

E-Cigarette Regulation Update

Introduction

Globally-speaking, we are in the midst of a very large natural experiment in which e-cigarettes are being regulated in different ways around the world. Some countries classify and regulate them as electronic cigarettes, others as tobacco or tobacco-related products, while other countries regulate them as consumer products and/or medicines. How these vastly different regulatory approaches affect smoking rates and public health are yet to be determined; time, nationally representative surveillance data and health research will eventually tell. The table below summarizes the most common ways that e-cigarettes are classified around the world.¹

Tobacco Products, Tobacco-Related Products, Tobacco Imitations, Tobacco Derivatives or Tobacco Surrogates (43 countries)	Consumer Products, in Addition to Another Class of Product (15 countries)	Medicinal/ Pharmaceutical Products (23 countries)	E-Cigarettes/Electronic Nicotine Delivery Systems (ENDS) (59 countries)	Poisons/Hazardous Substances (3 countries)
e.g.: United States, Argentina, Austria, Brazil, Brunei Darussalam, Costa Rica, Finland, Germany, Italy, Mexico, New Zealand, Korea, Poland & Singapore	e.g.: Canada, ² England, Australia, France, Germany & Korea	e.g.: Canada, England, United States, France, New Zealand, Japan, Sweden & Thailand	e.g.: Argentina, Belgium, Denmark, Ecuador, England, Italy, Finland, France, Kuwait, Germany, Oman, Ireland, Jordan, Lebanon, Norway, Panama, Poland, Qatar, Saudi Arabia, Scotland, Spain, Sweden, Switzerland, Thailand & United Arab Emirates	Australia, Malaysia, & Brunei Darussalam
Banned in some countries including Singapore, Brazil, Argentina & United Arab Emirates		Permitted to make a cessation claim and/or must contain a specific threshold of nicotine		Nicotine content must be above 7.5 mg/ml

¹ Institute for Global Tobacco Control. Country Laws Regulating E-cigarettes: A Policy Scan. Baltimore, MD: Johns Hopkins Bloomberg School of Public Health. Institute for Global Tobacco Control. Country Laws Regulating E-cigarettes: A Policy Scan. Baltimore, MD: Johns Hopkins Bloomberg School of Public Health. 19 March 2018. <http://globaltobaccocontrol.org/e-cigarette/country-laws-regulating-e-cigarettes>

² Not passed; *Bill S-5* has yet to have Third Reading and receive Royal Assent.

The “Precautionary Principle” is often cited as a reason for restrictive e-cigarette regulation: in situations of scientific uncertainty, it’s better to be safe than sorry. Specifically, this often relates to fears of the renormalization of tobacco smoking and the desire to protect young people from nicotine addiction and the much-feared gateway from e-cigarette use to tobacco smoking.³ However, policy makers often fail to evaluate the potential negative consequences of taking an extremely cautious regulatory approach to e-cigarettes. In most countries around the world the status quo is not “safe” and remains staggeringly harmful and completely unacceptable. The potential consequences of adopting more proportional regulatory frameworks that reflect e-cigarettes’ associated reduced harms compared with combustible cigarettes must absolutely be considered.



In Canada, five million Canadians continue to smoke, 45,000 people die prematurely each year and thousands more are sickened and disabled from smoking-related diseases.

Tobacco control policy should therefore seek to strike a balance to prevent and discourage cigarette use while at the same time incentivizing cessation and use of less harmful products, using policy levers such as taxation, price, places of permitted use, warnings, packaging, labelling and flavours. Concerns about renormalization can be mitigated by clearly communicating the relative risks of e-cigarettes compared to combustible tobacco through differential policies and public education campaigns using mass and social media. The risks of youth experimentation with e-cigarettes and nicotine addiction can be reduced by such policy measures as minimum age of sale laws, restrictions on advertising and promotion, and public education.

Unfortunately, a significant barrier that continues to hinder objective policy-making is a lack of complete scientific clarity and conflicting conclusions regarding both the cessation effectiveness of e-cigarettes and their associated harms.⁴ This ongoing lack of scientific certainty has exacerbated the deep divide in the public health community between those that believe that any form of addiction is harmful and the more pragmatic tobacco harm reduction advocates. As a result the debate continues to be highly emotional and fraught with bias, ideology and preconceptions on both sides.⁵

Bill S-5: Health Canada’s balancing act

Bill S-5, An Act to amend the Tobacco Act and the Non-smokers’ Health Act and to make consequential amendments to other Acts was first introduced in the Senate on November 22, 2016 and is still awaiting Third Reading and Royal Assent. The Bill establishes a new regulatory framework for and a definition of vaping products that includes substances with and without nicotine and creates two distinct classes of vaping products: those regulated by the new *Tobacco and Vaping Products Act* (“recreational” vaping products), and those regulated by the *Food and Drugs Act* that are

³ For more information on the gateway theory and e-cigarettes, consult the NSRA/SHAF March 2018 document, E-Cigarette Research Update. <https://nsra-adnf.ca/wp-content/uploads/2018/04/e-cig-research-update-march-2018-final.pdf>

⁴ Ibid.

⁵ Etter JF. E-cigarettes and the obsolescence of combustion. Expert Review of Respiratory Medicine, March 2018. <https://doi.org/10.1080/17476348.2018.1453809>

manufactured and sold for the treatment of nicotine dependence and for which health claims can be made (therapeutic vaping products). Health Canada has stated that the Bill aims to strike a balance between protecting youth and others from development of nicotine addiction and allowing adults to legally access vaping products as less harmful alternatives to tobacco use. For a more thorough analysis of *Bill S-5*, along with background information on what the legislation is meant to accomplish, consult the NSRA/SHAF 2017 document entitled [A New Legislative Framework for E-Cigarettes in Canada](#). Many of the specific details of *Bill S-5* will be confirmed via regulation, which will be published after the Bill receives Royal Assent. In the interest of time, Health Canada consulted⁶ Canadians on proposed regulations for vaping products in the fall of 2017, after the Standing Senate Committee on Social Affairs, Science and Technology had amended the Bill in May 2017, but before it was studied, amended and passed by the Standing Committee on Health in March 2018.

Bill S-5: Key vaping product-related amendments

1. Regulatory authority established for advertising and promotion

This amendment is important for ensuring that the government can control, via regulations, how vaping products are advertised and promoted. Having regulatory authority enables the government to strike a balance by permitting certain forms of advertising and promotion to maximize the potential of switching large numbers of Canadian smokers to less harmful products, while also prohibiting or restricting other forms deemed to have a high likelihood of being seen by youth, such as internet and television advertising.



2. A prohibition on lifestyle advertising in publications that are addressed and sent to named adults and in places where young persons are not permitted by law

This amendment, which was strongly supported by health groups, is critically important for ensuring that vaping products are recognized by Canadians as less harmful alternatives for addicted smokers and not regarded as the next must-have lifestyle accessory for everyone, especially young people and non-smokers.

3. Regulatory authority established to make health claims and comparative statements about vaping products

Health Canada has established an expert advisory panel to review the latest scientific information on vaping products and to advise on the creation of relative risk statements.

The initial ban on relative risk statements was a primary concern with *Bill S-5*; it is important for smokers to receive potentially life-saving information about the relative risks of e-cigarettes compared to combustible cigarettes. Note that this amendment relates to “recreational” products—although *Bill S-5* preserves a path to market for therapeutic products for which health claims can be made, the barriers may be too great for companies to seek market authorization; thus there may only be non-therapeutic products on the market for the foreseeable future. Furthermore, not all smokers appreciate a medical model for cessation; access to relative risk and health information for recreational e-cigarettes will hopefully facilitate greater public awareness and uptake among smokers who would not otherwise have sought out a therapeutic product to help them cut down or quit smoking.

⁶ Health Canada. Proposals for the Regulation of Vaping Products: Document for Consultation. August 2017. <https://www.canada.ca/content/dam/hc-sc/documents/programs/consultation-regulation-vaping-products/pub1-eng.pdf>

4. Regulatory authority established to give or offer to give a vaping product

Two randomised control trials have already established that e-cigarettes are as effective as nicotine replacement therapy. If/when future evidence confirms the cessation effectiveness of e-cigarettes, it will be useful for health professionals and cessation counsellors to be able to provide free samples for their clients, even if the only products available on the market are non-therapeutic.

5. An exemption for vaping products from the *Consumer Chemicals and Containers Regulations, 2001*

In its consultation document, Health Canada proposed that vaping liquids containing between 10 mg/ml and 66 mg/ml of nicotine be sold in child-resistant containers in accordance with the *CCCR, 2001*. NSRA/SHAF, along with other stakeholders, pointed out that this requirement would essentially amount to a de facto ban on open system (tank style) vaping devices, which would be regulated as containers.⁷ These devices deliver nicotine more effectively than many other types of e-cigarettes and offer real promise for moving large numbers of smokers away from cigarettes. This amendment to exempt vaping products from the *CCCR, 2001* is good public policy: to effectively ban open system devices via over-regulation would be a terrible unintended outcome for tobacco harm reduction efforts. 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. Also note that cigarettes are exempt from the *Canada Consumer Product Safety Act* and its regulations; this exemption creates a more level playing field for e-cigarettes to compete with cigarettes.

6. A requirement for a review of the Act every two years with a report to be tabled in each House of Parliament

Science and technology are changing quickly—it makes sense for the Act to be reviewed regularly to ensure that it does not become obsolete and continues to achieve its intended goals.

Regulating e-cigarettes as cessation aids

Health Canada has stated that it is exploring options regarding the regulation of therapeutic vaping products under the *Food and Drugs Act*. It is important that therapeutic vaping products (for which health claims can be made) be available to Canadians: benefits include potential endorsements from doctors and other health care professionals, potential inclusion on provincial drug formularies, and coverage under private health insurance plans. NSRA/SHAF has voiced concerns regarding the risk of heavy-handed regulation that could prohibit therapeutic vaping products coming to market in Canada.⁸ In this respect the UK has taken a “light touch” regulatory approach: the Medicines and Healthcare products Regulatory Agency (MHRA) welcomes abridged applications in relation to safety and efficacy by allowing comparative studies in which the new product can be compared with an appropriate reference medicinal product such as the Nicorette Inhaler. In the interest of tobacco harm reduction and recognizing that it is difficult to demonstrate the long-term safety of new vaping products, it has also been recommended that the MHRA grant short-term licences. Such flexibility and creativity are needed in Canada to encourage innovation and to facilitate a more level playing field for small companies to effectively compete alongside Big Tobacco, Big Pharma and perhaps even Big Tech.

⁷ Non-Smokers' Rights Association. Proposals for the Regulation of Vaping Products. 19 October 2017. <https://nsra-adnf.ca/wp-content/uploads/2018/03/nsra-s-5-vaping-products-regulations-submission-final.pdf>

⁸ Ibid

Provincial regulation: a tobacco harm reduction approach is needed

Eight Canadian provinces have passed legislation regulating the sale of e-cigarettes and their use in public places and workplaces. Quebec, New Brunswick, Nova Scotia, Prince Edward Island, and Newfoundland & Labrador all combine vaping with the definition of smoking (PEI even defines aerosol as second-hand smoke), and their smoke-free legislation does not specify that restrictions or prohibitions do not apply to products intended for use in nicotine replacement therapy. Conversely, British Columbia, Manitoba and Ontario keep the terms separate and specify that their smoke-free legislation does not apply to products intended for use in nicotine replacement therapy. All eight provinces have prohibited the use of e-cigarettes indoors and outdoors where smoking is banned.⁹



NSRA/SHAF does not recommend this “one-size-fits-all” approach, as it fails to recognize and harness the potential public health benefits of vaping products in steering Canadians away from combustible tobacco. A tobacco harm reduction approach is needed that would apply restrictions concomitant with the degree of risk inherent in the products. Blanket prohibitions against vaping in all environments, particularly *outdoors* where people are not crowded together, are excessively precautionary and implicitly send the wrong message to Canadians about the risks posed by exposure to second-hand vapour.¹⁰ However, NSRA/SHAF recognizes that Canadians currently enjoy clean indoor air in enclosed workplaces and public places, and acknowledges that permitting vaping in these environments would

unnecessarily introduce pollutants, albeit at significantly-reduced levels compared with second-hand smoke.

One exception to this statement is the need to permit the testing of vaping products in specialty vape shops. There is a global scientific consensus that vaping is significantly less harmful than smoking. Policy measures should therefore promote and facilitate the use of vaping products by current smokers. Evidence also indicates that vaping devices, particularly later generation models, can be at least as effective as nicotine replacement therapy in helping smokers stop smoking. To help encourage the transition from smoking to vaping, smokers need to see and be shown the technology, to handle the products, and to test different devices and e-substances to find a combination that can meet their particular needs. This is best done in an adults-only specialty vape store, where knowledgeable and trained staff can assist customers to navigate the wide variety of product options. British Columbia and Manitoba are currently the only provinces that permit in-store testing for customers, although it has been proposed in Ontario. To help mitigate risks for staff and customers, NSRA/SHAF recommends that testing (inhalation) be permitted by customers only and be limited to a specified number of customers at a time and that regulations be developed to minimize risk of communicable diseases.

⁹ Non-Smokers' Rights Association/Smoking and Health Action Foundation. Provincial/Territorial E-Cigarette Legislation in Canada. March 31, 2018. For more detailed information, consult the NSRA database of smoke-free laws.

<https://database.nonsmokersrights.ca/>

¹⁰ Non-Smokers' Rights Association/Smoking and Health Action Foundation. E-Cigarette Update: Secondhand Vapour. March 2017. https://nsra-adnf.ca/wp-content/uploads/2017/04/e-cig_update_3-secondhand_vapour_2017-final.pdf

In outdoor places where people are likely to be forced into close proximity with one another, such as on patios and around entrances and exits of enclosed public places and workplaces, it makes sense to prohibit vaping so that aerosol isn't being blown into bystanders' faces, even if the health effects of breathing second-hand vapour have not been confirmed. NSRA/SHAF also supports a prohibition on the use of e-cigarettes in other locations such as on children's playgrounds and within sporting areas. However, given the lack of evidence regarding the health risks of exposure to second-hand vapour indoors let alone outdoors, and given the enormous potential public health benefits from switching smokers to e-cigarettes, it is the position of NSRA/SHAF that vaping should be permitted in certain outdoor locations, giving vaping a significant advantage over smoking. These outdoor locations should include parks; within 20 metres of playgrounds; in public areas within 9 metres of sporting areas and adjacent spectator areas; on hospital campuses, 9 metres away from building entrances, exits and operable windows; and on the outdoor grounds of certain Ontario government office buildings, 9 metres away from entrances, etc. These recommendations are consistent with the evidence, as to date there is no credible demonstration of a gateway effect, nor of vaping leading to a renormalization of smoking.

Vaping on hospital campuses

As of 1 January 2018, every hospital campus in Ontario must be 100% smoke-free with no outdoor designated smoking areas. The government has also proposed that they be 100% vape-free.

However, the "Ottawa Model," a best practice for hospital-based smoking cessation, is not yet in place across the province. Despite the fact that 20% of general hospital beds are occupied by current smokers, the routine provision of interventions for tobacco dependence in Ontario hospitals is not yet a practice norm. Even when it does become a practice norm, which could still be years away, the Ottawa Model will not necessarily reach or benefit all patients who smoke.

Not all patients are necessarily prepared to quit upon arrival at the hospital; being permitted the use of a vapour product on hospital property could help some patients manage their nicotine withdrawal symptoms for the duration of their stay and could even catalyze a later quit attempt.

Municipal smoke-free bylaws

There are dozens of municipal smoke-free bylaws in Canada, including 14 in Ontario, that include vaping in the definition of smoking and that prohibit the use of e-cigarettes in areas that go beyond provincial legislation—most often outdoors on municipal property, in parks, on playgrounds, and at sports and recreational fields and facilities.¹¹ As previously stated, it is not in the best interest of public health to define vaping as smoking and to uniformly ban the use of e-cigarettes everywhere that smoking is prohibited. This sends the wrong message to Canadians about their relative risks and will negatively impact their uptake by smokers.

¹¹ Non-Smokers' Rights Association. Smoke-Free Laws Database. 28 March 2018. <https://database.nonsmokersrights.ca>

Conclusion

The NSRA prides itself on objective, evidence-based policy analysis and has come to these conclusions after careful analysis. While we recognize and appreciate the challenges posed by the current incomplete body of evidence on e-cigarettes, we are encouraged that there is international consensus that e-cigarettes are less harmful than tobacco cigarettes. Canadians, and especially smokers, have a right to receive accurate and objective information about e-cigarettes with which they can make decisions that affect their health. Unfortunately, reduced-harm messages are being lost in the noise of low quality scientific studies, sensationalist headlines in the media, blanket prohibitions against vaping in all environments, and ideological biases.



We do not need to wait decades until there is absolute clarity on the degree of reduced risk, nor until the cessation effectiveness of e-cigarettes is confirmed via randomised control trials. The Cochrane Collaboration has already established that e-cigarettes (obsolete “cig-a-likes”, no less) are as effective as NRT and that the short-term health effects are minimal.¹² While there will be long-term health effects associated with e-cigarette use and some uptake among youth and non-smokers, these risks will be outweighed by the significant public health gains to be made by shifting large numbers of smokers away from

combustible cigarettes. It is incumbent upon governments to balance potential risks and benefits. Health Canada has committed to less than 5% tobacco use by 2035; this goal will not realistically be reached without tobacco harm reduction policies that harness the potential of e-cigarettes.

¹² Cochrane Tobacco Addiction Review Group. Written evidence submitted to the UK Parliament Science and Technology Committee inquiry into the health, regulatory and financial implications of e-cigarettes.

<http://data.parliament.uk/writtenevidence/committeeevidence.svc/evidencedocument/science-and-technology-committee/ecigarettes/written/75240.pdf>