

Policy Options for the Regulation of Electronic Cigarettes

A consultation document

Citation: Ministry of Health. 2016. *Policy Options for the Regulation of Electronic Cigarettes: A consultation document*. Wellington: Ministry of Health.

Published in August 2016
by the Ministry of Health
PO Box 5013, Wellington 6140, New Zealand

ISBN 978-0-947515-43-0 (online)
HP 6458

This document is available at health.govt.nz



MANATŪ HAUORA



This work is licensed under the Creative Commons Attribution 4.0 International licence. In essence, you are free to: share ie, copy and redistribute the material in any medium or format; adapt ie, remix, transform and build upon the material. You must give appropriate credit, provide a link to the licence and indicate if changes were made.

Contents

Overview	v
Introduction	1
Purpose	1
Context	1
Scope of this paper	2
How to have your say	2
Background	3
What are e-cigarettes?	3
Evidence on the effects of using e-cigarettes	3
The current situation	5
The Ministry of Health’s position	5
The regulatory framework	5
What is the problem with the status quo?	7
Enforcement	7
Promotion to young people	7
Product safety and quality control	8
The impact of vaping on others	8
The need for future-proofing legislation	8
Illicit drug use	9
Potential environmental impacts	9
Tobacco industry involvement	9
What are other countries doing?	10
Policy objectives	11
Reduction of harm from tobacco smoking	11
Prevention of harm from e-cigarettes	12
Product safety	12
Considering change – proposals for consultation	12
Next steps	14
Consultation submission	15
Consultation questions	17

Overview

Electronic cigarettes (e-cigarettes) are a relatively new and evolving product. Currently, the sale and supply of nicotine e-cigarettes are prohibited, while smoked tobacco, which is more harmful for users, can be sold legally. Users obtain nicotine e-cigarettes through importation and illegal local sales. The existing provisions for the regulation of e-cigarettes, found primarily in the Smoke-free Environments Act 1990 (SFEA) and the Medicines Act 1981, are not adequate. The legal status of e-cigarettes is currently confusing and, as a consequence, the laws are not routinely enforced.

The risks and benefits of e-cigarettes are uncertain. There is a lack of clarity about long-term health risks to users and the potential adverse effects on non-users exposed to e-cigarette vapour. It has been suggested that the availability of these products could undermine current tobacco control initiatives. There is ongoing scientific debate about whether e-cigarettes are an effective tool for smokers who want to quit. At the same time, there is general scientific consensus that the exclusive use of e-cigarettes is significantly less harmful than smoking. There is emerging evidence that e-cigarette use may substantially reduce the burden of disease caused by smoking.

The Ministry of Health is now consulting on policy options for the regulation of e-cigarettes, including possible amendments to the SFEA. This consultation aims to clarify the legal position. Proposed amendments would mean that all e-cigarettes (with and without nicotine) would be available for sale and supply lawfully in New Zealand, but sale of e-cigarettes would be restricted to people 18 years of age and over, advertising of e-cigarettes would be restricted and the use of e-cigarettes would be prohibited in areas defined as smokefree in the SFEA.

The Ministry also seeks your feedback on whether other controls currently in place under the SFEA for smoked tobacco products should be applied to e-cigarettes and whether there is a need for quality control and product safety.

After the public consultation on the proposals presented in this paper, the Ministry will develop precise regulatory proposals and report back to Cabinet by the end of this year.

This paper contains a consultation submission form to guide your submission; it includes specific questions.

Introduction

Purpose

This paper seeks public input on proposals to change the way electronic cigarettes (e-cigarettes)¹ are regulated.

After considering evidence and concerns about e-cigarettes, the Government has agreed in principle to nicotine e-cigarettes being legally available for sale and supply in New Zealand, with appropriate controls and for the Ministry of Health to consult on possible legislative amendments.

This paper uses the term e-cigarettes to capture both vapouriser devices and their liquids and refill cartridges, which may or may not contain nicotine. People use e-cigarettes to inhale the vapour (that is, to 'vape').

Context

Tobacco use is a leading modifiable health risk factor (that is, a factor causing preventable death and disease) in New Zealand, accounting for around 4500–5000 deaths per year. Tobacco is the only legal consumer product that, when consumers use it as manufacturers intend, kills over half its users.

The 2013 Census and the New Zealand Health Survey of 2012/13 reported rates of daily smoking in the adult population over 15 years of age to be 15.1 percent and 15.5 percent respectively.

Overall, the rate of daily smoking among men is generally higher than the rate of daily smoking among women (according to the New Zealand Health Survey 2012/13, rates at that time were 16.1 percent and 13.9 percent respectively). The daily smoking rate among Māori is higher than that among the total population (New Zealand Health Survey 2012/13 rates were 35.5 percent and 15 percent respectively), and more Māori women smoke daily than Māori men (New Zealand Health Survey 2012/13 rates were 40 percent and 30.5 percent respectively).

Recently, the rate of tobacco consumption nationally has fallen. After falling gradually between 2000 and 2008 (generally hovering around 1000 cigarette equivalents per person over 15 years age per year), it dropped from 861 cigarette equivalents in 2010 to 667 in 2014: a decrease of approximately 23 percent. The sale of all types of tobacco products – manufactured cigarettes, roll-your-own cigarettes, cigars and pipe tobacco – is in decline.

Smoking prevalence and tobacco consumption are in decline, but rates remain higher among Māori, Pacific people, young adults and socioeconomically disadvantaged populations. Those communities bear a disproportionate burden of smoking-related illness and death.

¹ Research and policy documents variously refer to e-cigarette products as electronic nicotine delivery systems (ENDS), alternative nicotine delivery systems (ANDS) and personal vapourisers. Such products may be marketed as e-shisha, e-hookahs, pens or vapes, among other labels.

Scope of this paper

This paper discusses nicotine and nicotine-free e-cigarette products, evidence on these products, concerns about their use and current regulation (primarily through the Medicines Act 1981 (Medicines Act) and Smoke-Free Environments Act 1990 (SFEA)) and possible amendments to the SFEA. It does not propose amendments to the Medicines Act, meaning that e-cigarette manufacturers would still be able to apply to register their products as medicines for smoking cessation.

How to have your say

Your views are important. Please take the time to make a submission on this paper. You can make a submission by filling out the questions in the submission form at the back of this document (under the heading 'Consultation submission') and emailing the form to: **ecigarettes@moh.govt.nz**

If you are sending your submission in PDF format, please also send us the Word document.

In making your submission, please include or cite relevant supporting evidence if you are able to do so.

All submissions are due with the Ministry by **5 pm, Monday 12 September 2016**. The Ministry will not include any submissions received after this time in its analysis of submissions.

Background

What are e-cigarettes?

E-cigarettes are electrical devices that mimic smoked tobacco products but produce a vapour (rather than smoke) by heating a solution (e-liquid) that the user inhales. The term ‘vaping’ describes the use of e-cigarettes.

E-liquids are available with or without nicotine. They usually contain flavouring agents. There are many different flavourings available; the most popular among adults in the United Kingdom are tobacco, fruit and mint/menthol.²

E-cigarettes have been available on the international market since 2005. At first, most e-cigarettes looked like smoked cigarettes; later, they evolved into a range of products. In general, first-generation products look similar to cigarettes; second-generation products are refillable tank systems; and third-generation products are devices with large batteries and adjustable power.

First generation



Second generation



Third generation



Evidence on the effects of using e-cigarettes

Nicotine is a widely used addictive substance, which has a psychoactive effect and can be lethal in large quantities.³

On the other hand, the long-term use of small quantities of nicotine in approved nicotine replacement therapy (NRT) products (such as gum, patches or lozenges) is considered to be safe.

² Action on Smoking and Health. 2016. Use of electronic cigarettes (vapourisers) among adults in Great Britain. URL: www.ash.org.uk/files/documents/ASH_891.pdf (accessed 8 July 2016).

³ The medium lethal dose is estimated to range between 6.5 and 13 mg/kg.

Ref: Mayer B. How much nicotine kills a human? Tracing back the generally accepted lethal dose to dubious self-experiments in the nineteenth century. *Arch Toxicol*. 2014 Jan; 88(1):5–7. DOI: 10.1007/s00204-013-1127-0 (Epub 4 October 2013).

The scientific consensus is that using e-cigarettes poses less health risks to smokers than continuing to smoke and that short-term use is associated with few adverse effects. People often report that they vape because they want to reduce the harm from smoking tobacco.

A 2014 Cochrane Review on the use of e-cigarettes as a tool for smoking cessation and reduction found that the quality of the evidence overall is low and only based on two randomised control trials.⁴ The Review concluded that e-cigarettes containing nicotine appear to help smokers quit smoking but that further studies are required to reach conclusive results about their effectiveness.

In 2015, Public Health England commissioned and published an expert review report called *E-cigarettes: an evidence update*.⁵ This concluded that e-cigarettes are significantly less harmful to health than smoked tobacco and have the potential to help smokers quit smoking.

The Royal College of Physicians published their report *Nicotine without Smoke: Tobacco harm reduction*⁶ earlier this year. This report provides a fresh update on the use of all nicotine products that are not smoked, and in particular e-cigarettes, as a tool to reduce harm from tobacco smoking. It concludes that, for all the potential risks involved, a complete switch to e-cigarettes has significant potential to prevent death and disability from tobacco use and to hasten progress towards a tobacco-free society.

Mild adverse effects such as headaches, dry mouth or throat, throat or mouth irritation, dry cough or nausea have been reported by some users. The Cochrane Review found no serious adverse effects in trials as a result of short- to mid-term electronic cigarette use. However, smoking, even at a reduced level, remains harmful for smokers.⁷

In summary, there is emerging evidence that, if smokers switch completely to e-cigarettes, these products pose less health risks to them than smoked tobacco but there is not yet enough data to confidently recommend these as a smoking cessation tool.

⁴ McRobbie H, Bullen C, Hartmann-Boyce J, et al. Can electronic cigarettes help people stop smoking or reduce the amount they smoke, and are they safe to use for this purpose? *Cochrane Database Syst Rev* 2014, Issue 12, Art. No. CD010216. DOI: 10.1002/14651858.CD010216.pub2 (accessed 8 July 2016).

⁵ McNeill A, Brose LS, Calder R, et al. 2015. *E-cigarettes: An evidence update. A report commissioned by Public Health England*. London: Public Health England. URL: www.gov.uk/government/uploads/system/uploads/attachment_data/file/457102/E-cigarettes_an_evidence_update_A_report_commissioned_by_Public_Health_England_FINAL.pdf (accessed 8 July 2016).

⁶ Royal College of Physicians. 2016. *Nicotine without Smoke: Tobacco harm reduction*. London: Royal College of Physicians. URL: www.rcplondon.ac.uk/projects/outputs/nicotine-without-smoke-tobacco-harm-reduction-o (accessed 8 July 2016).

⁷ Tverdal A, Bjartveit K. 2006. Health Consequences of Reduced Daily Cigarette Consumption. *Tobacco Control* 15(6): 472–80.

The current situation

The Ministry of Health's position

The Ministry of Health has to date taken a precautionary approach and advised that there is not yet enough evidence to be able to recommend e-cigarettes as an aid to stop smoking. The Ministry advises smokers to use approved smoking cessation medicines, such as NRT, to stop smoking and to seek behavioural support from stop-smoking services, such as Quitline.

The Ministry monitors emerging research and is developing guidance for health professionals and stop-smoking support workers on how to support smokers who want to use e-cigarettes to quit smoking.

Under the Medicines Act, only medicines approved by Medsafe can be sold for smoking cessation support in New Zealand. At this time, no company has met the requirements under that Act to have an e-cigarette approved to support smokers to quit.

The regulatory framework

The regulatory regime in New Zealand covering e-cigarettes and e-liquids, primarily comprising the SFEA and the Medicines Act, was developed before the emergence of these products and regulates their sale, advertising and use.

The sale and supply of e-cigarettes in New Zealand is currently unlawful if:

- the product contains nicotine derived from tobacco (this is a breach of the SFEA, which regulates the sale, supply and advertising of tobacco products and prohibits the sale or distribution of 'oral tobacco products' that are not smoked)
- the product contains nicotine and has not been approved for supply by Medsafe (this is a breach of the Medicines Act, which controls nicotine as a scheduled medicine; note that the Medicines Act does allow medical practitioners to prescribe unapproved products, including e-cigarettes)
- the producer or supplier makes therapeutic claims about their products (whether or not they contain nicotine) (for example, that they assist with smoking cessation) if they do not have a Medsafe approval for therapeutic use (this is a breach of the Medicines Act).

The SFEA provides that products that look like smoked tobacco products (that is, toy tobacco products) and that can be used to simulate smoking, must not be sold to persons under 18 years of age. Apart from this restriction, nicotine-free e-cigarettes can be sold freely in New Zealand.

The SFEA does not prohibit the use of e-cigarettes in smokefree areas. However, organisations and/or workplaces can prohibit the use of e-cigarettes as part of their own smokefree policies. For example, the use of e-cigarettes is currently prohibited by Air New Zealand and in Wellington City Council's smokefree areas.

Under the Medicines Act and the SFEA, people can import nicotine-containing e-cigarette products to use personally as a smoking cessation tool but cannot supply them, sell them or give them away to anyone else.

The Government has agreed to repeal and replace the Medicines Act with a comprehensive and modern therapeutic products regulatory regime. This regime will regulate medical devices for therapeutic use. Under the new regime, e-cigarettes for therapeutic use would need to meet standards for safety, quality and efficacy under this regime, just as they do now.

Legislation other than the SFEA and the Medicines Act applying to the advertising, selling and distribution of e-cigarettes includes the Consumer Guarantees Act 1993, the Hazardous Substances and New Organisms Act 1996 (HSNO) and the Customs and Excise Act 1996. For example, nicotine is classed as a hazardous compound under the HSNO, and this Act specifies recording and handling requirements for it, particularly in bulk. Certain provisions in the Fair Trading Act 1986 relevantly regulate consumer products through consumer information standards, product safety standards and unsafe goods notices (which can be issued to ban dangerous products).

What is the problem with the status quo?

Currently, the sale and supply of nicotine e-cigarettes is prohibited, while the sale and supply of tobacco for smoking is legal, even though evidence shows that smoking tobacco is more harmful for users than using e-cigarettes.

However, some have expressed wider concerns about e-cigarettes, including the difficulty of enforcing the law, the promotion of products to young people and non-smokers, product safety and quality control, the impact of vaping on others, the need for future-proofing legislation of e-cigarettes, the association of e-cigarette products with illicit drug use, the potential environmental impacts of e-cigarettes and the increasing role of the tobacco industry in the manufacture of e-cigarettes. The remainder of this section discusses these issues in more detail.

Enforcement

There is anecdotal evidence that illegal sales of nicotine e-cigarettes and nicotine e-liquid on the local market are increasing and that the number of retailers and suppliers importing, supplying, selling and promoting nicotine e-products is rising.

Due to the lack of clarity on the legal position of e-cigarettes (including the lack of clarity of legal definitions and what constitutes adequate evidence of a breach of the law), the Ministry has been unable to carry out enforcement actions against retailers.

Promotion to young people

There is some overseas evidence of promotion of e-cigarettes targeting young people. Some have raised concerns that certain e-cigarette flavours (such as chocolate, strawberry and mint) may particularly appeal to young people. Anecdotal evidence and survey data show that nicotine and nicotine-free e-cigarettes are being sold to minors overseas and in New Zealand.

There is also evidence of an increase in New Zealand of young people trying e-cigarettes, as follows.⁸

- A 2014 survey found an increase in the percentage of Year 10 students who had tried e-cigarettes, from 7 percent in 2012 to 20 percent in 2014.⁹
- In another 2014 survey, 21 percent of students reported having tried an e-cigarette (most of them were non-smokers).

⁸ It is important to note that survey questions in general did not make the distinction between nicotine and non-nicotine e-cigarettes; the relative consumption of these products is unknown.

⁹ White J, Li J, Newcombe R, et al. 2015. Tripling use of electronic cigarettes among New Zealand adolescents between 2012 and 2014. *Journal of Adolescent Health* 56(5): 522–8.

There have been claims that young people's experimentation with and more regular use of e-cigarettes is likely to lead to nicotine addiction or have a gateway effect (that is, lead to them taking up smoking). So far this has not been borne out by evidence, but there is a need to monitor survey data.

Product safety and quality control

There are no health and safety or quality controls for e-cigarettes available on the local market or from internet sales, which may put users and children who might access these products at risk. Specifically:

- there are no restrictions on the level of nicotine content or other potentially harmful ingredients e-cigarettes may contain
- labelling of product content is inconsistent; it is sometimes lacking or inaccurate
- there is no requirement for health warnings on products about the potential risks of vaping during pregnancy, the risk of accidental nicotine poisoning and the need to keep products out of reach of children
- there is no requirement for products to come in child-proof containers to prevent accidental poisoning.

The impact of vaping on others

There is agreement that the impact on others from second-hand vapour poses significantly less health risks than from smoking. However, there is insufficient evidence to assess the impact of this type of second-hand exposure; ongoing concern remains.

There are concerns that the increasingly visible use of e-cigarettes may increase the risk of making smoking behaviour seem normal again and initiation to smoking, especially among young people. These concerns are an area of debate; ongoing monitoring is necessary.

E-cigarette vapour can produce vaping clouds and aromas that may be a nuisance to others, especially in enclosed spaces.

The need for future-proofing legislation

There has been considerable innovation in the production of e-cigarettes since they first appeared on the market; this is expected to continue. E-cigarettes themselves are an example of innovation in the area of alternative nicotine products. Other consumer nicotine products are currently available on the global market,¹⁰ and there are likely to be future innovations. New Zealand regulators need to consider developing and implementing regulatory controls that, as far as possible, are fit for purpose in this changing environment.

¹⁰ See, for example: www.pureniccino.com

Illicit drug use

Overseas media have occasionally reported on e-cigarettes being used for illicit drugs such as cannabis and methamphetamine. This has been raised as a concern in New Zealand.

Currently, any device or utensil re-purposed or modified as a tool with which to take drugs could become regulated as a drug utensil under the Misuse of Drugs Act. The Misuse of Drugs (Prohibition of Cannabis Utensils and Methamphetamine Utensils) Notice 2014, issued under the Misuse of Drugs Act, identifies such products and prohibits them for sale, supply or import.

The Government is currently reviewing the regulation of drug utensils to ensure they further the goals of the National Drug Policy 2015–2020 in a separate process. The Ministry of Health will publish a discussion document – *Review of Drug Utensils Regulation* – on its website, seeking views on the use of drug utensils to consume illicit drugs.

Potential environmental impacts

There is limited information on the environmental impacts associated with the production, use and disposal of e-cigarette devices and their liquid. As the use of e-cigarettes increases, the potential chemical waste (comprising lead and nicotine, among other substances) and electronic waste (comprising batteries and devices) may become problematic. There are currently no legislative disposal requirements for these products.

Tobacco industry involvement

There are indications that tobacco industry involvement in the production and marketing of e-cigarettes has been increasing over the last few years.¹¹ There is no information currently available to quantify the current market share.

New Zealand is a party to the World Health Organization Framework Convention on Tobacco Control (WHO FCTC). A report on e-cigarettes to the sixth WHO FCTC Convention of Parties in 2014 included observations and considerations of the role of the tobacco industry and expressed concern about their growing involvement.¹²

¹¹ See, for example: Tobacco Control Research Group. 2014. *Tobacco Industry's Investment in Non-cigarette Nicotine Products*. Bath: University of Bath. URL: www.tobaccotactics.org/images/3/3b/Ecig_investment_timeline_Sept_2014.pdf (accessed 8 July 2016).

¹² WHO. 2014. *Electronic Nicotine Delivery Systems*. Geneva: World Health Organization. URL: http://apps.who.int/gb/fctc/PDF/cop6/FCTC_COP6_10Rev1-en.pdf?ua=1 (accessed 8 July 2016).

What are other countries doing?

Generally, overseas jurisdictions have applied their existing legislation to regulate e-cigarettes, resulting in differing positions on e-cigarettes. Some ban them from sale. Some regulate them as medicines, some as tobacco products and some as consumer products. Others have very little regulation at all.

Policy objectives

The Ministry of Health is considering the regulatory framework for e-cigarettes against the following policy objectives:

- reduction of harm from tobacco smoking
- prevention of harm from e-cigarettes
- product safety.

The rest of this section discusses these objectives in more detail.

Reduction of harm from tobacco smoking

Because of the lack of data, it has been difficult to assess the potential contribution of e-cigarettes to reducing harm from tobacco smoking and the potential contribution these products could make towards the Government's goal of Smokefree 2025. Emerging data from the United Kingdom and Europe could inform policy decisions in New Zealand. For example, a recent English report estimated that 2.5 percent of smokers who used an e-cigarette in their quit attempt (22,000 people) succeeded where they would have failed if they had used nothing or a licensed nicotine product bought (similar to NRT in New Zealand) from a shop.¹³

The current evidence on the potential of e-cigarettes to reduce harm from tobacco smoking is discussed under the heading 'Evidence on the effects of using e-cigarettes'.

The health effects (positive or negative) of the dual use of e-cigarettes and smoked tobacco products are less clear. There is no long-term population data available to help us understand whether e-cigarette products help, delay or hinder dual users to quit smoking, although emerging evidence shows that they may be useful in helping smokers to quit.

A recent blog on the University of Otago's Public Health Expert advises that 'the safest option for smokers using vaping to reduce their health risk would be to limit the duration of dual use with cigarette smoking (ie, switching completely to vaping as soon as possible'. The blog recommends that vapers 'limit the total duration of vaping with a goal of reaching abstinence from both smoking and vaping, wherever possible without relapsing to smoking, which represents the greater risk to health'.¹⁴

¹³ West R, Shahab L, Brown J. 2016. Estimating the population impact of e-cigarettes on smoking cessation in England. *Addiction* 111(6): 1118–9. DOI: 10.1111/add.13343 (accessed 8 July 2016).

¹⁴ Wilson N, Gartner C, Edwards R. 2016. What does recent biomarker literature say about the likely harm from e-cigarettes? *Public Health Expert Blog*. URL: <https://blogs.otago.ac.nz/pubhealthexpert/> (accessed 8 July 2016).

Prevention of harm from e-cigarettes

The evidence about the potential health harms of e-cigarettes to the wider public is inconclusive because of a lack of data. Such potential harms are discussed above under the heading ‘What is the problem with the status quo?’

Concerns have been expressed about promoting e-cigarettes to young people and the potential risks that vaping in public places poses to both the objectives and enforcement of the SFEA.

There is some overseas evidence to suggest that advertising of e-cigarettes may be targeting young people. Data shows that the number of young people experimenting with e-cigarettes is growing, and some researchers have suggested that e-cigarettes may act as a gateway to smoking for young people or create a generation addicted to a different type of nicotine-containing product.

Despite the lack of scientific certainty, it may be warranted to apply a precautionary approach to regulating e-cigarettes. This could be achieved by applying the provisions of the SFEA for smoked tobacco products – prohibiting sales to minors, restricting advertising and preventing use in areas designated smokefree under the SFEA – to e-cigarettes.

Product safety

Concerns relating to the long-term risks of using e-cigarettes and the health effects of second-hand exposure to e-cigarette vapour relate to:

- the long-term effects of e-liquids – especially vapourised nicotine, propylene glycol and vegetable glycerine – on users
- the safety of some e-liquid flavours for inhalation
- the effects of e-cigarettes on pregnant women and their foetuses, infants and children, young people, and people with respiratory and chronic illness.

A lack of standards and regulations for the manufacture and labelling of e-cigarettes means that there are risks of:

- users unknowingly ingesting nicotine from products that are incorrectly labelled as nicotine-free or that do not list nicotine as an ingredient
- users ingesting more nicotine than they think they are ingesting because of unreliable descriptions of nicotine content¹⁵
- children being poisoned by e-cigarette products due to a lack of warning about the dangers to children on packaging or a lack of child-proof packaging.

Considering change – proposals for consultation

Given the lack of available evidence on the topic, the Ministry of Health proposes to make legislative changes that will maximise the potential benefits of e-cigarettes and minimise potential risks to smokers and to the wider population. The remainder of this section outlines the Ministry’s proposals.

¹⁵ Cheng T. 2014. Chemical evaluation of electronic cigarettes. *Tobacco Control* 23: 11–17.

The Ministry notes that suppliers of e-cigarettes who wish to market them for smoking cessation purposes can, under the existing legislation, seek an approval from Medsafe. Medsafe bases approval on an assessment of the evidence on the safety and efficacy of particular products. The control under the Medicines Act on the use of e-cigarettes as a therapeutic product (that is, for smoking cessation) will remain in place.

The Ministry proposes to amend the SFEA to make nicotine e-cigarettes lawful as a consumer product and to regulate all e-cigarettes in a way similar to that by which smoked tobacco products are regulated. That is, the proposed amendments would prohibit:

- the sale and supply of e-cigarettes to children and young people under 18 years of age
- advertising of e-cigarettes
- the use of e-cigarettes in areas designated smokefree under the SFEA.

The Ministry is seeking feedback on whether other controls in the SFEA in regard to smoked tobacco should also apply to e-cigarettes; that is:

- the requirement for graphic health warnings
- the prohibition on displaying products in sales outlets
- the restriction on use of vending machines for sales
- the requirement to provide annual returns on sales data
- the requirement to disclose product content and composition
- regulations concerning ingredients (eg, nicotine content and/or flavours)
- the requirement for annual testing of product composition
- the prohibition on free distribution and awards associated with sales
- the prohibition on discounting
- the prohibition on advertising and sponsorship
- the requirement for standardised packaging.

The Ministry seeks your comments on whether e-cigarette liquid containing nicotine should be subject to some form of excise or excise-equivalent duty to financially deter uptake in a similar manner to the way excise duties apply to tobacco products.

The Ministry also seeks your comments on whether regulation of the quality and safety of e-cigarettes as consumer products needs enhancing. For example, regulations could set requirements and standards for:

- the extent to which product containers are childproof
- the safe disposal of e-cigarette devices and liquids
- the safety of devices (eg, in terms of their ability to prevent accidental burns, explosions and spillage)
- good manufacturing practice
- registration of products
- the purity and grade of nicotine in the products
- a testing regime to confirm product safety and quality
- a maximum allowable volume of e-liquid in retail sales
- a maximum concentration of nicotine in e-liquid
- the mixing of e-liquids at (or before) the point of sale.

Next steps

The Ministry of Health will consider advice from submitters before it develops policy and provides advice to the Government.

The Ministry will provide a report to Cabinet towards the end of this year on consultation findings and proposals for specific regulatory changes. Subject to decisions Cabinet takes at that stage, the Government will then amend the legislation.

Consultation submission

Your details

This submission was completed by: *(name)* _____

Address: *(street/box number)* _____
(town/city) _____

Email: _____

Organisation *(if applicable)*: _____

Position *(if applicable)*: _____

(Tick one box only in this section)

Are you submitting this:

- as an individual or individuals (not on behalf of an organisation)?
- on behalf of a group, organisation(s) or business?

(You may tick more than one box in this section)

Please indicate which sector(s) your submission represents:

- Commercial interests, including e-cigarette manufacturer, importer, distributor and/or retailer
- Tobacco control non-government organisation
- Academic/research
- Cessation support service provider
- Health professional
- Māori provider
- Pacific provider
- Other sector(s) *(please specify)*:

(You may tick more than one box in this section)

Please indicate your e-cigarette use status:

- I am using nicotine e-cigarettes.
- I am using nicotine-free e-cigarettes.
- I currently smoke as well as use e-cigarettes.
- I am not an e-cigarette user.
- I have tried e-cigarettes.

Privacy

We intend to publish all submissions on the Ministry's website. If you are submitting as an individual, we will automatically remove your personal details and any identifiable information.

If you do not want your submission published on the Ministry's website, please tick this box:

Do not publish this submission.

Your submission will be subject to requests made under the Official Information Act. If you want your personal details removed from your submission, please tick this box:

Remove my personal details from responses to Official Information Act requests.

If your submission contains commercially sensitive information, please tick this box:

This submission contains commercially sensitive information.

Declaration of tobacco industry links or vested interest

As a party to the global tobacco control treaty, the World Health Organization Framework Convention on Tobacco Control, New Zealand has an obligation to protect the development of public health policy from the vested interests of the tobacco industry. To help meet this obligation, the Ministry of Health asks all respondents to disclose whether they have any direct or indirect links to, or receive funding from, the tobacco industry. The Ministry will still carefully consider responses from the tobacco industry, and from respondents with links to the tobacco industry, alongside all other submissions. Please provide details of any tobacco company links or vested interests below.

Please return this form by email to:

ecigarettes@moh.govt.nz by **5 pm, Monday 12 September 2016.**

If you are sending your submission in PDF format, please also send us the Word document.

Consultation questions

Although this form provides blank spaces for your answers to questions, there is no limit to the length of your responses; you should take as much space as you need to answer or comment. Feel free to enlarge the boxes or attach additional pages.

Q1 Do you agree that the sale and supply of nicotine e-cigarettes and nicotine liquids should be allowed on the local market, with appropriate controls?

Yes No

Reasons/additional comments:

Q2 Are there other (existing or potential) nicotine-delivery products that should be included in these controls at the same time? If so, what are they?

Yes No

Reasons/additional comments:

Q3 Do you think it is important for legislation to prohibit the sale and supply of e-cigarettes to young people under 18 years of age in the same way as it prohibits the sale and supply of smoked tobacco products to young people?

Yes No

Reasons/additional comments:

Q4 Do you think it is important for legislation to control advertising of e-cigarettes in the same way as it controls advertising of smoked tobacco products?

Yes No

Reasons/additional comments:

Q5 Do you think it is important for the SFEA to prohibit vaping in designated smokefree areas in the same way as it prohibits smoking in such areas?

Yes No

Reasons/additional comments:

Q6 Do you agree that other controls in the SFEA for smoked tobacco products should apply to e-cigarettes? For example:

Control	Yes	No	Reasons/ additional comments
Requirement for graphic health warnings	<input type="checkbox"/>	<input type="checkbox"/>	
Prohibition on displaying products in sales outlets	<input type="checkbox"/>	<input type="checkbox"/>	
Restriction on use of vending machines	<input type="checkbox"/>	<input type="checkbox"/>	
Requirement to provide annual returns on sales data	<input type="checkbox"/>	<input type="checkbox"/>	
Requirement to disclose product content and composition	<input type="checkbox"/>	<input type="checkbox"/>	
Regulations concerning ingredients (eg, nicotine content and/or flavours)	<input type="checkbox"/>	<input type="checkbox"/>	
Requirement for annual testing of product composition	<input type="checkbox"/>	<input type="checkbox"/>	
Prohibition on free distribution and awards associated with sales	<input type="checkbox"/>	<input type="checkbox"/>	
Prohibition on discounting	<input type="checkbox"/>	<input type="checkbox"/>	
Prohibition on advertising and sponsorship	<input type="checkbox"/>	<input type="checkbox"/>	
Requirement for standardised packaging	<input type="checkbox"/>	<input type="checkbox"/>	
Other	<input type="checkbox"/>	<input type="checkbox"/>	

Q7 Do you think it is important for legislation to impose some form of excise or excise-equivalent duty on nicotine e-liquid, as it does on tobacco products?

Yes No

Reasons/additional comments:

Q8 Do you think quality control of and safety standards for e-cigarettes are needed?

Yes No

Additional comments:

Area of concern	Yes	No	Reasons/additional comments
Childproof containers	<input type="checkbox"/>	<input type="checkbox"/>	
Safe disposal of e-cigarette devices and liquids	<input type="checkbox"/>	<input type="checkbox"/>	
Ability of device to prevent accidents	<input type="checkbox"/>	<input type="checkbox"/>	
Good manufacturing practice	<input type="checkbox"/>	<input type="checkbox"/>	
Purity and grade of nicotine	<input type="checkbox"/>	<input type="checkbox"/>	
Registration of products	<input type="checkbox"/>	<input type="checkbox"/>	
A testing regime to confirm product safety and contents purity	<input type="checkbox"/>	<input type="checkbox"/>	
Maximum allowable volume of e-liquid in retail sales	<input type="checkbox"/>	<input type="checkbox"/>	
Maximum concentration of nicotine e-liquid	<input type="checkbox"/>	<input type="checkbox"/>	
Mixing of e-liquids at (or before) point of sale	<input type="checkbox"/>	<input type="checkbox"/>	
Other	<input type="checkbox"/>	<input type="checkbox"/>	

Q9 Are there any other comments you would like to make?

Additional information on sales and use

Q10 Can you assist us by providing information on the sale of e-cigarettes in New Zealand (for example, size of sales or range of products for sale on the local market)?

--

Q11 Would the Ministry of Health's proposed amendments have any impact on your business? If so, please quantify/explain that impact.

--

Q12 If you are using nicotine e-cigarettes: how long have you been using them, how often do you use them, how much do you spend on them per week and where do you buy them?

How long have you been using them?	How often do you use them?	How much do you spend on them per week?	Where do you buy them?