Comments from
Physicians for a Smoke-Free Canada on :

Canada Gazette, Part I, Volume 155, Number 25: Order Amending Schedules 2 and 3 to the Tobacco and Vaping Products Act (Flavours)

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Canada Gazette, Part I, Volume 155, Number 25: Standards for Vaping Products' Sensory Attributes Regulations

August 2021

Introduction

In general, Physicians for a Smoke-Free Canada supports the proposed changes to the schedules and the proposed sensory attributes regulations.

Some parts of the proposals are particularly commendable, while others would benefit from changes. Part 1 of these comments focuses on the proposed Order and Regulations and offers suggestions for improvement of the proposed Order and the related Regulatory Impact Assessment.

PSC continues to view the context in which these draft regulations are offered as structurally flawed. The foundational law (the *Tobacco and Vaping Products Act*, TVPA) is based on the premise that a competitive and open market for alternative nicotine products serves the public health interest and that governments should focus on demand reduction when seeking to reduce tobacco use. In our view, this is not the optimal basis for public health regulation of a consumer market involving addictive and dangerous products. Part 2 of these comments addresses these structural concerns and offers recommendations for steps that could be taken in the coming months.

Part 1: Comments related to specific issues in the proposed Order and Standards

1. Especially commendable features of the draft amendments to Schedules 2 and 3

- The relationship between flavours and their chemical components was thoroughly researched and the proposed regulations appropriately account for this relationship.
- The three-part approach to flavour and sensory regulation is ground-breaking and worthy of praise and retention.
- The related cost-benefit analysis and related break-even analysis, while employing some questionable assumptions, contain new information that will help improve understanding of vaping.

2. Elements of the draft order where changes are recommended

a) Acids

The current draft order would ban some organic acids, but not others. Organic acids are used to produce nicotine salts that greatly increase nicotine yields, nicotine inhalation and nicotine bioavailability. Because nicotine salts make vaping liquids easier to inhale deeply and in larger quantities, they contribute both to the

attractiveness/palatability and addictiveness of vaping products. Banning all acids will help protect young people and non-smokers this additional risk of addiction. Banning some, but not all, organic acids will remove some products from the market, but not all.

The proposed order will ban substances which "have flavouring properties or that enhance flavour, including: ingredients identified as flavouring agents by the Joint FAO/WHO Expert Committee on Food Additives in the Committee's evaluations, as published from time to time in the WHO Technical Report Series; ingredients identified as generally recognized as safe (GRAS) flavouring substances by the Flavor and Extract Manufacturers Association (FEMA) Expert Panel in its lists of GRAS substances referred to as "GRAS 3" to "GRAS 29" and subsequent lists of GRAS substances, as published from time to time, if any." Excluded from this prohibition are "benzoic acid (CAS 65-85-0); citric acid (CAS 77-92-9), sorbic acid (CAS 110-44-1)" and 3 other substances.

Non-excluded acids which are used in the production of nicotine salts, [1] and which are included in the FAO/WHO and FEMA/GRAS lists include, perhaps among others:

- Lactic acid
- Levulinic acid
- Salicylic acid,
- Malic acid
- Tartaric acid.

On the basis of current formulations, the impact of the exclusion for 3 acids will be to allow JUUL (made with benzoic acid) to market nicotine salts but to prohibit VUSE (made with lactic acid) from being sold. This partial exclusion will encourage manufacturers to seek out and use acids which are not on the restricted list.

Nicotine salts emerged as a technology to permit high levels of nicotine to be palatable for inhalation. Canada recently adopted a maximum concentration level for nicotine of 20 mg/ml nicotine. The rationale for this change was to reduce the appeal of vaping products to youth. The measurement standard used in these regulations has permitted suppliers to re-categorize nicotine salt liquids that previously sold as 34 mg/ml and newly label them as under 20 mg/ml.[2] Prohibiting the use of all acids which produce nicotine salt would protect young people from this unanticipated circumvention of the new nicotine standard.

Recommendation 1:
Modify Schedule 3 to prohibit all acids from use as ingredients for vaping products.

b) Mint and Menthol

In the RIAS that accompanies the proposed order, Health Canada claims that allowing menthol flavours will provide "balance". We submit that this argument is poorly justified and contrary to the available evidence on menthol and mint flavours.

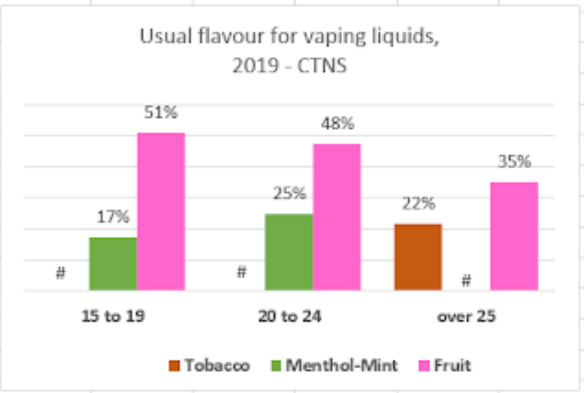
There are several reasons that menthol should be included in the list of prohibited ingredients:

i. Menthol and mint additives make vaping products more attractive to young people and are an inducement for young people to use vaping products

Over the past few years, Health Canada has conducted a number of consumer studies on vaping behaviour in Canada. These establish that menthol is a flavour which induces young people to use vaping products.

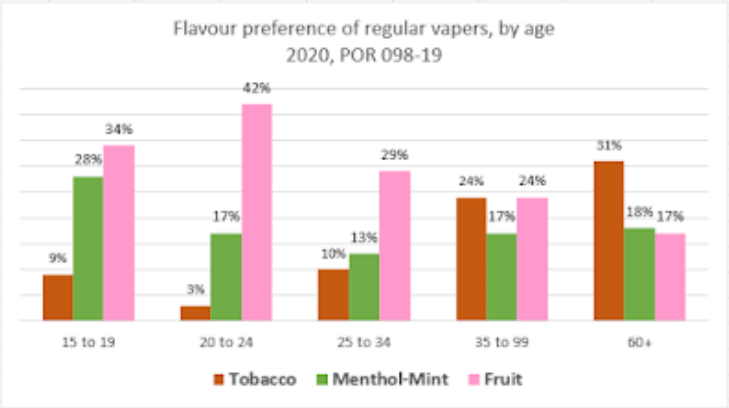
The Canadian Tobacco and Nicotine Survey, 2019[3].

The 2019 Canadian Tobacco and Nicotine Survey found that fruit and menthol were the first and second choice flavours for young people. So few young people said they usually smoked tobacco flavour that the results were deemed "unreportable" (shown in the figure as '#'). The selection of menthol by those over 25 years of age was similarly too small to report.



The Environics Vaper Panel (POR 098-19)

This an on-line return-to-sample survey was commissioned by Health Canada. In the spring of 2020, the flavour preferences of regular vapers (those who had vaped at least once a week in the past month) were revisited. Fruit and menthol were found to be the favourite flavours of young people.



ii. Menthol and mint increase the addictiveness and attractiveness of vaping liquids.

With the benefit of mandatory European ingredient reporting, Dutch researchers[4] were able to identify which vaping flavours contained chemical menthol and also which additives were included in menthol-flavoured vaping products. The researchers conclude that these (and other) flavour ingredients are found to increase the addictiveness of e-cigarettes because they:

> *"enhance the rewarding and reinforcing effects of nicotine in e-cigarettes in young adult smokers. [60, 61] For example, menthol and the green apple flavoring, farnesene, facilitate nicotine dependence through upregulation of nACh receptors in the brain [62,63]. Furthermore, flavorings reduce the nicotine metabolism (e.g., menthol, cinnamaldehyde and benzaldehyde) [64,65] and are known to facilitate inhalation and nicotine uptake due to their cooling and bronchodilating effects (e.g., menthol, theobromine and eucalyptol) [62.] In addition, flavorings such as vanillin, ethyl vanillin, and coumarin inhibit monoamine oxidase enzymes, which results in a delayed degradation of dopamine in the brain, an extended feeling of pleasure, and an increase in reinforcing behavior 66,67. ....In summary, flavors stimulate palatability as well as reward from nicotine in e-cigarettes, and, hence, contribute to nicotine dependence not only through their physical properties (e.g., cooling) but also through their history of associative learning."*

Health Canada has previously acknowledged that menthol increases the attractiveness of inhalation for young people and plays a role in addiction. When publishing its 2017 regulation to ban menthol in cigarettes, it reported:

> *"Menthol in tobacco products has numerous pharmacological effects, one of them being to mask the irritating effect of tobacco smoke, making it easier to inhale, which facilitates experimentation among*

novice users. Promoting experimentation among youth increases the potential for continued tobacco use that leads to addiction and an increased risk of tobacco-related diseases."[5]

iii. Health Canada officials previously accepted the need to ban menthol and mint flavouring

In August 2020, as part of its cost benefit analysis research, Health Canada was consulting with international regulators about a potential ban on vaping additives. At that time, four options were identified as being under consideration, each of which proposed to ban all flavours including menthol.[6] Four months later, a similar consultation exercise was taken with vaping suppliers, but at this point the options included an exemption for menthol. Given the regulatory approval process within the federal government, it would appear that the advice to ban menthol was subsequently over-ruled.

August 2020	**October 2020**	**June 2021**
Questions to European Regulator (quote)	**Questions to Importers (quote)**	**Proposals in Canada Gazette (paraphrase)**
Option I would prohibit all vaping product ingredients that impart a flavour other than the flavour of tobacco, including sugars and other sweeteners. The restrictions would be put into place by amending the list of prohibited ingredients under Schedule 2 of the Tobacco and Vaping Products Act (TVPA). *Option II would prohibit the promotion of flavours (with the exception of tobacco flavour) on vaping product packaging and advertising.* *Option III would include both the restrictions on flavours specified in Option 1 and the restrictions on the promotion of flavours specified in Option II.* *Option IV would specify the flavoring substances that could be used in vaping products. The substances specified would be limited to those that impart the flavour of tobacco.*	*Health Canada might prohibit vaping product ingredients that impart certain flavours (see below). The restrictions would be put into place by amending the list of prohibited ingredients under Schedule 2 of the Tobacco and Vaping Products Act (TVPA).* *Health Canada might specify the flavouring substances that could be used in vaping products; hence, flavoured liquids remaining on the market would be required to use only the approved substances.* *Health Canada might prohibit the promotion of certain flavours on vaping product packaging and advertising.* *Health Canada might enact flavour and promotion restrictions together in a single rulemaking.* *Health Canada is still considering which flavours would be eliminated from the market. For purposes of discussion, three scenarios are possible:* *Elimination of flavours other than tobacco;* *Elimination of flavours other than tobacco and mint/menthol; and* *Elimination of flavours other than tobacco, mint/menthol, or fruit.*	Amending the list of prohibited ingredients under schedule 2 of the Tobacco and Vaping Products Act (TVPA). Specifying the flavouring substances that can be used in vaping products Prohibiting the promotion of certain flavours on product packaging. Flavour and promotion restrictions in a single rule making.
Industrial Economics Incorporated . Compliance Costs and Market Impacts Associated with Restrictions on Flavours in E-Liquids – Questions for (redacted)	*Industrial Economics Incorporated. Compliance Costs and Market Impacts Associated with Restrictions on Flavours in E-Liquids – Questions for Importers of E-Liquids. Provided by Health Canada to Physicians for a Smoke-Free Canada on October 14, 2020.*	*Canada Gazette, Part I, Volume 155, Number 25: Order Amending Schedules 2 and 3 to the Tobacco and Vaping Products Act (Flavours)*

iv. Canada should learn from the U.S. experience with a ban that did not include menthol.

In 2020, the U.S. Food and Drug Administration adopted an enforcement policy which aimed to end the sale of cartridge-based e-cigarettes that contained flavours other than menthol and tobacco flavour. Eighteen months later, more than half of the U.S. state attorneys general have formally called on the FDA to expand the flavour ban to include all products and all flavours other than tobacco.[7] They noted:

"Following menthol's exception from the FDA's restriction on flavors, there has been a surge in popularity among youth of e-cigarette products with menthol flavoring. Menthol-flavored ecigarette sales jumped 54.5% in market share over the four weeks following the FDA 2020 guidance, and 82.8% over eight weeks. Despite industry arguments, it is clear that menthol appeals to youth, just like all other non-tobacco flavors."

Recommendation 2:
Health Canada should revert to its August 2020 intention to ban all non-tobacco flavours, including mint and menthol.

c) Flavour descriptors

Proposed amendments to Schedule 3 would, in theory, restrict promotion to only mint/menthol and tobacco flavoured vaping products, and restrict brand descriptors. It appears that the intention is to permit terms like "mint", but to prohibit "candy cane." Less clear is whether the term "peppermint" will be allowed ("peppermint" describes the plant *Mentha × piperita* and also a category of candy), or whether the names of mint plants will be allowed, such as apple mint (*mentha x suaveolens*), Mojito mint (*mentha x villosa*).

The vagueness of the prohibition is an invitation for vaping suppliers to use terms which will be interpreted as having flavours, lifestyle imagery or other attributes which are prohibited under the TVPA. Health Canada may find it difficult to clamp down on these practices.

This problem is already evident in the widespread non-compliance with existing restrictions on flavour descriptors. The TVPA currently disallows communicating confectionery, cannabis, dessert, soft drink and energy drink flavours. Our recent review of websites of vaping industry leadership nonetheless found wide range of flavour descriptors that circumvented this restriction, as well as flavour names which had other image-based associations, including lifestyle images. [8] (The report is attached and forms part of this submission).

- Examples of flavour names which communicated prohibited flavours: Apple 3.14 (apple pie); Cotton Fluff (cotton candy); "C is for…" (cookie); Stacks (pancake); Banana Dread (banana bread); Red Bovine (Red Bull); Root Drink (root beer).
- Examples of flavour names which promoted lifestyle images include Royal Blood, Hustler, Jolly, Freedom, Lady Luck, Pillow Talk, Nirvana, Death and Summer Bliss.

In designing this new Order, Health Canada must take into consideration its capacity to ensure compliance and the willingness of vaping suppliers to ignore restrictions. A simple regulation permitting only a small number of flavour names will be easier to monitor and police.

Notably, in the weeks since the proposed Order was issued, BAT has expanded its range of "mint" descriptors to include flavour names which evoke imagery more than flavour (eg .River Mint and Forest Mint),[9] even though they are the common names of mint varieties. (*mentha australis* and *mentha laxiflora*).

Recommendation 3:
It is recommended that Schedule 3 be modified to permit only the following brand descriptor and only in the case of a tobacco-flavoured product: "tobacco flavour", as shown in amended text below.

Items 1 to 5 of Schedule 3 to the Act are replaced by the following:

Item	Column 1 Flavour	Column 2 Vaping Product
1	Tobacco, mint, menthol, a combination of mint and menthol, cannabis, confectionery, dessert, soft drink, energy drink or any other flavour	Vaping products, except those that are (1) referred to in items 2 and 3 (2) the subject of an authorization issued under the Food and Drugs Act, including a licence, authorizing their sale, ~~(3) manufactured or sold for export~~
2	A flavour other than tobacco	Vaping products that have a flavour of tobacco, and are labelled "tobacco flavour", except those that are (1) the subject of an authorization issued under the Food and Drugs Act, including a licence, authorizing their sale, ~~(2) manufactured or sold for export~~
~~3~~	~~A flavour other than mint, menthol or a combination of mint and menthol~~	~~Vaping products that have a flavour of mint, menthol or a combination of mint and menthol, except those that are~~ ~~(1) the subject of an authorization issued under the Food and Drugs Act, including a licence, authorizing their sale,~~ ~~(2) manufactured or sold for export~~

3. Cost-benefit and break-even analyses

The cost-benefit and break-even analyses, while a Treasury Board requirement, necessitate some assumptions and estimates that are poorly justified or unjustified. In particular an unnamed panel of "experts" proposed that vaping carries a risk that is 20% of the risk of tobacco. In this analysis and in other communications, Health Canada continues to rely on scientific reviews that are now several years out of date.

The overall risk of vaping relative to tobacco is still not established. Quantifying the overall risk, based on no evidence, is not justified.

Recommendation 4:
Health Canada should commission a review of the evolving evidence on health consequences of vaping. It should no longer rely on the 2018 report of the National Academies of Sciences, Engineering and Medicine which relied on evidence that is now more than 6 years old. Absent of this review or transparency of its scientific basis, Health Canada should not make statements which quantify the overall risk of vaping.

Part 2: Structural concerns with the foundational laws and policies

The proposed Order on flavours and Standards for Sensory Attributes are made under the authority of the *Tobacco and Vaping Products Act* and reflect the policy decisions that underly the federal government's approach to vaping regulation. Specifically, the law and the proposed regulations reflect Health Canada's intention to:

1. Accept a trade-off ("balance") between the anticipated health interests of one group of Canadians and those of another. ("Health Canada aims to strike a balance between reducing the appeal of vaping products, to protect youth from inducements to use vaping products, and leaving some flavour options for adults who smoke and who have transitioned, or wish to transition, to vaping.")[10]
2. Focus on reducing the demand for tobacco products (and for vaping products among youth), but not to aim at reducing the supply of these goods.
3. Reduce the harms caused by tobacco products by encouraging smokers to switch to vaping products ("helping those who can't or won't quit using nicotine to identify less harmful options").[11]
4. Achieve public health benefits through the liberalization of the market for vaping products ("leveraging" the marketing of the products to "move smokers from cigarettes to less harmful vaping products.").[12]

1. The zero-sum game of balancing the health interests of children against vapers

The proposed restrictions on flavours are opposed by vaping trade associations as being too restrictive and by public health agencies as being insufficiently restricted. Health Canada's position that it has to "strike a balance" between the interests of protecting young people and their goal of reducing harm ignores the potential to modify its regulatory regime so that these interests are no longer in opposition. This "balance" is being struck in the context of vaping products being widely available (30,000 or more retail outlets) and provided in a non-therapeutic context. At the same over 400,000 people under 25 who never smoked use vaping products.[13] Vapers who never smoked have increased harm, not decreased harm.

There is currently no scale on which the benefits of vaping products can be accurately measured against the harms.

It is not yet scientifically established that shifting individual smokers to alternative nicotine sources or transitioning a commercial market from combustible to non-combustible nicotine products will reduce the economic or health burden associated with tobacco smoking. Nor are the harms from vaping sufficiently known that it is possible to confidently calculate a trade-off between the possible negative health consequences of newly-recruited vapers (with some additional youth who transition to smoking) against the possible health benefits of an additional number of smokers ceasing to use tobacco products. Notably, attempts to do so have already been markedly adjusted (reducing anticipated benefits of vaping) as knowledge about the risks and use of these products increases.[14]

Attempts to establish a trade-off between the health interests of children and those of adults lack a transparent policy framework.

Health Canada (and other agencies of the federal government) have yet to make public any framework on which policy decisions to impose a potential risk on children against a potential benefit for adults can be assessed. The absence of transparency in such important decisions leaves children vulnerable to caprice of decision-makers and lobbyist pressure.

The proposed Order is opposed by some who advocate for measures to increase the use of e-cigarettes by current smokers.[15] Health Canada's policy choice of a "balanced" approach has put policy-makers in the unnecessary position of having to find the point at which the responsibility of protecting children justifies removing access to the vaping flavours that are important to at least some number of Canadians. This assessment is made more difficult because many key factors are unknown – including the impact of the regulation on individual and corporate behaviour, the ability of regulators to respond in a timely way to implementation challenges, the view of the courts which will be asked to review the measures, etc.

Alternatives to the balanced approach are needed. They may be available.

E-cigarettes are a relatively new drug technology. The market is developing rapidly, as is the scientific knowledge that can guide the development of policies to regulate these products. Canada's regulatory system does not function well in such a fast-moving environment and is ill-equipped to re-adjust a "balance" when circumstances change.

A preferable approach would be one where the public health interest is embedded in the provision of new nicotine technologies to smokers. In a context where nicotine products with the potential to reduced harm were provided only to those for whom harm reduction was relevant, the issues of product regulations (like nicotine formulations or flavours) could be managed in ways which address the health needs and priorities of existing nicotine users. By abandoning the "balanced" approach in favour of a "tightly targeted" market, Health Canada could allow continued access to products for which widespread marketing is a public health risk. Australia (which requires prescription for access to e-cigarettes) and New Zealand (which sets different restrictions for flavours used as part of a smoking cessation program) provide examples of models that could be considered for Canada.

Recommendation 5:
In implementing any nicotine policies which seek to "balance" the interests of one group of Canadians against another, the department should make public its estimates of the benefits and risks faced by each population group.

Recommendation 6:
Health Canada should develop options to permit access to vaping products which do not inherently pose a risk to young persons or non-smokers

2. The benefits of a supply-side approach are missing

For decades, Health Canada has chosen to focus on reducing the demand for tobacco products, but has not pursued adjustments to their supply that would contribute to reduced smoking. This is in contrast to the federal government's approach to other substances where there is a public need for reduced or controlled consumption. Examples of policy domains where the federal government has or intends to exercise supply controls include prescription medications (e.g. addictive pain killers), energy-inefficient products (e.g. incandescent light bulbs), noxious compounds (e.g. Certain pesticides, chlorofluorocarbons), pollutants (single-use plastics), carbon emitters (combustible fuel passenger vehicles).

With respect to vaping products, the impact of a continued focus on demand reduction resulted in alternative policy measures being largely unexplored. Canada did not, for example, offer Parliament or consult with the public about the option of supplying vaping products in a therapeutic (prescription) context, as Australia is now doing. By contrast, in implementing harm reduction for opioids, Health Canada has imposed significant restrictions on service providers of safe injection sites.[16] Health Canada requires that access to harm reduction treatments, such as methadone, involve a health practitioner.[17]

There is no evidence that widespread availability of nicotine-based consumer products in convenience stores is the optimal means of assisting smokers to convert to alternative nicotine. There is a need to explore whether it is possible to establish mechanisms to allow smokers to access these products from dispensaries or networks where individuals are trained in smoking cessation and where the incentives and rewards are directed at ending tobacco and nicotine use, not selling nicotine products.

Recommendation 7:
In addition to its demand reduction measures, Health Canada should develop options to control the supply of tobacco and nicotine products in ways that accelerate reduction in their use and which place responsibility on suppliers to contribute to the achievement of policy objectives.

3. The Holy Grail of less harmful smoking

Health Canada's inclusion of harm reduction in its 2018 Canada's Tobacco Strategy is the third time that the federal government has given priority to measures which reduce the harm for existing smokers. The first attempt was in the 1970s when the department focused on "less hazardous smoking" and helped fund the development of lower-tar tobacco blends and on shifting smokers to lower-tar products. The second, smaller and quickly-abandoned effort, was in the early 2000s when they looked for ways to demand that certain toxins be removed from cigarette smoke. Neither of these previous efforts was shown to have improved the health status of Canadians.

Health Canada's current harm reduction approach for tobacco use is poorly explained and thus difficult to assess. It is ambiguously expressed: the policy objective stated in the proposed Order is to **"provide access"** to products that Health Canada has variably termed "likely less harmful" and "less harmful". Elsewhere the policy objective is stated as "**to move smokers from cigarettes to less harmful vaping products**."[18] The department has not yet made public its specific objectives for harm reduction, either for "access to products" or for "switching to less harmful products". Without these objectives or indicators to monitor their achievement, it is impossible to assess how the proposed Order contributes to reducing harm.

Recommendation 8:
Health Canada should conduct a review of the extent to which liberalizing the vaping market has contributed to reduced harm among adult smokers. The review should also identify the extent to which harm has been increased among never-smokers, especially never-smokers under 25. Health Canada should make the results of this review public as part of its mandated report to Parliament in May 2022.

Recommendation 9:
If no substantial smoking cessation benefit can be identified in the above review, the objective of supporting smokers in switching to vaping products should be restructured to ensure it is more carefully targeted and more effective.

Recommendation 10:
If vaping is found to be a source of new harms to those who never smoked, steps should be taken to restructure the policy and legislative framework to ensure that vaping products can be accessed only by those who are using them to quit smoking.

4. Leveraging the commercial sector to achieve public health objectives.

Even if it had been established that encouraging smokers to switch to vaping products was in the public health interest, it is does necessarily follow that the commercial sector should be entrusted with providing this encouragement. Nor does it relieve the government of the responsibility to protect health from the vested interests of the tobacco industry.

Health Canada's intention to "leverage" commercial activity to help switch smokers was reflected in the permissive regulatory regime initially drafted. The version of the Tobacco and Vaping Products Act initially presented to public did not prohibit lifestyle advertisements for these products and permitted a number of promotions that were no longer permitted for tobacco products. This was in stark contrast to the approach taken by the province of Quebec or other jurisdictions where e-cigarettes are regulated as tobacco products. A review of the adoption of Canada's vaping regulations concluded that Canada has adopted "business-friendly harm reduction."[19]

In 2018, the department made clear its intention to "leverage" or engage the commercial vaping market to encourage switching amongst smokers. This was communicated through websites, [20] conferences proceedings,[21] and regulatory priorities.[22] Since that time, the federal government has significantly rolled back the permissions it gave to this market. In addition to the proposed regulations, it has also introduced new restrictions on vaping promotions, [23] has reduced the concentration of nicotine permitted in vaping liquids, [24] and has signalled its intention to impose a tax on vaping products.[25] Health Canada's Departmental Plan formerly announced the intention to pursue "potential benefits of vaping products", but since 2020-2021 it has pivoted to a focus on "the rapid rise in youth vaping" and to "redouble its efforts to protect young Canadians from inducements to vape".[26]

These important and time-consuming policy changes are more evidence that the foundational legislation and the "business-friendly harm reduction" on which it was based were not well constructed. The proposed Order will not address the underlying frailties of the TVPA, such as the permissive structure for vaping products that is embedded in the law (all promotions are permitted unless they are specifically forbidden) and the difficulties in achieving compliance.

Recommendation 11:
Concurrent with the drafting of its mandated report to Parliament on the implementation of the TVPA, Health Canada should consult with provincial health authorities, experts and community representatives on alternative legislative structures that will better achieve public health objectives, including requirements for the planned reductions in the supply of and demand for tobacco and vaping products.

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