Acrylamide	CA
Acrylonitrile	CA, RT
Aflatoxin B1	CA
4-Aminobiphenyl	CA
1-Aminonaphthalene	CA
2-Aminonaphthalene	CA
Ammonia	RT
Anabasine	AD
o-Anisidine	CA
Arsenic	CA, CT, RDT
A-α-C (2-Amino-9H-pyrido[2,3-b]indole)	CA
Benz[a]anthracene	CA, CT
Benz[j]aceanthrylene	CA
Benzene	CA, CT, RDT
Benzo[b]fluoranthene	CA, CT
Benzo[k]fluoranthene	CA, CT

Benzo[b]furan	CA
Benzo[a]pyrene	CA
Benzo[c]phenanthrene	CA
Beryllium	CA
1,3-Butadiene	CA, RT, RDT
Cadmium	CA, RT, RDT
Caffeic acid	CA
Carbon monoxide	RDT
Catechol	CA
Chlorinated dioxins/furans	CA, RDT
Chromium	CA, RT, RDT
Chrysene	CA, CT
Cobalt	CA, CT
Coumarin	Banned in food
Cresols (o-, m-, and p-cresol)	CA, RT
Crotonaldehyde	CA
Cyclopenta[c,d]pyrene	CA
Dibenz[a,h]anthracene	CA
Dibenzo[a,e]pyrene	CA
Dibenzo[a,h]pyrene	CA
Dibenzo[a,i]pyrene	CA
Dibenzo[a,l]pyrene	CA
2,6-Dimethylaniline	CA

Ethyl carbamate (urethane)	CA, RDT
Ethylbenzene	CA
Ethylene oxide	CA, RT, RDT
Formaldehyde	CA, RT
Furan	CA
Glu-P-1 (2-Amino-6-methyldipyrido[1,2-a:3',2'-d]imidazole)	CA
Glu-P-2 (2-Aminodipyrido[1,2-a:3',2'-d]imidazole)	CA
Hydrazine	CA, RT
Hydrogen cyanide	RT, CT
Indeno[1,2,3-cd]pyrene	CA
IQ (2-Amino-3-methylimidazo[4,5-f]quinoline)	CA
Isoprene	CA
Lead	CA, CT, RDT
MeA-α-C (2-Amino-3-methyl)-9H-pyrido[2,3-b]indole)	CA
Mercury	CA, RDT
Methyl ethyl ketone	RT
5-Methylchrysene	CA
4-(Methylnitrosamino)-1-(3-pyridyl)-1-butanone (NNK)	CA
Naphthalene	CA, RT
Nickel	CA, RT

Nicotine	RDT, AD
Nitrobenzene	CA, RT, RDT
Nitromethane	CA
2-Nitropropane	CA
N-Nitrosodiethanolamine (NDELA)	CA
N-Nitrosodiethylamine	CA
N-Nitrosodimethylamine (NDMA)	CA
N-Nitrosomethylethylamine	CA
N-Nitrosomorpholine (NMOR)	CA
N-Nitrosonornicotine (NNN)	CA
N-Nitrosopiperidine (NPIP)	CA
N-Nitrosopyrrolidine (NPYR)	CA
N-Nitrososarcosine (NSAR)	CA
Nornicotine	AD
Phenol	RT, CT
PhIP (2-Amino-1-methyl-6-phenylimidazo[4,5-b]pyridine)	CA
Polonium-210	CA
Propionaldehyde	RT, CT
Propylene oxide	CA, RT
Quinoline	CA
Selenium	RT
Styrene	CA
o-Toluidine	CA

Toluene	RT, RDT
Trp-P-1 (3-Amino-1,4-dimethyl-5H-pyrido[4,3-b]indole)	CA
Trp-P-2 (1-Methyl-3-amino-5H-pyrido[4,3-b]indole)	CA
Uranium-235	CA, RT
Uranium-238	CA, RT
Vinyl acetate	CA, RT
Vinyl chloride	CA