

Submission in response to:
**Order Amending Schedules 2 and 3 to the Tobacco and Vaping Products Act
(Flavours)**

As published in:
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Submitted to:

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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

I sit on the Board of Directors for the Vaping Industry Trade Association (VITA) of Canada. VITA will be making its own submission.

I am the CEO and own half of the shares for *Alternatives & Options – Vapourizers and E-liquids Ltd.* This privately held corporation operates two vaping products retail locations in central Alberta and will not be submitting comments on this matter.

I am a former smoker. I had my first cigarette at the age of 9 and my last at the age of 42.

I currently use vaping products as a reduced harm substitute for cigarettes and to remain abstinent from smoking. I have used vaping products for the last seven years. I intend to continue to use vaping products for as long as I choose to use nicotine, as long as they are practical, more appealing, and less harmful than smoking.

I am a vocal advocate for vaping products, both as a harm reduction option and for cessation.

None of the above statements invalidate my Canadian citizenship. Nor do any of the above statements invalidate my right as a Canadian citizen to submit comments to legislation and regulation proposed by the Canadian government.

No "international obligation" invalidates the fiduciary responsibility of the Government of Canada to its citizens. No matter in what legal manner they derive income to feed their families, no matter what legal organizations they belong to, and no matter who they may choose to sit at a table with and have discussions.

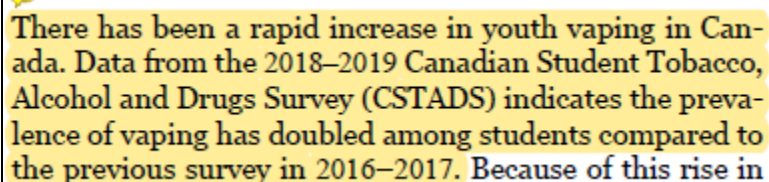
I expect that as a Canadian citizen, my submitted comments on this regulation will be accepted, read in total, and given equal consideration as afforded to other stakeholders, no more and indeed, no less. I expect that Health Canada will assess my submission based on the substance of what I have to say and not who I am or how I legally make my living.

I am deeply disappointed in this -my- government for putting me in a position where I feel I have to clarify my rights, the government's obligations, and my expectations.

Thomas Kirsop

Comments on statements made in the Regulatory Impact Analysis Statement

"Issues" *Canada Gazette Part I, Vol. 155, No. 25 - Page 2928*



There has been a rapid increase in youth vaping in Canada. Data from the 2018–2019 Canadian Student Tobacco, Alcohol and Drugs Survey (CSTADS) indicates the prevalence of vaping has doubled among students compared to the previous survey in 2016–2017. Because of this rise in

Figure 1: Canada Gazette Part I, Vol. 155, No. 25 - page 2928

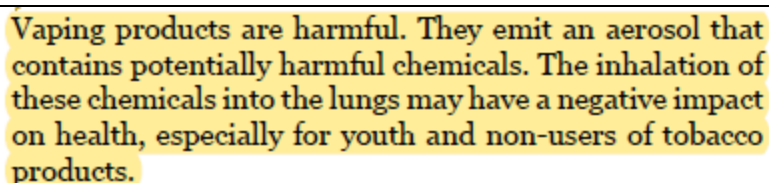
StatsCan has not published the CSTADS data for the 2020-2021 cycle. However, some preliminary data from CTNS (Canadian Tobacco and Nicotine Survey) 2020 has been published in "The Daily" and shows a 1% drop in youth past 30-day use compared to the previous cycle (14% compared to 15%).

That 1% equates to 27,995 fewer youth with past 30-day vaping behaviour in 2020 than in 2019. This 1% drop at a population level is an 8.8% drop in youth vaping in a single year (population size accounted for).

See Appendix.

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

"Health Concerns and Nicotine Addiction" *Canada Gazette Part I, Vol. 155, No. 25 - Page 2930*



Vaping products are harmful. They emit an aerosol that contains potentially harmful chemicals. The inhalation of these chemicals into the lungs may have a negative impact on health, especially for youth and non-users of tobacco products.

Figure 2: Canada Gazette Part I, Vol. 155, No. 25 - page 2930

Hypothetical or potential risks do not provide substantive evidence of definitive harm. "This product *will* hurt you because the contents *might* be dangerous" is an illogical statement. This error of logic appears within most Health Canada publishings regarding vaping products.

If one "knows" a product causes harm, then one knows what damage it causes and how. One can defend the position statement in absolute terms using evidence.

adults do.² Exposure to nicotine during adolescence can also negatively alter brain development, including long-term effects on memory and concentration abilities.^{3,4,5}

Figure 3: Canada Gazette Part I, Vol. 155, No. 25 - Page 2931

Given the purported effects are "long-term," where are all the addle-minded adults from the '70s and '80s when our smoking rates were far higher? What evidence from the '50s and '60s when they were greater than 50%? Smokers from those eras are still alive, and the majority of them started smoking well before adulthood.

Again: "Risk" perceived does not immediately equate to "Harm" realized.

Significant harm (impairment, negative impact on daily function) is not *absolute harm* (Any harm, including harms compensated by the natural regenerative process).

"Role of flavours in facilitating switching from cigarette smoking to vaping" Canada Gazette Part I, Vol. 155, No. 25 - Page 2942

Health Canada notes that no vaping products have been approved as smoking cessation aids. To seek such an

Figure 4: Canada Gazette Part I, Vol. 155, No. 25 - page 2942

The act of quitting smoking is not a medical intervention. Medical intervention can facilitate quitting smoking, for example, a prescription for a pharmaceutical drug that inhibits nicotine uptake or cravings, but not every cessation aid has or needs Health Canada's approval.

Health Canada's approval as a cessation aid has nothing to do with the product's academically reported effectiveness as a cessation aid. The academic data not only shows that vaping is an effective cessation aid, but in a lot of cases, it's starting to show that vaping is more effective than your approved products.

I stopped smoking seven years ago by switching to vaping. Not only did Health Canada not approve of my method, but Health Canada was also of the opinion I was breaking the law by quitting according to the notice issued by the department in 2009.

Hundreds of thousands of Canadian adult vapers self-identified as ex-smokers in the 2019 CTNS survey. We are called "anecdotes."

The government's then open disapproval. The government's current non-approval. Neither has any impact or bearing on the outcome. We are ex-smokers.

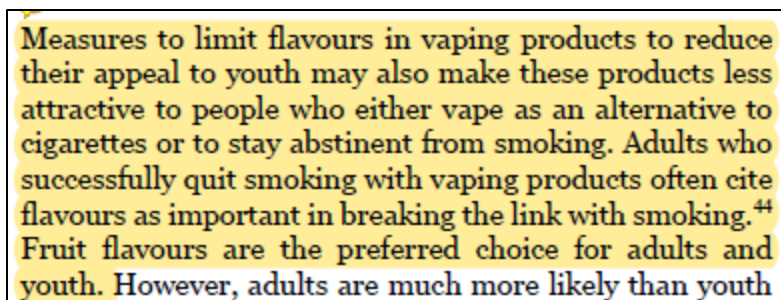
By constantly beating the "not approved for cessation" drum, Health Canada (and others who parrot the statement) gives the impression of being unaware of the academic data, ignorant of science, and in unkind but truthful terms, petulant.

Canadian Tobacco and Nicotine Survey (CTNS): 2019 detailed tables - <https://www.canada.ca/en/health-canada/services/canadian-tobacco-nicotine-survey/2019-summary/2019-detailed-tables.html>

Hajek et al. - A Randomized Trial of E-Cigarettes versus Nicotine-Replacement Therapy - <https://www.nejm.org/doi/full/10.1056/nejmoa1808779>

Cochrane Library - Electronic cigarettes for smoking cessation - <https://www.cochranelibrary.com/cdsr/doi/10.1002/14651858.CD010216.pub5/full>

Smith et al. - E-cigarettes versus nicotine replacement treatment as harm reduction interventions for smokers who find quitting difficult: Randomised controlled trial - <https://onlinelibrary.wiley.com/doi/10.1111/add.15628>



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. Adults who successfully quit smoking with vaping products often cite flavours as important in breaking the link with smoking.⁴⁴ Fruit flavours are the preferred choice for adults and youth. However, adults are much more likely than youth

Figure 5: Canada Gazette Part I, Vol. 155, No. 25 - page 2942

There is a significant disparity in the physical numbers of adults who vape over youth. This statement understates the impact a flavour restriction would have on Canadian adults who have, are, or may transition(-ed, -ing) to vaping from smoking.

While it is true that only 3.2% of the adult (25+) population identified as using vaping products in the past 30 days in 2020, 3.2% equates to 854,600 adults over 25. If we include all adults, the number of people swells to over 1.1 million.

14.4% of youth who report past-30-day vaping behaviour equates to 291,300 physical bodies.

See Appendix.

or unflavoured vaping products.⁴⁸ 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.

Figure 6: Canada Gazette Part I, Vol. 155, No. 25 - page 2943

I find this statement dubious.

There are multiple references in the Cost-Benefit Analysis that refer to the potential for adult users of vaping products to return to exclusively smoking.

Some statements anticipate vape shops will go out of business.

Health Canada has stated in the proposal that vapour products manufacturers who are also tobacco products manufacturers would recoup lost vaping revenue through increased combustible tobacco sales.

There are also references to black-market access.

The publisher proclaiming "we don't know what will happen" is disingenuous if not outright deceptive.

"Regulatory Development: Consultation" *Canada Gazette Part I, Vol. 155, No. 25 - Page 2946*

Over 24 000 submissions were received in response to this consultation, including 288 unique responses from a variety of stakeholders, 100 template submissions from health professionals, health organizations and the general public, nearly 23 000 postcards and almost 1 450 template emails from people who vape.⁵⁶

Figure 7: Canada Gazette Part I, Vol. 155, No. 25 - page 2947

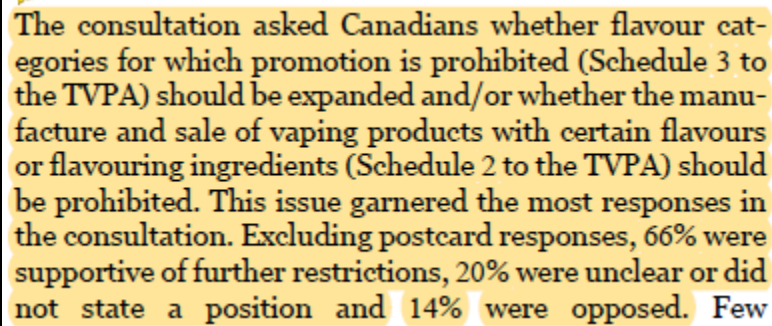
By classifying only "unique responses," Health Canada has disenfranchised over 23,000 Canadian voices.

It might have been a mass-produced postcard, but it was a Canadian who agreed with its messaging. It was a Canadian who entered their vaping statistics, and it was a Canadian hand that wrote their name on it, identifying that this was their opinion. Those hand-printed additions by their inclusion made every single postcard "unique."

Similarly, the template e-mails were authorized by Canadian citizens who provided their legal names, postal codes, and personal e-mail addresses to send that e-mail to Health Canada. They had access to edit the body of that submission in any way they saw fit. Some did, others did not.

This paragraph says that those Canadians, and their submissions, are not important, are not valued, and are not cared for by Health Canada.

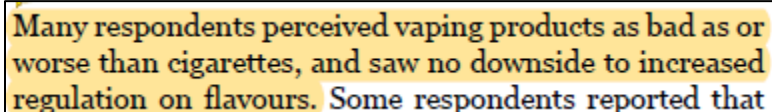
Health Canada denied those Canadians their voice. Deliberately and with the intent to justify predetermined action that would be contrary to their interests.



The consultation asked Canadians whether flavour categories for which promotion is prohibited (Schedule 3 to the TVPA) should be expanded and/or whether the manufacture and sale of vaping products with certain flavours or flavouring ingredients (Schedule 2 to the TVPA) should be prohibited. This issue garnered the most responses in the consultation. Excluding postcard responses, 66% were supportive of further restrictions, 20% were unclear or did not state a position and 14% were opposed. Few

Figure 8: Canada Gazette Part I, Vol. 155, No. 25 - page 2948

Had Health Canada not disenfranchised more than 23,000 Canadians. The percentage of those supportive of further restrictions would not have been 66%. It would have been less than 1%.



Many respondents perceived vaping products as bad as or worse than cigarettes, and saw no downside to increased regulation on flavours. Some respondents reported that

Figure 9: Canada Gazette Part I, Vol. 155, No. 25 - page 2948

The perception of vaping products as being "as bad or worse than cigarettes" is demonstrably incorrect and academically unsupported. Had Health Canada not ignored 23000 responses from the consultation process, this statement would have no justification for inclusion.

cigarettes. Some people who vape reported that flavours helped them quit smoking and help them maintain abstinence from tobacco. Many people shared that their sense of

Figure 10: Canada Gazette Part I, Vol. 155, No. 25 - page 2948

84% of 23,000 Canadians who put their personal data on a postcard that said "Flavours helped me stop smoking" identified that they used flavours other than tobacco, mint, menthol, or unflavoured vaping products to stop smoking.

"Some people" is deceptive in the most polite terms.

"Health Canada's response to key stakeholder concerns" Canada Gazette Part I, Vol. 155, No. 25 - Page 2950

Illicit market

Some stakeholders, including some members of the industry, said further flavour restrictions would lead to an increase in black-market sales of vaping products with prohibited flavours.

Response: Health Canada recognizes that an illicit vaping products market could be a concern. However, the proposal leaves room for the continued availability of some flavour options that should help deter people from procuring non-compliant vaping products (illicit market). The Government of Canada will continue to monitor market trends and take appropriate actions where necessary.

Figure 11: Canada Gazette Part I, Vol. 155, No. 25 - page 2951

The proposal eliminates all flavours except tobacco, mint, menthol, and unflavoured vaping liquids.

Health Canada has proposed severe restrictions to the number of compounds permitted to make those profiles and further proposed a "sensory attributes" test, which means that if the industry should come up with something that comes across as "pleasant," it will very likely be prohibited.

The Canadian vaping industry only gained legitimacy in 2018. The knowledge, access channels, and mindset that fostered the grey market industry before legitimacy still very much exist within the public consciousness. Health Canada underestimates how large a black market will be, how quickly it will form, and the harms that will likely result.

84% of Canadians who submitted a consultation response indicated that they preferred flavour profiles outside of what Health Canada proposes. Suppose consumers do not find what remains on the market to be palatable, and the product they like is readily available through illicit channels. In that case, we can expect that a significant portion of them will use those channels.

So will the youth.

"Regulatory Analysis – Benefits and Costs" *Canada Gazette Part I, Vol. 155, No. 25 - Page 2956*

ure to second-hand smoke. The break-even analysis indicates that a decrease in the rate of vaping initiation of 2.55% relative to the baseline initiation rate, assuming a 10% decrease in the annual rate at which people who smoke switch to vaping, would be sufficient to produce public health benefits equivalent to or greater than the estimated monetized costs.

Figure 12: Canada Gazette Part I, Vol. 155, No. 25 - page 2956

Due to the disparate sizes of the population groups and the expected health outcomes of the respective users, these percentage values can be a bit misleading as indicators.

Further, these measures are not nuanced enough to isolate "which" adult initiators will be impacted regarding "intent" to quit smoking, any more than they can identify which youth initiators we should allow because otherwise, they would smoke instead. There are smokers, there are former smokers, and there are never smokers in each age group.

CTNS 2020 indicates that youth (15-19) past-30-day vaping rates are roughly 14%. In the 20-24 age bracket, 13% of young adults (legally entitled to access nicotine products) had vaped in the past 30 days, and the 25+ "Adult" group has a 3% past 30-day usage rate.

However, the 3% of adult users dwarfs the 14% of youth users, 854,600 to 291,300 (or roughly 3:1). Three percent of adult users are more extensive than both the youth and young adults combined at 854,600 to 600,400 (1.4:1). If we use an "age of access" delineation, the ratio of legal users vs. illicit users shifts to 1,163,700 to 291,300 or 4:1.

It is also important to note that of the three groups, the adult category also has the highest smoking rate and forms the most considerable portion of Canada's smoking population, at the

most significant risk of encountering smoking-related morbidity and mortality. This group also has the lowest percentage of vapers who classify as "Never Smokers."

Precisely, to determine what 2.55% and 10% mean in terms of human beings, we will need to look at a common source of data that looks at both groups. CSTADS does not track adult usage and uptake. CTNS 2020 has not been entirely made public. So we will have to compare CTADS 2017 to its replacement survey CTNS 2019 and cross-reference both years to the population statistics available from StatsCan.

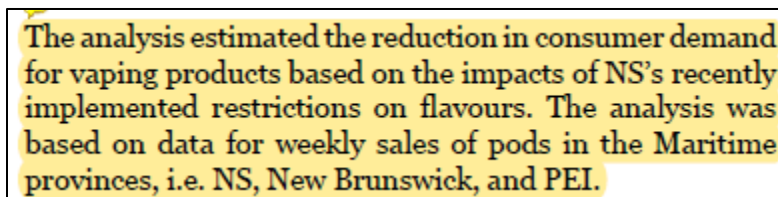
Using these values, we find that annualized initiation rates for youth between 2017 and 2019 were 93,794 a year. Young Adults - 116526/annum, and Adults 25 and over - 90830.

Applying the percentages Health Canada has provided; Suppose we reduce youth initiation by 2.55%. In that case, we will have 2,391 fewer youth start vaping next year, and we are willing to accept 20,736 fewer adult initiators who may (and are more likely to) be using the product as either an escape from or alternative to smoking.

Even if we shift the delineation outside of legal access and amalgamate the youth and young adults, a 2.55% reduction in initiation equates to an impact of 5,362 fewer youth and young adults starting to vape, at the cost of 9083 potentially (likely) smoking adults.

This is without using the 2020 CTNS data that showed youth and young adults' past 30-day usage rates dropped by 27,995 and 67,183, respectively. In both cases, initiation rates did not keep up with attrition rates.

See Appendix for figures.



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.

Figure 13: Canada Gazette Part I, Vol. 155, No. 25 - page 2962

By focusing on pod sales, the analysis is weighted towards the Gas/Convenience store distribution model.

The NS case and review of the literature provide useful insights into the potential effect of flavour restrictions on consumer demand for vaping products. NS experienced a 14.3% reduction in pod sales following implementation of its “tobacco flavour-only” requirement (mint/menthol-flavoured vaping products are prohibited in NS). Hence, it is expected the decline in consumer demand for vaping products as a result of this proposal would be lower than in NS, i.e. at 10%. In light of the greater likelihood that industry would stop producing some tobacco, and mint/menthol variants, it was concluded that using the reduction in consumer demand for vaping products in NS could be better suited for the upper bound estimate. Thus, 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.

Figure 14: Canada Gazette Part I, Vol. 155, No. 25 - page 2962

Health Canada is not reflecting the full impact of Nova Scotia flavour restrictions.

Impact on vaping and smoking rates will not be assessable until the next cycle of the CTNS survey due to the timing of the implementation of the regulations. While pod sales data shows a reduction of 14.3%, it is only reflective of the gas and convenience store business model.

What was not included from the gas and convenience model was the reported increase in cigarette sales during the same period. (Atlantic Convenience Stores Association - <https://www.halifaxtoday.ca/local-news/cigarette-sales-in-nova-scotia-increasing-atlantic-convenience-stores-association-2792516>)

In the independent vape retail market (vape shops), 50% closed immediately following the regulation coming into force. Those remaining are struggling to stay in business pending outcomes of legal challenges and appeals.

Nor has Health Canada discussed black-market implications of the nicotine and flavour restrictions in Nova Scotia.

About 46% of current vapers (past-30-day use) aged 20 years and older are dual users (i.e. individuals who vape and smoke cigarettes).⁸¹ The total profit loss to the

Figure 15: Canada Gazette Part I, Vol. 155, No. 25 - page 2968

In Health Canada's repeated (including in this document) off-hand dismissal of dual users as "lost causes," the regulatory body fails to meet smokers where they are.

While Health Canada's position is that (<https://www.canada.ca/en/health-canada/services/smoking-tobacco/vaping/smokers.html>):

"completely replacing cigarette smoking with vaping will reduce your exposure to harmful chemicals."

"There are short-term general health improvements if you completely switch from smoking cigarettes to vaping products."

The truth is more nuanced. EVERY cigarette not smoked is avoiding the harmful chemicals that THAT cigarette would deliver. Of course, the maximum benefit is reached by completely transitioning, but like many things in life, the journey for some will be short and for others longer.

Instead of encouraging dual users to continue reducing cigarette consumption and transitioning entirely to a harm-reduced delivery system, Health Canada creates messaging that leads adult dual users to perceive that everything outside of complete transition is a failure. Once they have *failed*, being smokers, their experience tells them to forsake whatever quit (transition) attempt they are making and return to full-time smoking.

Health Canada is failing Canadian citizens in this manner of behaviour.

vape and smoke cigarettes).⁸¹ 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.

Figure 16: Canada Gazette Part I, Vol. 155, No. 25 - page 2968

This is the first reference in the Cost-Benefit Analysis that indicates that Health Canada is well aware that cigarette consumption will increase due to these regulations.

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.

Figure 17: Canada Gazette Part I, Vol. 155, No. 25 - page 2968

This is the second reference in the Cost-Benefit Analysis that indicates Health Canada is well aware that cigarette consumption will increase due to these regulations.

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 harm-

Figure 18: Canada Gazette Part I, Vol. 155, No. 25 - page 2969

This is the first reference in the Cost-Benefit Analysis that indicates that Health Canada is well aware that these regulations will support continued smoking behaviour in an at-risk population.

ers. These persons would continue to be exposed to harmful chemicals from the long-term use of tobacco products.

Figure 19: Canada Gazette Part I, Vol. 155, No. 25 - page 2969

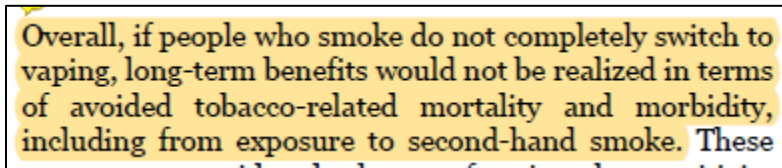
This is the first reference in the Cost-Benefit Analysis that indicates Health Canada anticipates and accepts that harm will occur to an at-risk group due to these regulations.

It is also anticipated that certain dual users would relapse to smoking only as a result of the proposal. However, benefits of vaping by people who smoke are only accrued if they completely switch to vaping.

Figure 20: Canada Gazette Part I, Vol. 155, No. 25 - page 2969

This is the third reference in the Cost-Benefit Analysis that indicates Health Canada is well aware that cigarette consumption will increase due to these regulations.

This is also the first reference in the Cost-Benefit Analysis that indicates Health Canada is willing to purposefully abandon dual-users (many of whom are trying to progress to smoke-free status) to pursue these regulations.

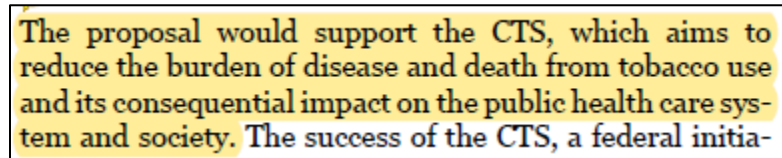


Overall, if people who smoke do not completely switch to vaping, long-term benefits would not be realized in terms of avoided tobacco-related mortality and morbidity, including from exposure to second-hand smoke. These

Figure 21: Canada Gazette Part I, Vol. 155, No. 25 - page 2969

This is the second reference in the Cost-Benefit Analysis that indicates Health Canada anticipates and accepts that harm will occur to an at-risk group due to these regulations.

This is also the second reference in the Cost-Benefit Analysis indicating purposeful abandonment of dual users to pursue these regulations.



The proposal would support the CTS, which aims to reduce the burden of disease and death from tobacco use and its consequential impact on the public health care system and society. The success of the CTS, a federal initia-

Figure 22: Canada Gazette Part I, Vol. 155, No. 25 - page 2970

Given the three references Health Canada made previously regarding increased cigarette consumption, two references to anticipated and accepted harm as a result of the regulations, and two statements that Health Canada stands ready to willingly abandon an at-risk group in a precarious position in pursuit of these regulations:

The statement that this proposal supports CTS as described here is patently erroneous.

The proposal is expected to primarily benefit youth by contributing to the reduction in the number of young persons who experiment with vaping products, which can lead to exposure to and dependence on nicotine and increased risk of tobacco use. Long-term benefits would

Figure 23: Canada Gazette Part I, Vol. 155, No. 25 - page 2970

CTNS 2020 results published in "The Daily" on the Government of Canada website indicate that the physical number of youth who have vaped in the past 30 days (291,300) has dropped by roughly 8.8% from CTNS 2019 (319,295).

In the young adult category, past-30-day vaping behaviour dropped by 18% (376,283 in 2019 vs. 309,100 in 2020)

This exceeds the target reduction rate for youth initiation of 2.55%. Without the nicotine restriction regulations that came into force on July 8th, 2021, and well ahead of this proposal

The only category that increased in numbers over the 2019-2020 reporting periods was adult (25+) users. The vast majority identify as either current or former smokers (782,908 in 2019 vs. 854,600 in 2020).

Past 30-day use does not indicate dependence - daily use does.

Specifically: All current assessment tools that measure dependence start with the question, "How long after you wake up (forced abstinence) do you use a nicotine delivery device (smoke)?" "Next Saturday at Tim's house party." is not one of the selectable answers.

As for the increased risk of tobacco use: Again, I respond that despite the gateway theory being consistently waved as a rallying flag since vaping became an item public concern, to date, there has been no accurately recorded, or reported, increase in youth smoking in Canada.

Unless CTNS 2020 data on full release shows an increase in youth current smoker status from 5.1% to 8.2%, it is relatively safe to say that the roughly 28,000 youth who no longer vape did not whip down to the convenience store this week to buy a pack of cigarettes.

See Appendix.

There is currently no data on the long-term health consequences of vaping due to the relatively recent use of these products in Canada. For example, tobacco-related mor-

Figure 24: Canada Gazette Part I, Vol. 155, No. 25 - page 2970

If there is no data on long-term health consequences of vaping, it is because Health Canada did not investigate or follow long-term users.

In 2009, Health Canada issued a notice regarding the availability and authorization status of vaping products within the country. This was not because "a handful" of Canadians were vaping. Quite obviously, the department was aware of the increase in vaping behaviour in the population.

That was ten years ago; If Health Canada does not know what the 10-year outcomes are, then it is because the department decided not to investigate.

We also do not need long-term data to determine "relative" harms compared to smoking (for which we have decades of research). Health Canada knows what causes damage to smokers and what bio-markers to observe. We can readily identify the compounds that cause the morbidity and mortality of smoking. All parties know that nicotine in itself is one of the least harmful substances delivered by a cigarette.

Yes, there may be some negative consequences from the long-term use of vaping products. However, everybody at the table, for and against, including Health Canada, when pinned to a wall, will admit vaping is less harmful than smoking. Science tells us this.

The Royal College of Physicians in London also tells us this. They, along with Public Health England, have been publishing that the long-term harms associated with vaping are "... unlikely to exceed 5% of those associated with smoked tobacco products, and may well be substantially lower than this figure." They have been repeating it for the better part of a decade now.

Health Canada can continue to figuratively jam its fingers in its ears while shouting "La La La, I can't hear you" for as long as it wants. It will not change published data. It won't erase science.

Those bodies continue to review and update their evidence and publish that figure. Annually.

of smokers aged 27 and older. As tobacco-related illnesses generally take several years to manifest, a latency period of 10 years between smoking initiation and the onset of nonfatal health effects is assumed. Available data indi-

Figure 25: Canada Gazette Part I, Vol. 155, No. 25 - page 2972

I only highlight this in service to my next item of concern.

2006. To estimate the potential adverse health effects of vaping, the model assumes the mortality and morbidity risks associated with vaping are 20% of the mortality and morbidity impacts of cigarettes. This assumption was developed in consultation with members of an expert panel composed of five academics in tobacco control who

Figure 26: Canada Gazette Part I, Vol. 155, No. 25 - page 2972

Only two publicly available documents have published a numerical value of 20% for relative morbidity and mortality statistics between vaping products and smoking. The first was the RIAS for the proposed nicotine concentration restrictions published in the Canada Gazette Vol. 1 in December 2020. The second is the RIAS for the currently proposed regulations on flavours I am responding to here.

20% morbidity and mortality is orders of magnitude greater than "unlikely to exceed 5% and may well be significantly lower than that value".

That's a pretty significant shift, bordering on monumental.

Now admittedly, we are probably a few years and more than a few converted smokers away from the point where we can expect to see Health Canada's projected 9,400 deaths a year from vaping-related causes. Given the current mandate of regulating vaping out of existence, we will likely never see a complete conversion from a smoking mortality rate to this speculative vaping mortality rate. Still, morbidity, that's a different story.

Morbidity precedes mortality and overshadows it in a breadth of scope. We have determined that Health Canada has been aware of vaping for ten years. In the previous paragraph, Health Canada has stated that it takes ten years for smoking-related morbidity to surface. Indeed we should be seeing some statistically significant portion of vapers developing non-fatal health effects somewhere.

Particularly in former smokers, given their systems have been previously abused.

Where is this emerging pool of morbidly ill vapers? To be clear, I am not referring to acute toxicity issues related to black market THC products. Even the Centers for Disease Control has had to bow its head and step back, admitting EVALI was not a nicotine vaping issue. Where is the emphysema, the COPD, the cancer rates, the heart attacks attributed to vaping that happened AFTER people started vaping? (See Glantz, Bhatta et al. retraction - <https://retractionwatch.com/2020/02/18/journal-retracts-hotly-contested-paper-on-vaping-and-heart-attacks/>)

The significant difference between Health Canada's assumption of relative harms and PHE and RCP led me to investigate the footnote supporting that assumption. Which we shall deal with next.

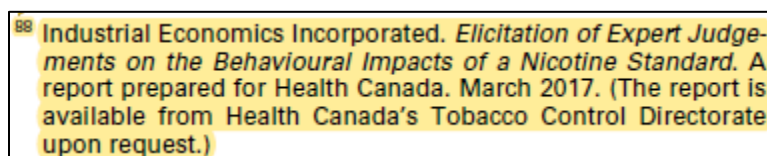


Figure 27: Canada Gazette Part I, Vol. 155, No. 25 - page 2973

At first glance, this footnote would lead a hurried reader to believe there was an actual academic document that supported the statement that vaping carries 20% of the morbidity and mortality risk of smoking.

I requested the referenced document in the footnote from the Tobacco Control Directorate on December 20th, 2020, for the VPNCR regulatory RIAS. I received the record the following day via e-mail.

This document does not assess comparative morbidity and mortality rates for vaping and smoking. This document has nothing to do with limiting flavours in vaping products, much like it had nothing to do with restricting nicotine in vaping products in December 2020.

"This assumption was developed in consultation with members of an expert panel composed of five academics in tobacco control who were previously consulted on exploratory work related to a nicotine standard."

The paper referenced in the footnote did identify five academics who formed an expert panel for that particular paper (Nicotine Standards for Very Low Nicotine Cigarettes - VLNCs):

Dr. David Abrams
Dr. Neal Benowitz
Dr. Geoffrey T. Fong
Dr. Dorothy Hatsukami
Dr. Raymond Niaura

I e-mailed those five professors in 2020 regarding the Vaping Products Nicotine Concentration Regulations RIAS reference and received no response.

After reviewing this RIAS, I e-mailed them again and received a response from one:

"Sorry, I do not have the data you are looking for."

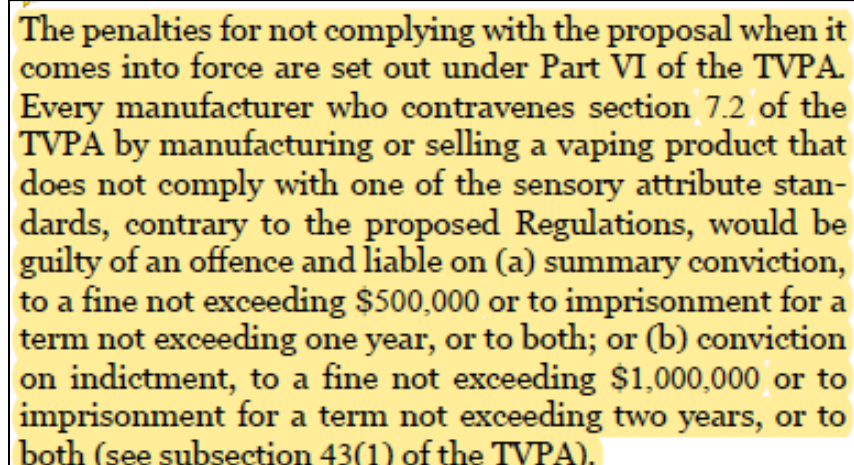
However, I am not the only person requesting feedback from the five academics - who consulted on the unrelated paper – used to infer credibility - to an assumption of a 20% relative morbidity and mortality for vaping vs. smoking.

One such person has to date, received replies from 3 of them.

I am confident that there was no academic study or even exercise behind this assumption.

I find Health Canada's round-a-bout way of feigning validation and reference for this value disingenuous and obfuscatory in polite terms.

"Implementation, compliance and enforcement, and service standards" *Canada Gazette*
Part I, Vol. 155, No. 25 - Page 2985



The penalties for not complying with the proposal when it comes into force are set out under Part VI of the TVPA. Every manufacturer who contravenes section 7.2 of the TVPA by manufacturing or selling a vaping product that does not comply with one of the sensory attribute standards, contrary to the proposed Regulations, would be guilty of an offence and liable on (a) summary conviction, to a fine not exceeding \$500,000 or to imprisonment for a term not exceeding one year, or to both; or (b) conviction on indictment, to a fine not exceeding \$1,000,000 or to imprisonment for a term not exceeding two years, or to both (see subsection 43(1) of the TVPA).

Figure 28: Canada Gazette Part I, Vol. 155, No. 25 - page 2986

Every manufacturer who contravenes section 7.21 of the TVPA by manufacturing a vaping product listed under column 2 with a prohibited ingredient listed under column 1 of Schedule 2 would be guilty of an offence. Every manufacturer who sells a vaping product listed under column 2 that contains an ingredient listed under column 1 of Schedule 2 would be guilty of an offence. The manufacturer found guilty would be liable on summary conviction to a fine not exceeding \$300,000 or to imprisonment for a term not exceeding two years, or to both (see section 43.1 of the TVPA).

Figure 29: Canada Gazette Part I, Vol. 155, No. 25 - page 2986

Every person who contravenes section 30.47 of the TVPA by promoting a vaping product set out in column 2 of Schedule 2, including by means of the packaging, through an indication or illustration that could cause a person to believe that the product has an ingredient set out in column 1, would be guilty of an offence. Every person who contravenes section 30.47 of the TVPA by selling a vaping product set out in column 2 of Schedule 2, if an indication or illustration referred to in the previous sentence is displayed on the product or its package, would be guilty of an offence. The offender would be liable on summary conviction to a fine not exceeding \$500,000 or to imprisonment for a term not exceeding two years, or to both (see section 47 of the TVPA).

Figure 30: Canada Gazette Part I, Vol. 155, No. 25 - page 2986

Every person who contravenes section 30.48 of the TVPA by promoting a vaping product set out in column 2 of Schedule 3, including by means of the packaging, through an indication or illustration that could cause a person to believe that the product has a flavour other than tobacco or mint/menthol would be guilty of an offence. Every person who contravenes section 30.48 of the TVPA by selling a vaping product set out in column 2 of Schedule 3, if an indication or illustration referred to in the previous sentence is displayed on the product or its package, would be guilty of an offence. The offender would be liable on summary conviction to a fine not exceeding \$500,000 or to

Figure 31: Canada Gazette Part I, Vol. 155, No. 25 - page 2986

imprisonment for a term not exceeding two years, or to both (see section 47 of the TVPA).

Figure 32: Canada Gazette Part I, Vol. 155, No. 25 - page 2987

The financial repercussions for selling an appropriately flavoured product to a minor (first offence) are at a *maximum*, 1% of those that a retailer or manufacturer could incur in creating or selling an inappropriately flavoured product to an adult consumer - with no incarceration time.

Sales to young persons, promotions

45 Every person who contravenes subsection 8(1) or 9(1) or section 11 or 12, or every retailer who contravenes section 29 or 30.5 or subsection 30.6(1) or (2), is guilty of an offence and liable on summary conviction

- (a) for a first offence, to a fine not exceeding \$3,000; and
- (b) for a subsequent offence, to a fine not exceeding \$50,000.

1997, c. 13, s. 45; 2018, c. 9, s. 60.

Figure 33: Tobacco and Vapor Products Act, Part IV, Offences and Punishment. <https://laws-lois.justice.gc.ca/eng/acts/T-11.5/page-9.html#h-449918>

Comments on the proposed regulation.

Things that I am confident the proposed regulations will accomplish

1. Health Canada will have given the *appearance* of "doing something" about youth vaping, if at the cost of enabling and in some cases increasing smoking behaviour and smoking-related morbidity and mortality, as Health Canada has itself stated in this document.
2. Where the intent is to significantly curtail the availability and appeal of flavoured vaping products in the legitimate market, the proposed regulations will be very effective. Law-abiding retailers will only offer three categories of flavours manufactured from a minimal list of available compounds. The sensory attributes standard will ensure that if manufacturers stumble upon a palatable one, it too can be prohibited.
3. The regulations certainly will impact initiation and usage rates, particularly among adult dual users and adult smokers who may wish to try vaping as a harm reduction or cessation tool and find they do not like what is available on the legal market. However, it will *only* impact those who, by nature, are averse to the illegitimate market.

4. Some adult users (those who find the new tobacco flavours tolerable, those who find "mint" without sweetener tolerable, and those who currently use either menthol or unflavoured vaping products) will adapt to the new regime.
5. Adulteration and DIY of vaping products by consumers (both legal age and youth) will increase. Most consumers are well aware that vaping products generally use food-grade flavouring compounds from flavour-houses. These consumers are also aware that these consumer-grade flavouring products are readily available at retail outlets ranging from specialty baking and candy-making shops to grocery stores and bulk items retailers.
6. A robust illicit market will flourish to meet the consumer demand of over 80% of 1.1 million-plus adult users. Health Canada can indeed regulate *appeal* out of the legitimate market, however as with all forms of prohibition, partial or complete, Health Canada cannot regulate the *demand* out of the consumer base. That consumer demand will be satiated; if not by the legitimate market, then by the illegitimate market. History shows this is the case, and it's a significant part of why Health Canada legitimized the Canadian industry in 2018.
7. Incidents will occur. Acute and non-acute toxicity reports will come in, and they will have multiple root causes. Adulteration of products with food-grade flavourings that are oil-based or otherwise incompatible for inhalation. Products made in unsanitary locations and conditions. Products made ad-hoc with no consistent, standardized manufacturing processes (GMP, ISO). In some cases, these incidents will be accidental, consumers attempting to meet their needs and not understanding the risks. In other cases, they will be negligence or even deliberate actions made by illicit suppliers looking to meet consumer demand most efficiently and profitably.
8. Existing standards will cease to be effective. The market that steps up to meet consumer demand will not be bothered by such trivialities as labelling standards, promotions restrictions on flavouring names, child resistance certifications, or nicotine content restrictions.

Things that I am confident the proposed regulations will not accomplish.

1. This regulation will do little in regards to meeting its stated goal. It will not meaningfully curb youth access to flavoured vaping products. It will not meaningfully impact initiation and uptake rates.
 - a. The internet exists – this will not change

- b. The black market exists – It will joyously bloat in response to these regulations. As mentioned in the last point of the previous section: it will not abide by current conventions either, including age gating.
2. This regulation will not support the Canadian Tobacco Strategy (CTS) goal of reaching a 5% or lower prevalence of smoking in the population by 2035.

Summary Comments.

1. I selected 32 points out of this proposal for a response. These were not the only points with which I found disagreement. The RIAS is riddled with cherry-picked data points, unfounded assumptions, and very selectively (and in more than one case - deceptively) worded arguments of support and justification. My first pass resulted in more highlighted paragraphs than those left unmolested. I could easily have provided 50 pages or more of comments. I have illustrated my point well enough.
2. I cannot fully express how disturbed I was as I read the highlighted sections on pages 2947 and 2948 (Figures 7 thru 10), and the theme I saw repeated more subtly throughout the publication. As a former smoker and a user of vaping products, I am accustomed to having my opinions downplayed and even ignored, despite the evidence I present and the validity of my arguments. To see 23000 accepted submissions *discarded* with such *blatant contempt* and *arrogant manner* generated such *disgust* and *outrage* that I am angry now reflecting on it. These acts of *bureaucratic disregard*, *autocratic dismissal*, and *open disrespect* towards the populace that Health Canada is supposed to serve and maintain accountability to; are actions I expect to read about in newspapers, perpetrated by despotic governments, in authoritarian regimes. I should *never* be seeing such *nonsense* in an official publication from the Government of Canada.
3. I find the proposal arrogantly deceptive and manipulative. I find the foundational arguments and assumptions to be misleading, poorly formulated, and inadequately supported.
4. I am not in support of these regulations. They are not fit for purpose; they will not achieve their intended goal. They will cause harm.

Final Word

Triage

/trē'äZH/

noun

The assignment of degrees of urgency to wounds or illnesses to decide the order of treatment of a large number of patients or casualties.

The process of determining the most important people or things from amongst a large number that require attention.

More than just a few years ago, when I was younger and more fit for purpose, I was trained and occasionally was called on to apply this principle in the field.

If I were to come across an accident this afternoon, and after making sure "I" was safe, I saw:

- A baby in a car seat, crying.
- A teen is sitting on the curb, yelling and cradling a broken arm.
- An adult whom I know, and don't particularly approve of, slumped over the steering wheel of a car, not moving.

I'd address the adult first.

My emotional drive to respond to the baby first and my moral judgment of the adult have no place in assessing their peril or reacting to it.

Appendix

Numerical data reflective of percentage values often used in discussing population-level vaping statistics

	StatsCan	% past 30 day	Population past 30 day	Identify as current smokers	Identify as Former Smokers	Identify as Never Smokers
2017 Population 15-19 (CTADS)	2,090,598	0.063	131708	No Data Available	No Data Available	No Data Available
2019 Population 15-19 (CTNS)	2,114,539	0.151	319295	61,943	*	236,598
2020 Population 15-19 (The Daily)	2,100,865	0.144	291300	Data Unreleased	Data Unreleased	Data Unreleased
2017 Population 20-24 (CTADS)	2,387,191	0.06	143231	No Data Available	No Data Available	No Data Available
2019 Population 20-24 (CTNS)	2,475,546	0.152	376283	142,611	79,019	154,652
2020 Population 20-24 (The Daily)	2,482,802	0.13	309100	Data Unreleased	Data Unreleased	Data Unreleased
2017 Population 25+ (CTADS)	26,141,160	0.023	601247	No Data Available	No Data Available	No Data Available
2019 Population 25+ (CTNS)	26,996,816	0.029	782908	382,842	288,110	*
2020 Population 25+ (The Daily)	27,382,924	0.032	854600	Data Unreleased	Data Unreleased	Data Unreleased
Initiation rate by age group 2017-2019		2 yr	Annualized		2019-2020	% change
15-19		187587.715	93793.8575		-27,995	-8.75%
20-24		233051.532	116525.766		-67,183	-17.85%
25+		181660.984	90830.492		71,692	9.16%
Age of access delineation.						
Target reduction in youth initiation 2.55%		2391				
Acceptable losses 20-24 initiation 10%		11653				
Acceptable losses 25+ initiation 10%		9083				
Youth - Young Adult vs. "Adult" delineation.						
Target reduction in youth initiation 2.55%		2391				
Target reduction in Y.A. initiation 2.55%		2971				
Acceptable losses 25+ initiation 10%		9083				

Source Data

Population values: <https://www150.statcan.gc.ca/t1/tbl1/en/tv.action?pid=1710000501>.

CTADS 2017: <https://www.canada.ca/en/health-canada/services/canadian-tobacco-alcohol-drugs-survey/2017-summary/2017-detailed-tables.html#t8>

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

The Daily: <https://www150.statcan.gc.ca/n1/daily-quotidien/210317/t001b-eng.htm>