

Proposals for the Regulation of Vaping Products

A Submission by the Non-Smokers' Rights Association

19 October 2017

Introduction

The Non-Smokers' Rights Association (NSRA) is Canada's oldest national tobacco control non-governmental organization. Through advocacy, public policy, research and education, the NSRA has worked for over 40 years to protect the public health of Canadians by seeking to eliminate the illness and death caused by tobacco industry practices and products.

E-cigarettes have been on the Canadian market for a decade without adequate regulation, causing much public confusion, as well as a lack of knowledge as to the health and safety implications of use. Federal leadership on this issue is welcome and long overdue.

We recognize both the potential reduced harm benefits for smokers that e-cigarettes offer, as well as the potential risks regarding youth access and uptake. It is imperative that the government strike the right regulatory balance to maximize the benefits and minimize risks to both individuals and public health. Much can be done to educate Canadians on the health and safety aspects of e-cigarettes and to incentivize smokers to choose less harmful alternatives through various policy levers including price, taxation, packaging, labelling, and advertising and promotion. We are pleased to provide the Government of Canada with our comments on the proposals for the regulation of vaping products. We have no perceived or actual conflicts of interest to declare.

Responses to Proposals: Tobacco & Vaping Products Act

Proposal #1: Health Canada proposes that all vaping products which contain nicotine display their nicotine concentration in milligrams/millilitre (mg/ml).

The NSRA supports this proposal.

Proposal #2: To prevent consumers from being misled about the presence or absence of nicotine, Health Canada proposes that any vaping product be considered to contain nicotine if nicotine is present at a concentration of 0.1 mg/ml or higher.

The NSRA supports the establishment of a threshold to determine what is considered nicotine-free, but questions Health Canada’s rationale in choosing 0.1 mg/ml as the threshold.

As noted in the consultation document, the threshold in the UK is 0.1 mg/ml; in France it is higher at 0.5 mg/ml; and the U.S is proposing that nicotine-free should mean no detectable level of nicotine. Although we are not experts in this area, we are aware that discussions in Europe regarding this issue resulted in a divergence of policy and that any specific threshold needs to be underpinned by evidence. To impose an arbitrary limit would be difficult to defend. For example, has the government tested any “nicotine-free” vaping liquids currently on the Canadian market to determine their concentration of nicotine, if any? We also question if there are any practical issues to consider related to imposing this low limit, such as the detection limits of technology.

Proposal #3: Health Canada proposes to require that vaping products that contain nicotine display a warning such as: “WARNING: This product contains nicotine. Nicotine is an addictive substance. Use of nicotine during pregnancy may harm the fetus.”

The NSRA supports the requirement for nicotine warnings, but advises caution in the messages used, including with pregnant women, and recommends the concurrent use of relative risk statements to educate Canadians.

It is important for nicotine warnings not only to be factually correct, but also to provide Canadians with useful and contextual information with which to make informed decisions. Canada does not currently track public perceptions of harm from e-cigarettes. However, in Great Britain, despite a favourable regulatory environment for e-cigarettes and a strongly supportive public health community, public perceptions remain inaccurate, with only 13% of the public in 2017 understanding that the vaping of e-cigarettes is a lot less harmful than smoking tobacco products. Among smokers, perceptions are becoming less accurate, with only 20% accurately believing in 2017 that using e-cigarettes is a lot less harmful than smoking, down from 31% in 2015.¹

While it is correct that use of nicotine during pregnancy may pose risks to the fetus, it depends on the source of delivery. For example, in the UK, nicotine replacement therapy (NRT) is widely prescribed to pregnant women who smoke and find it difficult to stop. A recent UK longer term study of a trial of NRT in pregnant smokers followed up the infants of

¹ Action on Smoking and Health UK. Use of e-cigarettes (vapourisers) among adults in Great Britain. May 2017 <http://ash.org.uk/download/use-of-e-cigarettes-among-adults-in-great-britain-2017/>

women who had stopped smoking using NRT. It identified that NRT is safe to use during pregnancy and that the priority was to support women not to smoke.² We cannot extrapolate from the NRT evidence to e-cigarettes, but need to be cautious about assuming that the evidence on nicotine use during pregnancy from smoking would be directly applicable to the use of e-cigarettes. The priority should be to help pregnant smokers to quit, and the proposed health warning may suggest to pregnant smokers that they would be better off continuing to use tobacco than using an e-cigarette. Based on current evidence this is unlikely to be the case, and further advice to midwives and other health professionals has been developed in the UK, for example, on that basis.³

With that in mind, it is worth noting that smoking during pregnancy is a real concern in Canada. The government of Nunavut reports extremely high rates of smoking among its Inuit population, with 80% of pregnant women in at least one Inuit community having reported smoking throughout their pregnancy. Tragically, but not surprisingly, Nunavut has the highest incidence of low birth weight and the highest rate of premature births in the country.⁴

The labelling of vaping products will play an important role in helping to incentivize adult smokers to choose them over cigarettes. Recent Canadian research suggests that false relative risk perceptions are amenable to change and can be improved using relative risk messages.⁵ The NSRA strongly urges Health Canada to consider including relative risk messages together with warnings to maximize public health benefits.

In addition, as with Proposal #9, we recommend that the selection of nicotine warnings “be amended from time to time to keep up with scientific knowledge.” We also recommend that like relative risk statements, the creation and periodic renewal of nicotine warnings be put into the hands of the newly created federal expert advisory panel and that these warnings be subject to public consultation. However, we are concerned about how long this process will likely take. Given how quickly the science on vaping products and inhalable nicotine is evolving, the government needs a process that will ensure that warnings and statements

² Cooper S, Taggar J, Lewis S et al. Effect of nicotine patches in pregnancy on infant and maternal outcomes at 2 years: follow-up from the randomised, double-blind, placebo-controlled SNAP trial. *Lancet Respir Med*. 2014; Sep;2(9):728-37. doi: 10.1016/S2213-2600(14)70157-2. Epub 2014 Aug 10.

³ Smokefree ACTION. Smoking in pregnancy challenge group. <http://smokefreeaction.org.uk/smokefree-nhs/smoking-in-pregnancy-challenge-group/>

⁴ Government of Nunavut, Department of Health and Social Services. Nunavut Tobacco Reduction Framework for Action, 2011 - 2016. <http://www.gov.nu.ca/sites/default/files/files/Nunavut%2520Tobacco%2520Reduction%2520Framework-ENG.pdf>

⁵ Czoli CD, Fong GT, Mays D, et al. How do consumers perceive differences in risk across nicotine products? A review of relative risk perceptions across smokeless tobacco, e-cigarettes, nicotine replacement therapy and combustible cigarettes. *Tobacco Control* 2017;26:e49-e58.

both reflect the latest evidence and are implemented as quickly as possible without compromising oversight.

We therefore recommend that Health Canada use the newly created ‘incorporation by reference’ power conferred by Bill S-5 to facilitate the expedient implementation of nicotine warnings.

Finally, it is incumbent upon us to note that there are other risks beyond nicotine that warrant consideration for warning requirements, the most obvious being the unknown long-term health effects of inhaling vapour and also the consequences of ‘compensatory’ vaping at lower nicotine levels which may result in smokers who switch to vaping using the devices in ways which may expose them to other non-nicotine toxicants.

We recommend that the expert advisory panel examine these additional risks for possible inclusion in required warnings.

Proposal #4: Health Canada proposes to require that products that contain a vaping liquid display a complete list of ingredients in descending order by weight.

The NSRA supports this proposal.

Proposal #5: Health Canada proposes that manufacturers be required to report the information set out below at the frequency specified.

The NSRA wholly supports this proposal, with the additions detailed below:

<i>Information</i>	<i>Frequency</i>
The name of the business and contact person; the name and contact person of parent company (if applicable)	Annually
Details about each vaping device or liquid, including the product name, model number and nicotine concentration	Upon introduction of each product, and annually thereafter
Details about the design of each vaping device, including engineering drawings and information about the materials and components used	Upon introduction of each product, and annually thereafter
Contents of vaping liquids, including quantities of each ingredient	Upon introduction of each product, and annually thereafter

<i>Information</i>	<i>Frequency</i>
Information on research and development activities, including research findings, especially regarding emissions	Annually
Information on promotional activities, including direct and indirect expenditures	Annually
Sales data for each product, including price	Quarterly

Proposal #6: Health Canada proposes that manufacturers of vaping products be required to provide supplementary information in a form, manner and within the time frame specified, once notified by the Minister. The form, manner and time frame allowed for manufacturers to provide the supplementary information would be specified in the request and could vary according to the nature of the information requested.

The NSRA supports this proposal.

Proposal #7: Health Canada proposes that manufacturers of vaping products be given a period of no more than 30 calendar days to address any deficiency in the reporting of information prescribed by the regulations, once they are notified of the deficiency by Health Canada. Should the manufacturer fail to address the deficiency, or should the information provided continue to be deficient, the sale of the product in question would be suspended until the missing information is submitted to Health Canada, and the manufacturer would be informed accordingly.

The NSRA supports this proposal, with a corollary.

Suspension of a vaping product from the market until missing information is provided is a fair penalty. However, given the much greater risks to health caused by cigarettes, the NSRA urges Health Canada to prioritize the implementation of the same consequence for tobacco companies that fail to provide the government with the information required under the Tobacco Reporting Regulations.

Furthermore, in the spirit of greater public access to industry information, and in keeping with Canada’s obligation as a Party to the Framework Convention on Tobacco Control (FCTC), we recommend that Bill S-5 be amended to make all information disclosed by both tobacco and vaping product companies to the Health Minister also available to the public, unless prohibited by the regulations, i.e., reverse the onus regarding public disclosure of company information provided to the government:

“Every manufacturer shall make available to the public, in the prescribed form and manner and within the prescribed time, unless otherwise exempted by the regulations, information that is supplied to the Minister about [tobacco and vaping products] and their emissions, as well as information about expenditures and activities related directly or indirectly to influencing public health policy related to [tobacco and vaping products], including any funding provided to third parties.”

Proposal #8: Health Canada proposes that manufacturers of vaping products be required to maintain all records and documents used to prepare their information reports for a period of six (6) years after the end of the year to which the document relates. This documentation would have to be kept in a form and manner prescribed by the regulations, so that it could be readily accessed and viewed in Canada during audits.

The NSRA supports the proposal to require manufacturers to maintain all records and documents, but recommends that the period of time be increased significantly to 25 or 30 years.

Experience with tobacco products indicates that the latency period for the development of a chronic disease is usually decades. Given that the long-term health effects of vaping products, both for users and bystanders, remain unknown, it is prudent for the government to require manufacturers to maintain all records and documents for decades. This information can be used for audits, but could also prove to be invaluable to health-related research and litigation. Moreover, to help preserve historical information, the government should require that all records and documents be transferred to the new owner in the case of a manufacturer being purchased.

Proposal #9: Health Canada proposes to establish regulations that would specify the conditions upon which manufacturers, retailers and others could use authorized relative risk statements in vaping product promotions. The regulations would incorporate by reference a selection of authorized statements regarding the relative health risks of using vaping products or comparing the potential health effects arising from the use of a vaping product relative to that of a tobacco product. As the authorized statements may need to be amended from time to time to keep up with scientific knowledge, these regulations would also set out the requirement for public consultations on such amendments.

The NSRA wholly supports the creation of regulations regarding the use of authorized relative risk statements in the promotion of vaping products.

One of the goals of the *Tobacco and Vaping Products Act* is to protect the health of Canadians and to reduce the incidence of numerous debilitating and fatal diseases caused by tobacco use; permitting the use of relative risk statements for vaping product promotions will help to facilitate the realization of this goal.

Given that combustible tobacco products, and specifically cigarettes, cause the most harm and are the most popular form of tobacco consumption in Canada, we urge Health Canada to authorize and prioritize the creation of relative risk messages for vaping products that focus on cigarettes as their point of reference. Smokers desperately need reliable information about vaping products on which to make informed decisions about their use. Research indicates that believing that vaping is as risky as smoking may impede some smokers from trying and regularly using e-cigarettes, choosing to continue smoking instead.⁶ Health Canada should not wait to permit the use of relative risk statements in promotions until there is absolute scientific clarity regarding the degree of reduced risk from vaping versus smoking, nor should Canadians have to wait until evidence proves that vaping products are effective aids in smoking cessation. While it is important for people to know that vaping products are not inherently safe to use, it is equally important for smokers to know that less harmful choices are available.

The NSRA also supports the creation of an expert advisory panel to help keep the government informed regarding the latest scientific information on vaping products and to advise on the creation of relative risk statements. However, as stated earlier, our organization is concerned with the length of time that would be needed for public consultation on relative risk statements.

If the expert advisory panel convenes just twice per year, and if the proposed public consultation follows the standard process for government consultations, then authorized relative risk statements could realistically trail the science by years.

We recommend that the expert group convene more often, even if not in person, to expedite this process. As above, we also highly recommend that Health Canada use the ‘incorporation by reference’ power conferred by Bill S-5 to facilitate the expedient implementation of relative risk statements to keep pace with the rapidly evolving science and technology of vaping products.

Finally, we encourage Health Canada to add relative risk statements to the Health Information Messages that are required for cigarette and little cigar packaging such that smokers understand there is a range of less harmful nicotine products available that are viable alternatives to the dirtiest nicotine delivery system—inhaling toxic tobacco smoke.

Adding relative risk messages to the list of HIMs included in cigarette and cigar packs will target smokers, providing information on tobacco harm reduction directly to those who need it most, including smokers who have not previously tried other products and those who have a low likelihood of purchasing one.

⁶ Brose LS, Brown J, Hitchman S, et al. Perceived relative harm of electronic cigarettes over time and impact on subsequent use. A survey with 1-year and 2-year follow-ups. *Drug Alcohol Depend* 2015;157:106–11.

Proposal #10: Health Canada proposes to establish regulations to help limit youth exposure to information and brand-preference advertising of vaping products. These regulations would include restrictions on the type, medium and content of advertising of vaping products. In line with the objectives of the proposed TVPA, the restrictions would be based on limiting advertising that has a high likelihood of being viewed by youth, while still allowing vaping product manufacturers to advertise their products and brands to adult smokers. Restrictions would therefore seek to limit advertising in or near locations that are attended predominantly by youth, such as schools, parks, recreational and sporting facilities. Restrictions would also be placed on advertising in certain media, for example by either prohibiting advertisements on television and radio or restricting the times of the day when such ads may appear or be heard to limit youth exposure to them.

The NSRA recommends amendments to Bill S-5 to delete exceptions that permit lifestyle advertising in places off-limits to minors and in publications addressed and sent to a named adult. Further, we recommend that the bill explicitly limit product advertising to only information and brand preference advertising.

In addition, we support the creation of regulations pertaining to information and brand-preference advertising and urge the government to implement additional restrictions on advertising and promotion during this first round of regulations. These recommendations support the stated objectives of Bill S-5 “to protect young persons and non-users of tobacco products from inducements to use vaping products; and (b) to protect the health of young persons and non-users of tobacco products from exposure to and dependence on nicotine that could result from the use of vaping products.”

Vaping products with nicotine should be available to adult smokers who should be fully informed about the absolute and relative risks of use, but this does not necessitate promotion of these products in media whose reach will likely result in widespread exposure by minors.

The table below summarizes our positions on vaping product promotions.

Promotion Type	NSRA Position	Rationale
Television	Prohibited	<ul style="list-style-type: none"> • History tells us that industry will likely play at the edges of legality, pushing the boundary between informational and brand-preference advertising and lifestyle advertising • Music, and even just a voice, can be used to associate a product with a certain lifestyle (i.e., classical music; rap music; rapping without the use of instruments) • Restricting the times of day when advertising on TV is permitted will likely do little to reduce youth exposure given the current media environment <ul style="list-style-type: none"> – Many young people watch TV beyond 9 or 10 p.m. – Young people’s access to on-demand TV and personal video recorders (PVRs) renders time restrictions for advertising irrelevant
Radio	Prohibited	<ul style="list-style-type: none"> • History tells us that industry will likely play at the edges of legality, pushing the boundary between informational and brand-preference advertising and lifestyle advertising • Music, and even just a voice, can be used to associate a product with a certain lifestyle (i.e., classical music; rap music; rapping without the use of instruments)
Print (newspapers, magazines, periodicals)	Permitted – but restricted to publications with 85% adult readership	<ul style="list-style-type: none"> • Without the use of music and/or voices, it will be easier to identify what is and is not lifestyle advertising • Although there will undoubtedly be some youth exposure to promotion in this medium, requiring an 85% adult readership will better target adults than no restrictions at all
Trade publications	Permitted	<ul style="list-style-type: none"> • Audience is largely adult retailers • Youth exposure is minimal
Print (flyers, postcards, etc.)	Permitted – in adults-only specialty vape shops	<ul style="list-style-type: none"> • Youth exposure is minimal

<i>Promotion Type</i>	<i>NSRA Position</i>	<i>Rationale</i>
Point of Sale <ul style="list-style-type: none"> • Display • Advertising and promotion • Sampling 	Permitted – but limited to adults-only specialty vape shops	<ul style="list-style-type: none"> • Point of sale is one of the best ways to target adults, and particularly adult smokers, and where the most liberal brand preference and informational promotions should be permitted, provided it is not visible from outside the premises • Limiting point of sale promotion to adults-only vape shops will prohibit promotions in convenience stores and other retail outlets where young people have access and will maximize exposure by adults in retail environments that typically have more knowledgeable staff and a wider variety of vaping products <ul style="list-style-type: none"> – This could lead to better conversion rates of triers becoming regular daily users • It is NSRA’s understanding that Bill S-5 does not prohibit in-store sampling; however, sampling should also be restricted to adults-only vape shops
Company and retailer websites <ul style="list-style-type: none"> • Advertising • Promotions • E-commerce 	Permitted – with measures taken to ensure that promotions cannot be accessed by young people	<ul style="list-style-type: none"> • Canadians who do not live near retail outlets, including specialty vape shops, need access to information and the ability to buy online
Social media <ul style="list-style-type: none"> • Testimonials • Endorsements • Blogs • Tweets • Reviews 	Prohibited by Bill S-5 Independent statements permitted by Bill S-5	<ul style="list-style-type: none"> • NSRA urges Health Canada to act on its regulatory authority to create regulations requiring manufacturers to disclose the details of their promotional activities <ul style="list-style-type: none"> – This would address the problem of bloggers and others receiving compensation/benefits to write what appear to be “independent reviews” favouring specific vaping product brands

Promotion Type	NSRA Position	Rationale
Internet advertising	Prohibited	<ul style="list-style-type: none"> • The reach is too broad and the risk of youth exposure too high • Although demographic data can target adults to mitigate youth exposure, it is adult smokers who need to be targeted and it seems unlikely that this advertising can be limited to adult smokers
Email advertising	Unsure – would the gov’t consider this a tele-communication?	<ul style="list-style-type: none"> • This type of promotion could be permitted if sent to a named adult; however, we are unsure of the feasibility of preventing youth access • If the Bill itself is amended to adopt more restrictive language regarding youth exposure via telecommunications (like in Bill C-45), we would support permitting email advertising
Text message advertising	Unsure – would the gov’t consider this a tele-communication?	<ul style="list-style-type: none"> • This type of promotion could be permitted if sent to a named adult; however, we are unsure regarding feasibility of prohibiting youth access • If the Bill itself is amended to adopt more restrictive language regarding youth exposure via telecommunications (like in Bill C-45), we would support permitting email advertising
Billboards	Prohibited	<ul style="list-style-type: none"> • The risk of youth exposure is too high because the reach is too broad • It is difficult to police location (i.e., near schools and other youth-focused places) • Billboard advertising contributes to the normalization of a product; the goal of S-5 is not to have e-cigarettes be seen as an everyday consumer product but rather as a less harmful alternative to smoking for current smokers
Cinema	Prohibited	<ul style="list-style-type: none"> • The risk of youth exposure is too great, given the high cinema viewership among youth • Music and even just a voice can be used in such a way as to promote a certain lifestyle (i.e., rap music; rapping without music)

<i>Promotion Type</i>	<i>NSRA Position</i>	<i>Rationale</i>
Fax	Permitted	<ul style="list-style-type: none"> • The risk of youth exposure is very low • Despite this technology being largely obsolete, it is still used by many doctors and others in the health care industry who are trusted sources of information for adult Canadians, including smokers
Mail (hardcopy and electronic)	Permitted by Bill S-5 when it is addressed and sent to a named adult	<ul style="list-style-type: none"> • The risk of youth exposure is low • However, note that NSRA does not support permitting lifestyle advertising in any advertising vehicle or venue
Advertising & promotions in adults-only venues (bars, casinos, specialty vape shops that prohibit minors)	Permitted by Bill S-5	<ul style="list-style-type: none"> • The risk of youth exposure is low • However, note that NSRA does not support permitting lifestyle advertising in any venue

Regarding minimizing the risk of youth exposure to advertising and promotion, we note that Bill C-45, *The Cannabis Act*, is more restrictive for telecommunications than Bill S-5. Parallels can be drawn between cannabis and vaping products with nicotine: both are addictive, both need to be kept out of the hands of youth, and both are currently illegal unless designated for medical/therapeutic purposes. However, we also note that the target market for vaping products containing nicotine (adults who smoke) is much narrower than that for recreational cannabis (adults). As such, we recommend that Bill S-5 be amended to adopt the more restrictive language found in Bill C-45. Specifically, we recommend an amendment to clause 36, Division 2 (page 21), Advertising appealing to young persons, that would add 30.1(a):

30.1

No person shall promote a vaping product, a vaping product-related brand element or a thing that displays a vaping product-related brand element by means of advertising if there are reasonable grounds to believe that the advertising could be appealing to young persons.

30.1(a) – For greater certainty

No person shall promote a vaping product, a vaping product-related brand element or a thing that displays a vaping product-related brand element by means of a telecommunication unless the person responsible for the content of the promotion has taken reasonable steps to ensure that the promotion cannot be accessed by a young person.

Other Applicable Legislation

Canada Consumer Product Safety Act

a. Child-resistant containers

- 1. Vaping liquids, which are to be sold as consumer products, containing equal to or more than 66 mg/ml will be prohibited from import, advertising or sale under section 38 of the *CCCR, 2001*.**

The NSRA supports this proposal for ready-to-use vaping liquid.

According to the Canadian Vaping Association, concentrations of 24 mg/ml and up are considered very high, and few people would benefit from this strength unless they were smoking more than two packs of cigarettes per day.⁷ However, the government has not proposed a limit for concentrated vaping liquids that would be imported by manufacturers and retailers to be diluted and custom-mixed after import. This is not our area of expertise, and the NSRA cannot comment on what this limit should be; however, we are concerned about unintended consequences from excessively restrictive measures.

- 2. Vaping liquids, which are to be sold as consumer products, containing between 10 mg/ml (1.0%) and 66 mg/ml (6.6%) will be required to be sold in child-resistant containers, and labelled in accordance with the *CCCR, 2001*.**

The NSRA supports the requirement for child-resistant containers for vaping liquids; however, we are very concerned that if devices themselves must also adhere to this requirement, it could amount to a de facto ban on open system vaping devices.

Given that it is these devices that most effectively deliver nicotine, they are our best hope for moving large numbers of smokers away from cigarettes. To effectively ban them via over-regulation would be a terrible unintended outcome for tobacco harm reduction efforts.

Cigarettes are exempt from the *CCPSA* and do not require child-resistant packaging. Given that e-cigarettes are significantly less harmful than cigarettes, and that the government can take policy decisions to influence and incentivize less harmful choices by Canadians, it follows that Health Canada could exempt vaping devices from this requirement. If exemption is not possible, a workable compromise should be sought,

⁷ Canadian Vaping Association. How to choose your nicotine strength.
<http://canadianvapingassociation.org/how-to-choose-your-nicotine-strength>

such as potentially limiting tank size. It is incumbent upon the government to balance potential risks and potential benefits. In the case of open system vaping devices, the very minimal risk of harm to a child (we are unaware of any reported cases of harm to a child from the ingestion of e-liquid in a tank device or from the leakage of e-liquid from a tank device) should not supersede the significant potential benefit to smokers who may be able to quit using tank style devices.

The first proposal regarding the *CCCR, 2001* is to ban liquids equal to or more than 66 mg/ml; therefore, it makes no sense to also require that liquids containing 66 mg/ml be sold in child-resistant containers. In the interest of reducing confusion and increasing compliance with the regulations, we recommend establishing thresholds that do not overlap from one category to the next. This recommendation also applies to liquids up to 10 mg/ml; a threshold of just below 10 mg/ml would clearly separate those liquids that do not meet the classification of toxicity from that that do, at 10 mg/ml and above.

b. Labelling requirements for vaping liquids, which are to be sold as consumer products and contain between 10 mg/ml (1.0%) and 66 mg/ml (6.6%) of nicotine.

The NSRA supports the labelling of vaping liquids to include information pertaining to safety, first aid, lot number, etc.

However, as expressed earlier, we are concerned about the unintended consequences of requiring warnings (including hazard symbols) that could contribute to Canadians' inaccurate relative risk perceptions and ultimate avoidance of vaping products in favour of cigarettes. Again, we note that cigarettes are not subject to the *CCCR, 2001*, and although they do carry graphic health warnings, they do not display a skull and crossbones, which is the toxic hazard symbol. The image of a skull and crossbones is widely regarded as a symbol of death as much as it is a hazard symbol. Without the concurrent provision of relative risk information to help contextualize the message, there is a real risk that Canadian smokers, especially those with low literacy, will see the deathly danger symbol and choose not to use e-cigarettes as a result.

c. Labelling requirements for vaping liquids, which are to be sold as consumer products and contain between 0.1 mg/ml (0.01%) and 10 mg/ml (1.0%) of nicotine.

The NSRA has serious concerns about requiring vaping liquids containing nicotine between 0.1 mg/ml (0.01%) and 10 mg/ml (1%) to adhere to all requirements of the *CCCR, 2001* for "toxic" products, including labelling requirements.

Exaggerating the risks of nicotine by requiring products with minimal levels of nicotine to bear a skull and crossbones and convey the same warning as products with much higher nicotine concentrations will undermine the goal of Bill S-5 to encourage adult smokers to switch to a form of nicotine delivery with greatly reduced risk. Both the absolute and comparative toxicity of the nicotine concentration should be taken into account.

Furthermore, we respectfully question the evidence used by Health Canada to determine nicotine toxicity, noting a significant discrepancy between the widely accepted lethal dose of 60 mg (0.8 mg/kg) for an adult, based on self-experiments from over 100 years ago, and published cases of nicotine intoxication. Available evidence suggests that the adult lethal dose for nicotine is much higher—at least 0.5 g.⁸

We recommend that Health Canada prioritize advancing the science on nicotine toxicity and lethal dose.

d. Regulatory path forward under the CCPSA

We understand that safety standards regarding batteries and chargers for consumer products already exist under the *CCPSA*, and that these will immediately apply to vaping devices and accessories upon proclamation of Bill S-5. If further measures specific to vaping devices and accessories are needed to protect consumer safety, we urge Health Canada to prioritize them. In order to help propel the uptake and regular use of e-cigarettes by smokers, smokers need to have confidence in the safety and quality of the vaping products they purchase. The longer Canadians see images in the media of grievous harm caused by exploding devices, the harder it will be to gain back consumer trust.

The Food and Drugs Act

The NSRA is concerned that the route to market for therapeutic vaping products (for which health claims are permitted) remains overly burdensome. It is estimated to cost a manufacturer millions of dollars, as well as take years, for a vaping product to receive market authorization as a drug. Given that vapour technology is changing rapidly and that it is entirely possible that a product could be outdated by the time it is approved, it seems unlikely that any manufacturer would choose this route to market—indeed, none has to date. The current regulatory framework also favours large manufacturers with deep pockets, effectively shutting small independent players out of the market and concomitantly curbing innovation.

While in theory Canadians could have access to therapeutic vapour products to assist with quitting smoking, under the current regulatory framework it seems only a distant possibility. We are therefore heartened to hear that Health Canada is exploring regulatory options for vaping products with therapeutic or health claims.

⁸ Mayer B. How much nicotine kills a human? Tracing back the generally accepted lethal dose to dubious self-experiments in the nineteenth century. *Archives of Toxicology*. 2014;88(1):5-7. doi:10.1007/s00204-013-1127-0.

Other vaping product-related priorities for which the government has regulatory authority but has not proposed regulations

- 1. Prescribing, for the purposes of section 7.5, information that manufacturers must make available to the public, and prescribing, for the purposes of section 7.6, information that the Minister must make available to the public** (page 9, clause 12, 7.8(h) and (i)), **including promotional activities** (page 27, clause 42, 32(1)):
 - In keeping with Article 5.3 of the FCTC, NSRA urges Health Canada to increase industry accountability by putting measures in place to improve the transparency of industry activities, including by providing information on promotional activities and expenses that are aimed at influencing public policy.
- 2. Regulating flavours** (page 26, clause 38, 30.49(1)):
 - We recommend that Health Canada exercise the authority granted by Bill S-5 to remove from the market, upon the Bill's coming into force, e-juice with names such as 'Unicorn Milk,' 'Unicorn Puke,' 'Dragon's Blood' and other fantasy-related flavours that are obviously attractive to children.
 - We also recommend that Health Canada prioritize amendments to Schedule 2, Prohibited Ingredients, to ensure that specific toxic flavourings such as diacetyl are added.
- 3. Requesting supplementary information pertaining to promotional activities** (page 27, clause 42, 32(2)):
 - We urge Health Canada to prioritize the creation of measures to ensure that manufacturers and retailers submit supplementary information pertaining to promotional activities in a timely fashion, and that enforcement measures are developed.
- 4. Regulating point of sale promotions** (page 27, clause 43, Regulations, 33(h)):
 - As mentioned in response to Proposal #10, we strongly recommend that regulations be developed to prohibit point of sale promotions of vaping products, including their display, in retail outlets where minors have access. Specifically, we recommend limiting point of sale promotions to adults-only specialty vape shops.

Conclusions

Vaping products have been available to Canadians for over a decade without regulation. The NSRA is heartened that the government is consulting on regulations before passage of Bill S-5 to help facilitate expeditious implementation. However, we note there are only ten proposals in this current consultation, despite regulatory authority conferred by Bill S-5 to address other important issues, such as regulation of flavourings, industry transparency, etc. We are also deeply concerned that without the Bill itself being strengthened, specifically regarding restrictions on advertising and promotion, it could take many years for further regulations to be developed.

E-cigarettes represent a game-changing opportunity to move large numbers of smokers away from cigarettes, which continue to kill 45,000 Canadians every year. If the government is sincere in its stated desire to drive down tobacco use in Canada to less than 5% by 2035, then vaping products need to be regulated such that they can compete effectively with cigarettes. It does not make sense to require the skull and crossbones toxicity warning on all e-liquids, regardless of their nicotine concentration, when cigarettes are exempt from this provision of the *Canada Consumer Products Safety Act*. Further, requiring that all vaping devices, including those potentially the most effective for smoking cessation (tank models), themselves be child-resistant and leak proof could strike a serious blow to tobacco harm reduction efforts. Health Canada must regulate carefully to strike the correct balance between minimizing potential risks (i.e., youth uptake, exploding batteries) and maximizing benefits to bring about significant drops in smoking prevalence.