

The Canadian Vaping Association's submission to: Order Amending Schedules 2 and 3 to the Tobacco and Vaping Products Act (Flavours).

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Executive Summary

The Canadian Vaping Association opposes further restrictions on flavoured vaping products. The Canada Gazette fails to provide any evidence to support its flawed risk assessment and contradicts the immense amount of research demonstrating that vaping is an effective harm reduction tool. Extensively acknowledged throughout the Gazette are the negative outcomes of restricting flavours, which include significantly increased smoking rates, a strong black-market, the closure of Canadian small businesses, and a disproportional impact on minority groups who were neither studied nor consulted. These negative outcomes have not been adequately weighted, and as a result, an extremely low value has been placed on human life.

Health Canada has acknowledged the emerging science finding that smokers who quit using a flavoured vape product are almost twice as likely to be successful quitting than those using an unflavoured product. Additionally, the department acknowledges the receipt of postcards from 23,000 vapers indicating that flavours are vital for their continued smoking abstinence. Yet, the statements of thousands of adult vapers are dismissed as anecdotal, and the modelling does not adequately account for their return to smoking.

While vapers returning to smoking are not appropriately represented within the modelling, dual users returning solely to smoking are. It is stated that there is no health benefit to dual use. This is contrary to the well accepted principle of harm reduction that is a cornerstone of every modern public health initiative. Instead, it rests on a fallacious binary option, where smoking and abstaining from nicotine use are the only alternatives for adults. This view is an endorsement of the discredited "abstinence" or "prohibition" models that have been discarded by modern democracies such as Canada in all other public health contexts as ineffective, unscientific, unrealistic, unenforceable, counterproductive, and ultimately harmful to public health.

Though once a leader in tobacco harm reduction, through regressive policy, Canada will become one of the most attractive western countries to operate in as a tobacco company. Flavour restrictions will give the industry, in its entirety, to tobacco companies and the blackmarket, while simultaneously increasing smoking rates. New Zealand and the UK have embraced vaping as a harm reduction tool and are on track to eliminate tobacco use within the decade, while Canada is proposing regulation that will push thousands of vapers back to smoking.

Canada has already seen the results of a flavour ban in Nova Scotia. Within 90 days of implementation, there was an unprecedented increase in cigarette sales, small businesses were decimated, and illicit channels surged. Nova Scotia is not the template on which to base federal regulation and should serve as a warning of the unintended consequences of restricting flavours.

New research finds that flavour restrictions put youth at greater risk, through increased odds of smoking and through easier access to potentially dangerous black-market products. Thus, flavour restrictions result in increased risk to youth, fewer jobs, and more smokers.

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Disclosure

The Canadian Vaping Association (CVA) is a registered national, not-for-profit organization, established as the voice for the independent Canadian vaping industry. The CVA represents over 200 retail and online vaping businesses in Canada and has no funding or affiliation with tobacco companies or their affiliates. The CVA acts as a liaison with the federal and provincial governments on all legislative and regulatory issues related to the independent vape industry.

The Canadian Vaping Association appreciates the opportunity to submit feedback on the proposed flavour restrictions.

Note*

References to flavours or flavour availability refer to all flavours, including but not limited to, fruits, desserts, and beverages.

Recommendation

The CVA's submission is in support of Option 1: Baseline scenario - no further restriction on flavoured vaping products.

Overview

In 2018, Canada created a legal pathway for nicotine vape products and sought to balance adult harm reduction with the protection of youth and non-smokers. Early vape regulation was inline with Canada's Drugs and substances strategy¹, which through harm reduction, seeks to support measures that reduce the harmful health, social and economic effects of substance use on individuals, their families and communities. Harm reduction is stated to be one of the four pillars of the strategy which recognises that harm reduction programs work to reduce risks and improve health.

While at this time, Canada was a world leader in tobacco harm reduction, Health Canada did not anticipate the changes that legalization would cause to the marketplace. Despite the CVA advocating for a ban on national advertising, no restrictions were put in place. The recognition of nicotine vapes as a legal product increased product awareness.

¹ https://www.canada.ca/en/health-canada/services/substance-use/canadian-drugs-substances-strategy/harm-reduction.html

To prevent youth from engaging in vaping, The Tobacco and Vaping Products Act (TVPA) and subsequent Vapour Products Labelling and Packaging Restrictions (VPLPR) were introduced and were supported by the CVA and vape industry.

The CVA raised concerns at several meetings with Health Canada over the lack of consistent enforcement of the existing regulations. The concerns ranged from variations in enforcement (enforcement lacked standardization and was often at the whim or interpretation of an individual tobacco enforcement officer), lack of enforcement, and concerns that the penalties for supplying to youth were insufficient. The CVA is on record requesting that Health Canada increase enforcement efforts and pursue bad actors more vigorously. On several occasions, the CVA reported known sales to minors through the channels provided by Health Canada. To our knowledge, no action was ever taken.

Notwithstanding adequate enforcement, the TVPA and VPLPR were effective at curbing youth use. The Canadian Tobacco and Vaping Survey, 2020, found that youth vaping has declined 1% since 2019². In 2020, 27,995 fewer youth indicate vaping in the past 30 days than in 2019.

However, despite the strides Canada has made in reducing youth use, a nicotine concentration limit of 20 mg/mL was introduced in hopes that reducing nicotine concentrations might further reduce youth usage. The Canada Gazette Part 1, Vol. 154, No. 51 makes several mentions of the harm the nicotine ceiling would have on a segment of vapers and smokers and curates the data to support the regulation.

Data suggests the majority of adult vapers are already using vaping products with a nicotine concentration below 20 mg/mL (Canada Gazette Part I, Vol. 154, No. 51, p.4214)

This statement disregards the Euromonitor report commission by Health Canada, "Study of Market Size, Characteristics and Growth Trends of the Vaping Products Market in Canada³, which found that 62% of all e-liquid sales contained concentrations greater than 20 mg/mL.

It is also anticipated that certain dual users could relapse to smoking only as a result of the proposed Regulations. However, benefits of vaping by people who smoke are only accrued if they completely switch to vaping. (Canada Gazette Part 1, Vol. 154, No. 51, p.4216)

Dual use being as or more harmful than smoking alone is a fallacy unsupported by any scientific evidence. It is contrary to the well accepted principle of harm reduction that is a cornerstone of every modern public health initiative. Instead, it rests on a fallacious binary option, where smoking and abstaining from nicotine use are the only alternatives for adults. This view is an endorsement of the discredited "abstinence" or "prohibition"

² https://www150.statcan.gc.ca/n1/daily-quotidien/210317/dq210317b-eng.htm

https://drive.google.com/drive/folders/1dHAIBsnSyLNV7J06w06Cz9-mpUQJIPZ6?usp=sharing

models that have been discarded by modern democracies such as Canada in all other public health contexts as ineffective, unscientific, unrealistic, unenforceable, counterproductive, and ultimately harmful to public health.

Each time a vape is used instead of a cigarette, that individual reduces exposure to the 7,000 harmful chemicals found in a cigarette. Additionally, dual use is often an indicator that a smoker is trying to guit or substantially reduce their cigarette intake.

The dual use "harm" fallacy defies common sense. Dual use is a spectrum ranging from mostly smokers to mostly vapers. An individual who primarily vapes and only occasionally smokes has greatly reduced exposure to toxic chemicals.

It is also assumed that approximately 75% of current users of vaping products above 20 mg/mL nicotine will switch to vaping products at 20 mg/mL nicotine or below after implementation of the proposed Regulations.

It is stated that the conversion percentage is an estimate as the actual conversion rate is unknown. Public healthy policy should be based on evidence and not based on unsupported assumptions. With a conversion rate of 75%, approximately 125,000 current vapers are left behind. Many of which will relapse to smoking or turn to the black-market to get access to desired levels of nicotine. The nicotine ceiling was enacted without a true understanding or public disclosure of the number of vapers this would harm or the outcome for the individuals that were unable to convert. It is not evidence-based policy making, it is a shot in the dark.

Since nicotine remains a lawful substance and adults can choose to use it in other forms, the onus rests with Canada to demonstrate the evidence that justifies restricting important personal health choices made by adults, especially those addicted to nicotine.

Taste is one of the five senses, and an important part of every adult's intimate personal choice. There are a wide range of flavours available for alcoholic beverages, products that can also be abused by youth. Canada has never suggested regulating the flavours of alcohol in an effort to curb the risk of under-age drinking, a chronic public health problem. Junk food and sugary beverages undoubtedly contribute to the scourge of childhood obesity, and yet Canada has done nothing to restrict consumer flavour choice in those products, many of which are directly marketed to children.

Prior to the nicotine ceiling coming into force, the proposal to restrict flavours was introduced. This did not allow sufficient time for Health Canada to gather data on the effects of the nicotine regulation. The need for further regulation cannot be accurately assessed prior to a comprehensive impact analysis on the effects of the nicotine limit. Further regulation is inappropriate given youth rates are declining.

The CVA recognises that Health Canada is aware of the regulatory history outlined above. We felt it pertinent to include this overview, as it demonstrates the industry is not anti-regulation and have on many occasions supported regulation and advocated for increased regulation. The CVA vehemently opposes the proposed restrictions, solely

based on the harm the proposed regulation will cause to public health. Flavoured vape products have been a lifeline for the hundreds of thousands of Canadians that have quit or reduced smoking through vaping.

All parties have stated that decisions will be science based. The science is clear – vaping is significantly less harmful than smoking. The proposal to restrict flavours is predicated on non-existent or flawed data and severely overestimates the threat that vaping poses to youth. It also ignores the evidence from Nova Scotia's flavour ban that the effect is to shut down the legitimate industry, create a thriving black market and to increase cigarette sales. The result: more risk to youth, more smokers and fewer jobs.

Relative risk

Vaping is significantly less harmful than combustible tobacco. Vaping adoption by adult smokers should be encouraged. As acknowledged by Health Canada, restricting flavours will slow adoption and will push many current vapers back to tobacco or to the potentially dangerous black-market.

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.

Public Health England has stated that vaping is 95% less harmful than smoking⁴. NHS Scotland have echoed this statement through issue of a consensus statement and are supported by many organisations including the Royal College of Physicians of Edinburgh and the Chief Medical Officer for Scotland⁵.

For 7 consecutive years, the UK has conducted independent studies to determine vaping's relative risk. In the UK, regulatory requirements for e-liquid manufacturing and testing protocols allow for evaluation of any potentially harmful compounds in e-liquid products registered to be sold in the UK. The analytical testing requirements in the UK include e-liquid viability using carbonyls and emissions testing and In-Vitro Cyto-toxicity testing to determine whether vaping products are toxic to live cells. In toxicology, the quantity of a substance is of great importance. The presence of any substance, by itself, in trace amounts does not cause the mixture to be toxic. It is through these testing methods used in the UK and EU, that the data is produced to determine the exact potential adverse health effects of vaping compared to combustible tobacco. It is

⁴ Royal College of Physicians. Nicotine Without Smoke: Tobacco Harm Reduction. London: Royal College of Physicians; 2016

⁵ http://www.healthscotland.scot/media/1576/e-cigarettes-consensus-statement_sep-2017.pdf

through these testing protocols that the UK maintains that vaping does not exceed 5% of the risk of tobacco. It is troubling that Health Canada is ignoring the science and research available to determine the mortality and morbidity risks associated with vaping. The assumption that vaping poses 20% of the risk of smoking is completely inaccurate and has been invalidated by harm reduction experts within the academic and scientific community.

Vaping has been prevalent in Canada for the better part of a decade with no incidents of mortality or morbidity. If Health Canada has determined the Royal College of Physicians' 5% risk assessment to be implausible, then why has Canada not conducted a proper risk assessment? Instead of using a published assessment to calculate the mortality and morbidity risks of vaping, risk was determined through consultation with 5 unidentified academics, whose comments were related to the nicotine standard not the flavour ban.

The CVA has determined the unnamed academics to be:

Dr. David Abrams

Dr. Neal Benowitz

Dr. Geoffrey T. Fong

Dr. Dorothy Hatsukami

Dr. Raymond Niaura

While the academics are Tobacco Control experts, they are all psychologists. To determine the mortality and morbidity risk of vaping toxicologists and other relevant experts needed to be consulted. Additionally, the document *Elicitation of Expert Judgements on the Behavioral Impacts of a Nicotine Standard*, which Health Canada states the risk assessment was derived from, does not assess comparative risks of vaping and smoking.

Health Canada has failed to provide any data to support the self-declared "assumption" that vaping is 20% of the comparable risk of smoking. This invalidates the projected vaping deaths and morbidity analysis within the Gazette. As much of the cost benefit analysis is predicated on this flawed figure, the proposal in its entirety should be deemed invalid. Moreover, even if one were to accept this 20% figure, a figure that seems to have been pulled out of a hat, it is still significantly lower than the risk of smoking tobacco.

Regulation modelled after unproven results

Canada is at the forefront of harm reduction initiatives by legalizing safe injection sites and cannabis. When we look at forward-thinking countries that include Portugal and the UK, their stance on addiction and relative risk demonstrates the potential of nations that

support rather than demean those with addictions. It is confounding to see Canada determine that Denmark is the template on which it has based the newly proposed vaping regulations. Denmark banned vape flavours in April 2021, therefore they will not be able to disclose the results of their changes in the foreseeable future.

Denmark isn't new to repressive drug policies; however, it is currently moving towards more punitive approaches as opposed to their 35 year *depanelized* policy. The perspective taken ignores scientific data that addiction is an illness and blames the user for any violations of the new laws with punishment⁶. An in-depth analysis of Danish enforcement intensity found that Denmark is one of the few Western countries to move towards a repressive drug control approach. This resembles the path of maintaining a coherent policy towards illicit drugs, adjusting the legal framework and enforcement intensity in steps to counter the incoherence that follows from periods with increasing problem pressure⁷. These significant changes in drug policy suggest that the flavour ban adopted by Denmark has the potential of not only increasing usage, but also goes against modern harm reduction initiatives being taken over the globe.

When looking at progressive nations, such as the UK and Portugal, we find notably contrasting evidence that dealing with addiction and substance abuse can be successful when using harm reduction methods and even radical adoption of acceptance. Portugal decriminalized drug use and now has some of the lowest usage rates in Europe among those between the ages of 15-348.

The importance of supporting Canada's harm reduction initiatives would be consistent with the current policies. The punitive damage that a flavour ban could inflict on consumers and the potential backlash of black markets and relapses to cigarettes would impede the objectives of reducing tobacco use by 2035. The non-coercive and non-judgmental approaches of other nations are exemplary in terms of harm reduction and fruitful results. It is questionable to see Canada basing its policies on Denmark, when proof of concept for a flavour ban hasn't been shown due to insufficient data as opposed to the years of data from the UK and Portugal.

The efficacy of the UK's harm reduction position on vaping is validated by its goal of being smoke-free by 2030⁹. This is a stark contrast to Canada's current goal of less than 5% tobacco use prevalence by 2035. If Canada continues down a regressive regulatory path it is unlikely that this goal will be achieved.

⁶ https://www.sciencedirect.com/science/article/abs/pii/S0955395920300013

⁷ https://link.springer.com/content/pdf/10.1007/s10610-020-09437-4.pdf

⁸ https://transformdrugs.org/blog/drug-decriminalisation-in-portugal-setting-the-record-straight

⁹ http://ash.org.uk/wp-content/uploads/2020/01/Roadmap-to-a-Smokefree-2030-FINAL.pdf

Efficacy

Health Canada is aware of self-reported information from people who vape indicating the important role flavours played in helping them transition away from smoking, and in continuing to help them maintain abstinence from smoking. (Canada Gazette Part 1, Vol. 155, No. 26)

23,000 vapers have indicated to Health Canada through previous consultation periods that flavours are necessary for continued tobacco abstinence. More recently, over 100,000 vapers¹⁰ sent emails to their Member of Parliament detailing the importance of flavours. Though a significant number of post cards and emails were sent, these submissions represent just a fraction of the close to 1 million vapers that use a flavoured product. Given the volume of responses, this data cannot be dismissed as anecdotal. If Health Canada remains unsure of the importance of flavours or the efficacy of vaping, it is because the department has chosen not to investigate. There are thousands of vapers willing to take part in studies, yet no Canadian study has taken place.

Many respondents indicated that the evidence supporting the effectiveness of vaping products for smoking cessation is mixed or poor, and that people who smoke should rely on proven quit methods. (Canada Gazette Part 1, Vol. 155, No. 26)

Health Canada must consider the validity of the response and act on fact not opinion. Any respondent indicating that the evidence of vaping's efficacy is mixed or poor is ignorant. Subsequently, it is assumed that proven quit methods is synonymous with approved cessation products. These nicotine replacement therapy (NRT) products have extremely low efficacy rates. In recent years, approved NRTs have had limited success in reducing smoking prevalence. In surveys, most smokers indicate that they want to quit. If traditional tobacco control strategies were effective tobacco use would be far less prevalent.

National Health Services (NHS) conducted a controlled trial¹¹ in which participants were randomly assigned to varying nicotine replacement therapy (NRT) products, or ecigarettes, plus one to one support for a minimum of 4 weeks. After one year 18% of ecigarette users had stopped smoking compared to 9.9% of NRT users. The trial concluded that vaping is nearly twice as effective as the leading NRT products.

Moreover, an international review, produced by Cochrane¹², a global network of independent researchers, has reviewed 50 of the top studies on vaping's efficacy. The

¹⁰ https://www.tobaccokills.ca/

¹¹ https://www.nejm.org/doi/full/10.1056/NEJMoa1808779

¹² https://www.cochranelibrary.com/cdsr/doi/10.1002/14651858.CD010216.pub4/full

review found that smokers who used vaping to quit were more likely to be successful. The results showed vaping to be 70% more effective than NRT.

Additionally, Public Health England issued a press release¹³ stating that vaping is better than all other nicotine replacement therapy products. The release referenced King's College London's study that found vaping to have a quit success rate of between 59.7% and 74% in 2019 and 2020, when paired with stop smoking services. The release reported that an estimated 50,000 smokers quit through vaping that otherwise would have continued smoking.

The UK attributes 1.5 million people's success quitting smoking to vaping¹⁴. "An estimated 2.9 million adults in Great Britain currently use e-cigarettes and of these, 1.5 million people have completely stopped smoking cigarettes. They carry a fraction of the risk of cigarettes and can be particularly effective when combined with extra quitting support." National Health Services, UK.

Evidence flavoured vape products support cessation

Within the Gazette Health Canada makes the following acknowledgements:

- Health Canada is aware of self-reported information from people who vape indicating the important role flavours played in helping them transition away from smoking, and in continuing to help them maintain abstinence from smoking.
- Measures to limit flavours in vaping products to reduce their appeal to youth may also make these products less attractive to people who either vape as an alternative to cigarettes or to stay abstinent from smoking.
- Fruit flavours are the preferred choice for adults and youth.
- A recent study conducted in both Canada and the United States shows that a variety of non-tobacco flavours, especially fruit, are popular among adults who vape, particularly among those who have quit smoking and are now exclusively vaping.
- [A study] indicates that people who vape, and use "sweet flavours" (which included 11 different flavour groups, namely fruit, candy, and desserts), were more likely to transition away from cigarette smoking and quit cigarette use, at

¹³ https://www.gov.uk/government/news/vaping-better-than-nicotine-replacement-therapy-for-stopping-smoking-evidence-suggests

¹⁴ www.nhs.uk/smokefree/help-and-advice/e-cigarettes

least in the short term, compared to those who used tobacco-flavoured or unflavoured vaping products.

At this time, it is unknown what the impact would be on people who vape if they
had no access to their preferred vaping product flavour.

Health Canada acknowledges that there is some research to support flavoured vapes as beneficial for smoking cessation and that fruit flavours are preferred by adults. Youth experimentation does not justify the dismissal of thousands of declarations of the importance of flavours and the emerging science.

Most concerning of the acknowledgements is that it is unknown what the impact will be on people who vape. To continue with regulation that may jeopardize the health of Canadians without an understanding of the impacts is a dereliction of duty. This regulation should not be considered until the impacts are known and disclosed.

Flavours aiding in smoking cessation is not a phenomenon unique to vapour products. It is documented with NRTs that flavours reduce cravings and increase success rates. There has been no connection made between flavours and increased abuse potential. A study by the Behavioural Pharmacology Research Unit, John Hopkins University School of Medicine¹⁵ found that, "Both flavors of nicotine gum decreased craving during 2 hr of abstinence. These effects were more pronounced in the adult group and mint gum was more effective than original gum. Younger subjects reported fewer withdrawal symptoms and lower ratings for drug effects and flavor. Improved flavor of nicotine gum does not increase abuse liability but may be associated with enhanced craving reduction."

In contrast to the proposed vape product flavour restrictions, all approved oral NRT products are available with flavours. These products are available off the shelves of pharmacies and grocery stores and have no age-verification requirement.

Youth risk and use

Flavour restrictions have been proposed to curb youth use and prevent harm and addiction. Despite the partial release of the Canadian Tobacco and Vaping Survey, 2020, more current data is excluded. The youth vaping data within the Gazette ends in 2019 and only indicates past 30-day use. Past 30-day use is not an indicator of addiction or continued use and is a metric of experimentation.

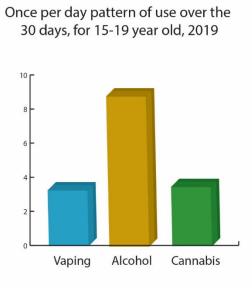
If other adult products were regulated consistent with the concern over past 30-day vape use, both cannabis and alcohol would require severe restrictions, as both daily

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¹⁵ https://www.ncbi.nlm.nih.gov/pubmed/12175452

and past 30-day use prevalence are greater than nicotine vaping. Alcohol is considerably more harmful than nicotine vaping and despite use being more prevalent than vaping among youth, flavour restrictions have not been considered. This is likely because like vaping, youth are not consuming alcohol for the flavours.

All products listed within the survey are known to negatively effect brain development, however alcohol carries greater external risks such as car crashes, falls, drowning, and other accidents, suicide, violence and can lead to being a victim of violent crime¹⁶. Given that alcohol use among youth is more than double that of vaping, it seems Health Canada is regulating in reverse priority. Canada's response to youth vaping is not proportionate to the risk posed and places an extremely low value on human life.

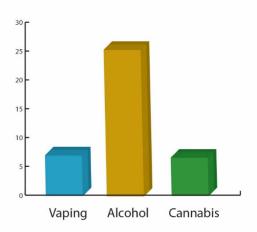


Canadian Tobacco and Vaping Survey, 2019

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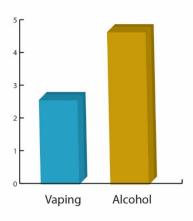
¹⁶ https://medlineplus.gov/ency/patientinstructions/000528.htm

At least once per month pattern of use over the 30 days, for 15-19 year old, 2019



Canadian Tobacco and Vaping Survey, 2019

Daily pattern of use over the 30 days, for 15-19 year old, 2019



Canadian Tobacco and Vaping Survey, 2019

Had the 2020 data 17 been published, along with the current daily use numbers, it would show that youth vaping is in continued decline. However, even the 2019 data finds daily use to be $4.7\%^{18}$.

¹⁷ https://www150.statcan.gc.ca/n1/daily-quotidien/210317/dq210317b-eng.htm

¹⁸ https://www.canada.ca/en/health-canada/services/canadian-tobacco-nicotine-survey/2019-summary/2019-detailed-tables.html#t6

Dr. Hammond whose research has driven much of Canada's vaping regulation, has stated "It looks like we may have reached the peak of youth vaping. I would expect that vaping will continue to decline among young people, and if that happens in parallel with the continued reduction in smoking, then that's very good news for everybody." ¹⁹

It should also be noted that the youth survey data is inclusive of age of majority respondents and the most common reason for use was curiosity. Depending on the province, respondents 18 and 19 years old are of legal age to purchase vape products. The survey doesn't indicate how many respondents of each age were surveyed or their province of residence. Without this information, there cannot be an accurate assessment of the number of minors vaping. While unlikely, it is possible that all respondents were of legal age to vape. The CVA suggests that future versions of the Canadian Tobacco and Vaping Survey include more specific data on the age and location of respondents to better assess the prevalence of minors vaping.

Additionally, the CVA has concerns around the data Health Canada has chosen to use in order to support the proposition that flavours are the driver for youth use. The two studies chosen to support this premise are a Longitudinal Vaper Panel Survey to measure Attitudes and Behaviours regarding Vaping Products and the 2019 Wave 3 International Tobacco Control Youth Tobacco and Vaping Survey. The citation for the former states that due to the nature of the survey, no estimates for sampling error can be assessed and the results cannot be statistically projected to the target population. The latter are unpublished results provided by Dr. David Hammond. These results are not publicly available and can not be substantiated.

Considering flavoured vape products account for about 90% of the products available in the marketplace²⁰, it is unsurprising that youth are using products consistent with product availability. However, there has yet to be a published study that finds that flavours are the primary reason for youth use, or that their removal would protect youth without harming the rest of the population.

The Youth and Young Adult Vaping Project 2020-2021²¹ survey found that the strongest influence to start vaping for the whole sample were peers, followed by the desire to quit smoking and social media exposure. Within the survey's findings, flavours are not listed as an influence. Interestingly, the second greatest influence to start vaping was to use the product as intended - to quit smoking. The survey finds that the majority of users surveyed were former tobacco users (64%). This indicates that vaping has reduced harm and, in most cases, transitioned combustible tobacco use to a less harmful nicotine delivery system.

 $^{^{19}\} https://www.stcatharinesstandard.ca/ts/business/2021/03/17/about-one-in-seven-young-canadians-are-regular-vape-users-statistics-canada-says.html$

²⁰ https://drive.google.com/drive/folders/1dHAIBsnSyLNV7J06w06Cz9-mpUQJIPZ6?usp=sharing

²¹ https://www.heartandstroke.ca/-/media/pdf-files/get-involved/yyav-full-report-final-eng-24-3-2021.ashx

The study, "Electronic cigarettes, nicotine use trends and use initiation ages among US adolescents from 1999 to 2018"²² concluded, "Electronic cigarettes may have offset conventional smoking among US adolescents between 2010 and 2018 by maintaining the total nicotine use prevalence and diverting them from more harmful conventional smoking. Additionally, electronic cigarette users appear to initiate at older ages relative to conventional smokers, which is associated with lower risk."

Vaping is clearly a gateway away from combustible tobacco as youth smoking rates drastically declined at the peak of youth vaping. This decline came at a time when youth smoking prevalence was already considered low. If vaping was in fact a gateway to tobacco, there should be a correlating increase in smoking rates among young adults who were teenagers at the peak of youth vaping, yet smoking rates continue to decline among all age demographics.

Several other surveys find flavours are not the primary reason for youth uptake. Most notable, the study named "Tobacco Product Use and Associated Factors Among Middle and Highschool Students²³," conducted by the CDC found that 77.7% of youth vaped for reasons other than flavours. The most common reason for use was curiosity.

Mental health is a driver for youth use

In Canada, the mental health of youth has degraded over the last decade. The prevalence of poor/fair perceived mental health increased from 4.2% in 2011 to 9.9% in 2018, an average increase of 0.8% per year (95% CI 0.5–1.0%).²⁴ There is a growing need for mental health care for Canadian youth to meet the rising need to navigate stress and anxiety. The vaping epidemic characterized by youth utilizing vaping products solely based on the flavours severely ignores the undercurrent of a generation that is seeking a healthier way to take care of themselves and a need for improved enforcement of current regulations, as well as an arsenal of coping strategies to ensure a successful adulthood.

While flavours may be a reason for vaping, there has yet to be any study which finds flavours to be the primary driver for youth use. Furthermore, removing flavours has been proven to be detrimental to vapers in the US and Canada, driving users to gray and black markets, as well as back to cigarettes. The focus of public opinion, media and government has been dialed onto flavours, while we ignore that the same study demonstrated that 35% of youth responded that stress is a prevalent reason that they vape.

²² https://pubmed.ncbi.nlm.nih.gov/32335976/

²³ https://www.cdc.gov/mmwr/volumes/68/ss/ss6812a1.htm#T6_down

²⁴ https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7214527/

The need for increased support for their mental health resonated through a BC study on youth vaping during the pandemic. Where 24%²⁵ of youth reported that vaping improved their mental health and 11%³ indicated that mental health counseling would help them quit vaping. In their comments, there are requests for judgement-free and shameless approaches to quit vaping, as well as education on how to quit. Finally, "there was a rise in survey respondents reporting high stress levels during the COVID-19 pandemic. This is important for adults to consider, as managing stress was one of the underlying reasons for some respondents to vape. Teaching stress management skills would be beneficial to all youth, particularly as some youth researchers have found that access to mental health resources has been limited by the pandemic³."

A straightforward approach has been suggested by UPMC Children's Hospital of Pittsburgh to reduce youth vaping. The study shows that setting goals and strong parental support reduces the likelihood that youth will vape. Positive future orientation and high levels of parental monitoring were both linked with a 10% to 25% lower prevalence of recently or ever vaping, compared to peers with lower scores on those protective factors²⁶.

When research and support is offered to youth in modern educational formats, the results can lead to encouraging outcomes. Yale researchers developed a video game, played by using a virtual reality headset, that not only educated teens on nicotine addiction and vaping, but teaches them to say no to vaping while maintaining their coolness and dignity²⁷. There was an 80% completion rate, and students reported a satisfactory gameplay experience. Empowering students to make enlightened decisions rather than removing adversity is a progressive way to prepare them for future addictive lures.

Canadian youth are subject to numerous appealing products that are categorized as unsafe for their health. Our society has a responsibility to prevent them from acquiring these products, as well as educating them to allow for conscious consumer decisions during their youth and into adulthood. It is imperative that youth learn to cope with strong emotions and deal with their mental health as opposed to self-medicating. This requires programs that would allow for education that is paired with an awareness of the social stakes and imperatives that surround them. As Health Canada considers removing flavours, it is vital to consider that flavours are only one part of the equation, and that removing them will not only impact adult vapers, but also the youth that risk continuing vaping or smoking due to lack of resources and educational programs on vaping.

²⁵ https://www.camh.ca/-/media/files/pdf---osduhs/drugusereport 2019osduhs-pdf.pdf

 $^{^{26}\} https://www.news-medical.net/news/20210726/Positive-future-orientation-and-strong-parental-support-linked-with-lower-risk-of-youth-vaping.aspx$

²⁷ https://medicine.yale.edu/news-article/virtual-reality-game-is-an-effective-tool-for-vaping-prevention-among-teens/

Black and gray markets

The lung illness outbreak EVALI (e-cigarette or vaping product use-associated lung injury) should serve as warning of the danger that the unregulated market poses to public health. The cause of EVALI was discovered to be vitamin E acetate²⁸. The CDC discovered that illicit black-market cannabis products were using vitamin E acetate as a thickening agent. While this outbreak was not related to nicotine vaping products (if vitamin E acetate was added to e-liquid it would be visually apparent and would prevent the coil from properly functioning), it demonstrates the danger in creating an environment for illicit products to flourish.

Additionally, research from the Yale School of Public Health²⁹ "Association of Vaping-related Lung Injuries with Rates of E-cigarette and Cannabis Use across US States," suggested that the outbreak was more pronounced in areas with a cannabis prohibition. This demonstrates that prohibition is ineffectual and poses a danger to public health. Blanket bans on flavours will eliminate responsible regulated manufacturers from the market, leaving a void to be filled by unregulated and potentially dangerous products. Eliquid consists of few ingredients and is relatively simple to manufacture. These factors, combined with the demand for flavours and high nicotine, make e-liquid an attractive product for black-market sellers. Illicit products will not be subject to manufacturing standards and their sale unregulated by Tobacco Enforcement and Public Health.

As it stands, there is next to no enforcement or screening for imports. Prohibition will cause an increase in online transactions from international vendors. Currently, Canada has the most restrictive regulation globally on non-youth appealing packaging. Further product restrictions will increase the visibility of products appealing to youth on foreign websites. Upon delivery of the product within Canada, there is no age verification procedure, as would be required for Canadian vendors. Youth are increasingly tech savvy and will easily circumvent the ban using foreign channels. For the past 3 years, the CVA has told Health Canada at quarterly meetings that this problem exists and needs to be rectified.

CVA board members have tested dozens of products from Chinese vendors and have found variations in nicotine content of up to 15% from the labelled amount. The CVA has on several occasions requested that manufacturing standards be implemented federally. Despite the absence of manufacturing standards within Canada, the limited number of manufacturers makes it far easier for the consumer to identify reputable products. However, through prohibition the international market will be appealing to consumers and much more difficult to navigate reputable products.

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²⁸ https://www.cdc.gov/tobacco/basic_information/e-cigarettes/severe-lung-disease.html

²⁹ https://onlinelibrary.wiley.com/doi/abs/10.1111/add.15235

Given the ease of importing and manufacturing unregulated products, it is inevitable a flavour ban will strengthen these channels. Historically, prohibition has never worked and is validated by Canada's serious problem with contraband tobacco. The Canadian government has estimated that contraband tobacco makes up roughly 30% of the total Canadian tobacco market. The contraband tobacco trade was worth nearly \$2.6 billion in 2008 and the share of contraband tobacco in the overall underground economy has been rising since 2002³⁰.

As it relates to flavours, the study "Evaluating the impact of menthol cigarette bans on cessation and smoking behaviours in Canada³¹," found that following the ban on menthol cigarettes, 19.5% of menthol users continued to access menthol cigarettes through other channels, primarily First Nations Reserves.

Flavour prohibition strengthening black-market channels is further supported by a study from New Zealand³² that suggests "...restricting the sale of liquid flavours may have negative unintended consequences. 57% of respondents indicated they would circumvent a ban on popular liquid flavours by mixing their own and/or buying liquids from overseas or the black-market." The study concludes, "Various legislative or policy initiatives proposed to regulate vaping may have unanticipated negative consequences for public health. The negative impacts are likely to be disproportional for groups with higher smoking prevalence such as Indigenous peoples, rural communities, and lower socioeconomic groups."

Additionally, a consumer survey report, Canadian vapers: Attitudes Towards Flavour³³, conducted by Ecigintellegence found that:

- Flavour is the top factor for Canadian vapers when choosing their e-liquid.
- Over half intend to continue using their favourite flavours if they are banned, both in provinces with restrictions and those without.
- Canadian consumers adapt their flavour preferences to the restrictions, but are much more likely than US vapers to return to combustible products in the face of any clampdown on flavours.

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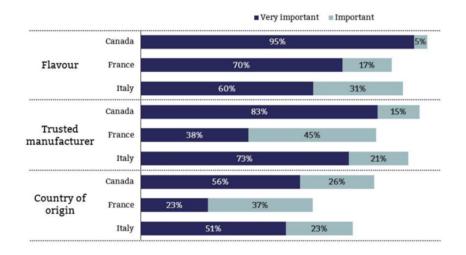
³⁰ https://www.fraserinstitute.org/sites/default/files/combatting-contraband-tobacco-trade-in-canada-rev.pdf

³¹ https://tobaccocontrol.bmj.com/content/early/2021/03/31/tobaccocontrol-2020-056259

³² https://f1000research.com/articles/10-

³³ https://drive.google.com/drive/u/1/folders/1dHAIBsnSyLNV7J06w06Cz9-mpUQJIPZ6 (The CVA distributed the survey through the CVA's social media platforms, but did not take part in the collection or analysis of data)

Importance of factors - country comparison

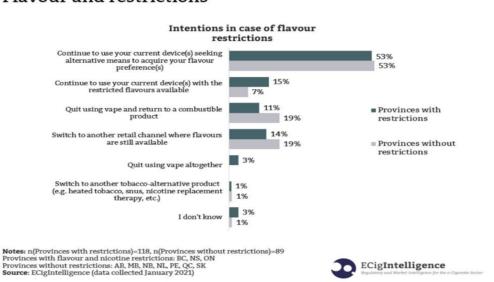


Notes: Canada n=110, France(2020) n=81, Italy(2021) n=369; sub-segment analysed: ages 21.59 who vaped for over two years

Source: ECigIntelligence (data collected January 2021)

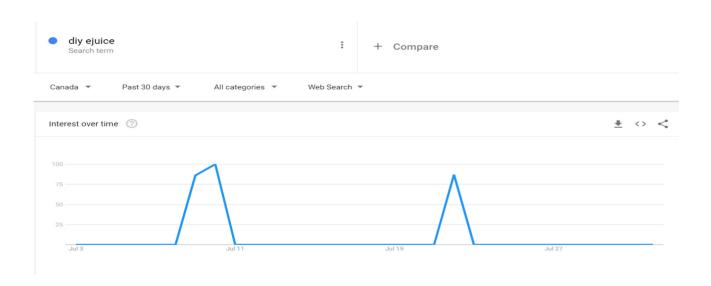
ECigIntelligence
Regulatory and Market Intelligence for the e-Cigarette Sector

Flavour and restrictions



When compared with data from vapers in the US, where flavours are also subject to restrictions at both local and federal level, Canadian consumers are much more likely to return to combustible products if restrictions on flavours are imposed. 53% of Canadian vapers indicated that they intend to find an alternative means to source flavoured products.

Flavour restrictions resulting in a booming black-market is widely recognised, but less talked about is the gray market. A popular means of sourcing flavoured product will be through DIY (Do It Yourself). This is referred to as the gray market because sourcing the raw materials will be legal and the materials easily accessible. Flavourings and glycerin will be easily acquired through grocery and baking supply stores and nicotine will be purchased online through foreign vendors. Illicit tobacco, is for the most part, produced by large scale organizations as tobacco plants can't be easily grown in peoples' homes, unlike e-liquid which can be easily produced through simple home set ups. According to Google Trend data³⁴, search prevalence for DIY ejuice has increased in Canada following the proposed restrictions.



This is concerning because while e-liquid is simple to manufacture, not all flavourings or glycerin is safe for inhalation. Many easily accessible flavourings are sold for food flavouring purposes and contain oils, alcohols, and other additives that may cause serious illness or death if inhaled. Flavour manufacturers are not required to disclose if the flavourings are oil, water, or alcohol soluble, nor are they aware that these products may be purchased for inhalation. If inhaled, oil and alcohol pose serious risks to health. Vapers will attempt to mix their own e-liquid out of desperation to remain smoke-free. Moreover, illicit sellers may unknowingly, or knowingly to reduce costs, use ingredients that are unsafe for inhalation. Prohibition of vape flavours in Canada will invite EVALI 2.0.

In response to concerns about the potential for a strong black-market, many tobacco control authorities, including Health Canada, have stated that it is likely that a parallel

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³⁴ https://trends.google.com/trends/explore?date=today%201-m&geo=CA&q=diy%20ejuice

market will exist, like after tobacco flavours were banned, but this further supports the need for regulatory changes. However, the impact of vape flavour restrictions is far more significant than the ban on menthol cigarettes; vape restrictions will impact a greater amount of people. Additionally, vape products are different from traditional tobacco products as they are much more easily produced by illicit channels. The illicit channels that manufacture vape products, through simple home set-ups, have already shown their ignorance and apathy towards the use of dangerous additives to cut costs.

Flavour restrictions will increase smoking rates

As previously discussed within this submission, Health Canada acknowledges that dual users will revert to smoking. The following additional acknowledgements are made indicating Health Canada is aware that the proposed regulation will increase smoking and lessen vaping adoption:

- Some people who vape indicated that flavours helped them quit smoking and maintain abstinence from smoking.
- The analysis estimated the reduction in consumer demand for vaping products based on the impacts of NS's recently implemented restrictions on flavours. The analysis was based on data for weekly sales of pods in the Maritime provinces, i.e. NS, New Brunswick, and PEI.
- This analysis assumes there would be a 10% to 14.3% reduction in consumer demand for vaping products and used a 12.15% reduction to estimate impacts.
- 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.
- Some adults who smoke who would try tobacco- and mint/menthol-flavoured vaping products may find these vaping products are not pleasant or palatable and could therefore end up being dual users or remain smokers. These persons would continue to be exposed to harmful chemicals from the long-term use of tobacco products.
- It is also anticipated that certain dual users would relapse to smoking only as a result of the proposal.

It is unconscionable that Health Canada has concluded that a consequence of restricting flavours is increased smoking – our nations largest killer – and deemed it appropriate to continue with this regulation.

Further, the analysis of the impact of consumer demand only examines the impact to the G&C channel. After the flavour ban in Nova Scotia, 50% of specialty stores closed

immediately, and 87.5% of specialty stores closed within 90 days. Pod users are more likely than open system users to use a tobacco flavour, as pod users generally favour convenience over experience, thus flavour restrictions have a more limited impact on this channel. With no evidence to suggest restricting flavours lessened youth vaping, we can conclude that all Nova Scotia accomplished with the ban was an increase in smoking and shifting buying patterns to outside sources.

Moreover, a recent study from the US found³⁵, "If restricted to tobacco flavors, 39.1% of e-cigarette users reported being likely (very/somewhat) to continue using e-cigarettes (30.5% not at all likely); 33.2% were likely to switch to cigarettes (45.5% not at all). Considering complete vape product sales restrictions, equal numbers (~39%) were likely vs. not at all likely to switch to cigarettes."

This is validated by the results of the ban in Nova Scotia³⁶. The Atlantic Convenience Store Association stated that after the ban they experienced an unprecedented spike in cigarette sales. Polling from Abdacus data found that 30% of vapers were at risk of relapsing to smoking.

Ironically, flavour bans also put youth at risk of increased smoking. A Difference-in-differences analysis³⁷ found that San Francisco's flavor ban was associated with more than doubled odds of recent smoking among underage high school students relative to concurrent changes in other districts. "While the policy applied to all tobacco products, its outcome was likely greater for youths who vaped than those who smoked due to higher rates of flavored tobacco use among those who vaped. This raises concerns that reducing access to flavored vape products may motivate youths who would otherwise vape to substitute smoking."

The CVA is disturbed that Health Canada has chosen a pathway that serves to disproportionately benefit international tobacco companies and government owned businesses over Canadian family run businesses.

Health Canada acknowledges the benefit to tobacco companies in these statements:

 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.

³⁵ https://academic.oup.com/ntr/advance-article-abstract/doi/10.1093/ntr/ntab154/6332852?redirectedFrom=fulltext

³⁶ https://www.halifaxtoday.ca/local-news/cigarette-sales-in-nova-scotia-increasing-atlantic-convenience-stores-association-2792516

³⁷ https://jamanetwork.com/journals/jamapediatrics/fullarticle/2780248?guestAccessKey=227700a4-e3cb-4ccf-8ad5-ae5133e0009c&utm_source=silverchair&utm_medium=email&utm_campaign=article_alert-jamapediatrics&utm_content=olf&utm_term=052421&fbclid=IwAR2oNtRUlf-yPkiRqxWB2tIWYqL9IF_XJP4-DETfCxwHc-5WQfg_UaXAy-w

- 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. Flavour restrictions could undermine this business model and result in business closures and job losses.
- Restrictions on flavours may lead those who continue to vape to switch from open systems to closed systems. Replacement pods for closed systems are sold primarily in G&C stores. Hence, G&C stores may disproportionately benefit from the switch of consumers to closed systems, as compared to vape shops.

There are an estimated 7,000 jobs tied to the independent vape industry through retailers, wholesalers, manufacturers and tertiary suppliers. As demonstrated in Nova Scotia, a flavour ban will decimate the independent industry and lead to thousands of job losses.

Further marginalization of minority groups

Canadian minority groups will be disproportionately affected by a flavour ban. Health Canada has stated that additional supports are already in place to help these groups, but to date these programs have had limited success. Flavoured vape products have superior efficacy and must remain available to all adult smokers if Canada is to achieve Health Canada's target of less than 5% tobacco use by 2035. With Canada's current lack of resources, these laws will have an adverse effect on minority groups including but not limited to Indigenous, LGBTQ2, and individuals with mental health and substance abuse issues. These communities may be more sensitive to nicotine addiction which can result in increased anxiety or physical cravings, as well as other negative side effects from quitting smoking cigarettes.

When comparing smoking rates in Canada, there is a higher prevalence in minority groups. In 2019, 11.9%³⁸ of the Canadian population smoked. In contrast, 36%³⁹ of the LGBTQ2 community smoked and for Indigenous groups, it ranged between 31%-65%⁴⁰. In Nunavut, for example, up to 80%⁴¹ of pregnant women reported smoking during pregnancy. Addressing disparities in smoking rates is an important component of developing tobacco endgame strategies⁴². Restricting flavours for these groups would remove a viable tool as they will already need substantially more interventions than the general smoking population.

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³⁸ https://www.canada.ca/en/health-canada/services/canadian-tobacco-nicotine-survey/2019-summary/2019-detailed-tables.html

³⁹ https://pubmed.ncbi.nlm.nih.gov/22530537/

⁴⁰ https://www.cps.ca/en/documents/position/tobacco-aboriginal-people

⁴¹ https://www.cps.ca/en/documents/position/tobacco-aboriginal-people

⁴² https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6437323/

Mental health and substance abuse are underlying factors that will greatly contribute to the effectiveness of the programs that will be catered to minority groups. One-half of Canadian smokers have experienced mental health or substance use disorders in their lifetime⁴³. These individuals are most likely to see the greatest impact in reducing the disparities that currently exist.

Several studies have demonstrated that there have been programs in place to help minority groups and they have shown promise. The caveat to this, is that there are several challenges that presented themselves regarding how the programs should be run to accommodate the participants. These communities are more likely to have mental health and addiction problems. It is imperative that they consider elements such as social anxiety and access to the meetings. Social interaction is much more limited when switching to vaping, therefore, vaping should remain among the quit smoking tools that are available. These groups tend to be underserved by studies in general, which is a common denominator that is brought up by the studies.

There is no evidence of consultation with these affected marginalized communities as part of this process. In particular, the Crown has a constitutional obligation to consult indigenous communities about laws restricting their rights. There has been no such consultation.

The proposed flavour restrictions may have adverse effects on marginalized groups who rely on vaping as a harm reduction tool. In order to understand how these bans will affect minority populations, disparities were examined in cigarette use between demographic groups. It is imperative to ensure that these communities are well served by the tobacco cessation initiatives that Canada is rolling out and that the very tools that are needed are not hampered by regulatory overreach.

Impacts on Canadian business and tax base

Health Canada States:

- Between 85% and 95% of the total volume of vaping liquid sold in Canada is manufactured in Canada. Vaping liquid sold in bottles is almost exclusively manufactured in Canada, while vaping liquid sold in pre-filled pods is almost exclusively imported into Canada. The majority of these businesses, including manufacturers, are considered to be small under the Treasury Board of Canada Secretariat definition.
- The proposal disproportionately benefits large companies that blend their own flavours. Domestic companies will have increased reformulation costs and may face logistical barriers and additional costs.

⁴³ https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6437323/

There could be some minor tax revenue loss to governments as a result of the
proposal given that vaping products with some flavours would be removed from
the market. The proposal and the possible associated changes in demand could
affect tax revenue for governments. Reduced sales of vaping products could
affect provincial sales tax collections, while manufacturer and retailer profit
losses could reduce corporate income tax revenue.

The CVA recognizes that the role of Health Canada is to regulate in the best interest of public health and the agency is not tasked with considering the economic consequences of regulation. Still, it is jarring for a Canadian institution to propose policy that by its own admission will harm Canadian businesses and favour foreign companies. It is common for countries to implement protectionist policies, yet Health Canada has chosen a pathway that will decimate Canadian industry.

It should also be noted that in addition to diverting money that otherwise would have stayed in Canada to foreign suppliers and criminals, the flavour ban will be a considerable detriment to the proposed excise tax. With a flavour ban in place, Canada can expect a reduction of approximately 50% in excise tax collection.

In addition to reducing smoking prevalence, vape products benefit society by reducing health care and social costs. Through an industry survey and Health Canada's assumed cost of \$2,600 annually per smoker (aged 27 and older), the CVA has determined that \$1 spent in the vape industry is worth \$2.70 to the economy.

Economic Analysis Impact and Contribution

Vape Shop Sales Impact on the Canadian Economy

Annual healthcare cost		\$2,600
Annual consumer spending		\$1,200
Percentage of sales: salaries	23%*	\$276
Percentage of sales: taxes	30%*	\$360
Total: healthcare cost and percentage of sales - salaries and taxes		\$3,236
1\$ spent in the vaping industry is worth \$2.70 to the economy		\$2.70

^{*} Industry survey sourced for percentage of sales for salaries and taxes.

Discrimination in enforcement timelines

The Gazette states, "The proposal would be made pursuant to the powers of the TVPA and would come into force on the 180th day after it is registered," in contrast to Canada Gazette, Part I, Volume 155, Number 25: Regulations Amending the Cannabis Regulations which states, "The proposed amendments have been designed to limit burden on all businesses, including small businesses. They would come into force 180 days after they are registered, giving licensed processors time to adjust their production processes, including labelling, and modify promotional materials. To limit the impact on small businesses, the proposal would allow licensed sellers and provincially and territorially authorized distributors and retailers to continue selling flavoured inhaled cannabis extracts to consumers until they deplete their inventory. This would avoid having licensed sellers and provincially and territorially authorized distributors and retailers return the products for destruction, which should help reduce financial losses for businesses."

As previously established in this submission, youth cannabis use is greater than vape use. Why then has Health Canada chosen to make allowances for cannabis retailers and not vape retailers?

Conclusion

The CVA does not support flavour restrictions. The proposal is not based on evidence, and indeed flies in the face of the available evidence. It is predicated on a flawed risk assessment and the negative outcomes are not adequately weighed. It is proven that flavour bans increase smoking, strengthen illicit channels and disproportionately impact minority groups who were neither studied nor consulted. If implemented, this ban will hamper Canada from achieving its goal of less than 5% smoking prevalence by 2035. Significant irreparable harm will be caused to smokers and their families.

Though once a leader in tobacco harm reduction, through regressive policy, Canada will push thousands of vapers back to smoking. New Zealand and the UK have embraced vaping as a harm reduction tool and have set goals to eliminate tobacco use within the decade, whereas Canada is proposing regulation that will push thousands of vapers back to smoking.

Flavour restrictions are the result of sensationalism and faux-moral outrage. Experts have stated that youth vaping has reached its peak and rates are expected to continue to decline. Continuing to pursue regulation that will cause demonstrated harm to adult smokers is morally reprehensible.