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# Regulatory Impact Statement: Regulation of e-cigarettes and emerging tobacco and nicotine-delivery products

## Agency disclosure statement

This Regulatory Impact Statement has been prepared by the Ministry of Health. It provides an analysis of options to regulate e-cigarettes and e-liquid as consumer products, as well as an analysis of high-level options for the regulation of emerging tobacco and nicotine-delivery products.

This work has been commissioned by the Associate Minister of Health, who is responsible for the tobacco control portfolio.

## Framing of the analysis

The context within which this analysis is conducted is that of tobacco control. The New Zealand Government has adopted a Smokefree 2025 goal:

To reduce smoking prevalence and tobacco availability to minimal levels, making New Zealand essentially a smokefree nation by 2025.

## Nature and extent of the analysis

In undertaking this analysis, the Ministry has:

- conducted a review of New Zealand and international evidence and commentary on the risks and benefits of e-cigarettes
- reviewed international regulatory approaches to e-cigarettes and emerging tobacco and nicotine-delivery products, and
- consulted publicly on proposals to regulate e-cigarettes and e-liquid as consumer products, with appropriate controls, as well as on whether there are other products that should be included in these proposed regulatory changes.

## Limits on the options analysed

There are limitations on the extent to which the problem can be accurately defined and the impacts of the proposals assessed and quantified. This reflects a lack of studies showing the long-term benefits and risks of e-cigarette use, for users and the wider population. There is also a lack of information about the e-cigarette market in New Zealand. Much less information exists about other emerging tobacco and nicotine-delivery products.

The literature on e-cigarette use is growing, but at this stage the evidence is not conclusive. It is clear that e-cigarettes are significantly less harmful than smoked tobacco and appears likely that

they can help people to quit smoking. Provided the regulatory controls are robust, the risks, known and theoretical, associated with e-cigarette use can be mitigated.

## **Previous Government decisions**

Cabinet has agreed to retain the requirement that e-cigarettes making a therapeutic claim (eg, for use as a tool to quit smoking) must have a product approval under the Medicines Act 1981 [SOC-16-MIN-0073]. This decision is not revisited in this regulatory impact statement.

At the same time, Cabinet decided in principle that nicotine e-cigarettes should be lawfully available for sale and supply, with appropriate controls. The Ministry of Health was directed to consult the public on the regulation of e-cigarettes as a consumer product, with controls as appropriate under the Smoke-free Environments Act 1990, and to explore the need for regulatory controls on product safety.

## **Further work**

This work is not subject to any particular constraints, for example, whether it must be achieved within a particular budget or timeframe.

A considerable amount of further work, in consultation with stakeholders, would be needed on the detailed development of proposals for the regulation of emerging tobacco and nicotine-delivery products, other than e-cigarettes. Some new devices can be used interchangeably for tobacco and cannabis, and consideration would be given to ensuring that the proposed changes did not inadvertently promote illicit drug use while removing barriers to access to reduced-harm tobacco and nicotine-delivery products.

Legislative change would be needed before any decisions could be implemented. This would be unlikely to be possible before the middle of 2018. Regulations and tertiary legislative instruments, such as guidelines, would also be needed to give effect to some of the more detailed proposals, for example, for product safety and advertising-related regulatory controls.

Work with industry stakeholders and technical experts would be necessary to develop detailed proposals to regulate product safety for e-cigarettes.

Further work would also be needed to consider whether some form of excise or excise-equivalent duty should be placed on nicotine e-liquid.

The Ministry of Health's advice on e-cigarettes and other emerging tobacco and nicotine-delivery products will be kept under review as new evidence emerges.

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# Executive summary

- 1 E-cigarettes are a diverse range of products comprising:
  - a. devices, with or without the e-liquid built in
  - b. e-liquid, which can be sold separately from the devices, is usually flavoured, may or may not contain nicotine, and typically comes in 10ml bottles although larger bottles can be bought.
- 2 **Nicotine** e-cigarettes and e-liquid fall under the Smokefree Environment's Act 1990 and the Medicines Act 1981. Their sale and supply is prohibited, however, users can obtain them through personal importation and local, illegal sales. The legal status of nicotine e-cigarettes and e-liquid is complex and the laws are not routinely enforced due to a lack of clarity and difficulty meeting evidential standards. Sales of nicotine e-cigarettes and e-liquid appear to be increasing, as retailers assess their chances of being prosecuted as low. **Non-nicotine** e-cigarettes are unregulated and able to be sold lawfully. The number of retail outlets selling these products is increasing.
- 3 The risks and benefits of e-cigarettes are uncertain. There is a lack of clarity about long-term product safety, and health risks to users and non-users. It has also been suggested that the availability of these products could undermine tobacco control initiatives. There is, to date, a lack of good quality data on whether e-cigarettes may be another tool for smokers to quit, although this appears likely to be the case. There is, however, scientific consensus that the use of e-cigarettes is significantly less harmful for smokers if they completely switch.
- 4 Given the lack of available evidence that would lead us to definitively conclude how e-cigarettes should be regulated, regulatory changes are proposed to maximise the potential benefits of e-cigarettes and minimise risks, not only to smokers but also the wider population.
- 5 The Ministry's recommendations are to amend the Smoke-free Environments Act 1990 to:
  - a. legalise the sale and supply of nicotine e-cigarettes and e-liquid as consumer products
  - b. regulate both nicotine and non-nicotine e-cigarettes and e-liquid as consumer products under the Smoke-free Environments Act 1990
  - c. continue to regulate e-cigarette products that make a therapeutic claim under the Medicines Act 1981
  - d. prohibit the sale, and supply in public areas, of nicotine and non-nicotine e-cigarettes and e-liquid to people under the age of 18 years
  - e. restrict the use of vending machines for nicotine and non-nicotine e-cigarettes and e-liquid to R18 settings and require that they be manually operated by a salesperson
  - f. prohibit promotion and advertising of nicotine and non-nicotine e-cigarettes and e-liquid, with exemptions for:
    - i. point-of-sale display for all retailers, in accordance with any regulations that may be prescribed
    - ii. in-store display, free samples, rewards (eg, loyalty points), discounts (eg, for old stock), co-packaging, window displays and promotion on the outside of the

store where settings are R18, for specialist vape shops, in accordance with any regulations that may be prescribed

- g. enable product safety requirements to be set out in regulations and/or tertiary legislative instruments, such as notices and guidelines.
- 6 The Ministry prefers a non-legislative option for vaping in legislated smokefree areas, that is, to develop guidelines to support business owners and employers to develop and implement vaping policies for their smokefree areas.
  - 7 There are products other than e-cigarettes, which are marketed as less harmful alternatives to smoked tobacco and are unlawful under the SFEA. Examples are heat-not-burn cigarettes and snus. New products will undoubtedly continue to emerge.
  - 8 The Ministry proposes that the scope of the regulatory scheme for e-cigarettes encompass emerging tobacco and nicotine-delivery products, thus providing a pathway for their regulation as consumer products.
  - 9 The Ministry will continue to monitor the evidence as it develops. A review, five years after any legislative changes commence, is proposed.

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# Status quo

## Tobacco control in New Zealand

- 10 Smoking rates and tobacco consumption have been declining over recent decades, however, between 4500 and 5000 New Zealanders still die prematurely each year from a smoking-related illness. Fifteen percent of adults are daily smokers. Māori are more likely (35.5 percent) to smoke daily than the rest of the population, and Māori women (40 percent) are more likely to smoke than Māori men (30.5 percent). Pasifika also have high rates of daily smoking (24.4 percent).
- 11 New Zealand's tobacco control programme is comprehensive and based on international best practice, consistent with the Framework Convention on Tobacco Control.
- 12 The Smoke-free Environments Act 1990 (SFEA) establishes the overarching statutory framework to control the supply and use of tobacco products. A comprehensive suite of tobacco control initiatives (both regulatory and non-regulatory) has been implemented over the past two or so decades to achieve the objectives of the Act and to meet Government's wider tobacco control policy aims. This includes:
  - excise duties on tobacco products
  - legislated smokefree areas
  - prohibitions on sales to under 18-year-olds
  - prohibitions on advertising
  - support for smokers to quit
  - graphic warnings
  - standardised packaging, which is currently being implemented.

## Electronic cigarettes

### Electronic cigarettes are a diverse and evolving set of products

- 13 E-cigarettes are electrical devices that produce a vapour, rather than smoke, by heating a solution (e-liquid) which the user inhales. E-liquids are available with or without nicotine and are usually flavoured. E-cigarettes and e-liquids can be sold separately.
- 14 Some of the first generation e-cigarettes are disposable and have the e-liquid built into the device. Others are re-useable, and use cartridges that contain the e-liquid. These are the type most likely to be sold in general stores. The tank systems are filled with e-liquid that is typically sold in 10 ml bottles, but larger volume bottles can be purchased.



Images courtesy of Anna Phillips

- 15 Regular smokers are dependent on nicotine and so most vapers use nicotine-containing e-liquid. Nicotine concentration typically ranges up to 36 mg/ml. The concentration or strength used is largely a personal preference. E-cigarettes can deliver peak blood nicotine levels similar to those obtained from oral nicotine replacement therapy (NRT) products (4–6 mg/ml),<sup>1,2</sup> however peak levels are achieved faster (eg, within five minutes). Faster nicotine delivery is generally associated with greater user satisfaction. By comparison, tobacco cigarettes give rise to peak levels of over 25 mg/ml.<sup>3</sup> The amount of nicotine delivered to the user is, however, dependent on a number of different factors including the concentration of nicotine in the e-liquid, the heating of the e-liquid, the other constituents of the e-liquid, and the technique of the user.

## The regulatory framework covering e-cigarettes is inadequate

- 16 The Medicines Act 1981 and the Smoke-free Environments Act 1990 (SFEA) regulate the sale and supply, advertising and use of e-cigarettes and e-liquid. E-cigarettes were not envisaged when these Acts were made. The legal situation is complex and the laws are not routinely enforced due to a lack of clarity and difficulty meeting evidential standards. Nicotine e-cigarettes are easily accessed via legal Internet sales and illegal local sales.
- 17 Under the Medicines Act, it is unlawful to sell and supply a product, including an e-cigarette or e-liquid, which has not been approved by Medsafe, if:
- a therapeutic claim is made, for example, to help smokers quit
  - it contains nicotine.
- 18 To date, no applications to approve an e-cigarette have been received by Medsafe (although an application to approve *Voke*, a cigarette-like inhaler, as a support for smoking cessation is currently being considered). Individuals can, however, import e-cigarettes (including those containing nicotine) for their own use as a smoking-cessation support, but they cannot supply them, sell them or give them away to anyone else. Medical practitioners may also prescribe unapproved products.
- 19 The SFEA prohibits the sale of tobacco products for oral use other than smoking. Nicotine e-cigarettes fall within this prohibition if the liquid is manufactured from tobacco, although this is difficult to prove. The SFEA also prohibits the sale of a product to a person aged under 18 years if it looks like a tobacco product and can be used to simulate smoking.
- 20 Other relevant legislation includes the Consumer Guarantees Act 1993, the Fair Trading Act 1986 and the Hazardous Substances and New Organisms (HSNO) Act 1996.



- 21 The **Fair Trading Act** (FTA) promotes accurate consumer information and product safety. There are provisions under the Act for regulating products with Consumer Information Standards (which require disclosure of information to a certain standard for certain consumer products and services), Product Safety Standards (existing standards for the purpose of preventing or reducing the risk of injury which may be implemented by reference in regulation) and Unsafe Goods Notices (which can be used to ban dangerous goods). Misleading claims and false descriptions are also addressed by the Commerce Commission under powers and duties conferred under the FTA.
- 22 The **Consumer Guarantees Act** (CGA), among other things, provides consumers with rights and protections where goods are not of acceptable quality, fit for purpose etc. These consumer rights are self-enforced through the Disputes Tribunal and civil courts and result in financial redress as opposed to prosecution and fines.
- 23 E-cigarettes must also comply with the Electricity Safety Regulations 2010 (made under the **Electricity Act 2012**). The regulations require that e-cigarettes comply with fundamental safety generally demonstrated by compliance with a recognised standard.
- 24 Under the **HSNO Act**, nicotine is classed as a hazardous substance and regulatory requirements (eg, handling, packaging, labelling) apply where threshold criteria are met. If the liquids/materials for e-cigarettes contain hazardous substances (i.e. meet the threshold for a hazardous substance) and do not already have an approval under the HSNO regulatory regime, then importers/manufacturers would need to seek one.

## **E-cigarette use in New Zealand is growing**

- 25 E-cigarette use is increasing rapidly in New Zealand; a pattern seen in other countries. The Health and Lifestyles Survey (HLS) and Youth Insights Survey (YIS) provide population estimates on e-cigarette use.
- 26 The 2014 YIS survey results show an increase among Year 10 students who have ever used e-cigarettes, up from seven percent in 2012 to 20 percent in 2014.<sup>4</sup> E-cigarette use was associated with male gender, smoking status (with use varying from 65 percent among current smokers to 41 percent among ex-smokers and 23 percent among non-smokers), close friends' smoking behaviour, and risky substance abuse. Most tried e-cigarettes out of curiosity, rather than for smoking cessation.
- 27 Among adults, the 2014 HLS shows that 14 percent have ever used an e-cigarette and one percent currently use them (approximately 30,000 adults).<sup>5</sup> Tobacco-smoking status predicted the use of e-cigarettes, with current smokers reporting the highest use (50 percent reported ever using and 4 percent reported current use). Among current smokers who had tried an e-cigarette, curiosity (49 percent) and desire to quit smoking (37 percent) were the most common reasons for trying one.<sup>5</sup>
- 28 The global market for e-cigarettes in 2015 was estimated at almost US\$10 billion. About 56 percent of this was accounted for by the United States and 12 percent by the United Kingdom.<sup>6</sup> There is an absence of information to estimate the size and value of the New Zealand market. The Ministry of Health sought information through a recent public consultation process, however, the information received does not give a good sense of the market, beyond a very small number of individual businesses.
- 29 E-cigarettes and e-liquid can be sold legally by any retailer in New Zealand, provided they do not contain nicotine. There are an increasing number of specialist vape shops in New Zealand cities. These sell non-nicotine e-cigarettes and e-liquid legally. Some may also sell

nicotine e-cigarettes and e-liquid unlawfully. There are also a number of New Zealand-based e-cigarette businesses that sell solely online.

- 30 Tobacco industry involvement has been increasing over the last few years,<sup>7</sup> however, there is no reliable information available to quantify its current or projected market share in New Zealand.

## The evidence-base for e-cigarettes is still developing

- 31 The scientific consensus is that the use of e-cigarettes is significantly less harmful for smokers than tobacco smoking and that short-term use is associated with few adverse effects. It also appears likely that they can help smokers to quit smoking. However, the long-term health risks are unknown at this stage.

### E-cigarettes are significantly less harmful than smoked tobacco

- 32 E-cigarettes have been available for over a decade and, apart from a relatively small number of case reports (eg, acute eosinophilic pneumonitis, acute asymptomatic atrial fibrillation), no serious health risks have yet emerged.
- 33 The inherent risks associated with the use of e-cigarettes relate primarily to the toxicants present in e-liquid. There are three main components of the liquid used in e-cigarettes: propylene glycol or glycerine (or a mix of these), nicotine, and flavouring.
- 34 **Propylene glycol** is found in many products and is generally recognised as safe.<sup>8</sup> It is used to create 'stage smoke' and has been used as an excipient in some old and new pulmonary inhalation devices, as well as in food and cosmetics. Animal studies have not found any major health risks from propylene glycol or glycerine exposure, but propylene glycol can cause cough and airway irritation in humans.<sup>9</sup>
- 35 **Nicotine** may have some adverse health effects, for example, in pregnancy.<sup>10</sup> There are reports of **nicotine poisoning** in children<sup>11-13</sup> and adults. Case reports of nicotine poisoning from intentional ingestion of nicotine-containing e-liquid in adults have been published.<sup>14,15</sup> One ingested more than 1,000mg of nicotine and died,<sup>15</sup> the others recovered.
- 36 Nicotine replacement therapy has been available for several decades and nicotine use, even long-term, is associated with few health risks in smokers.<sup>16</sup> However, other than its use in tobacco smoking, there are no data available on the safety of long-term inhaled nicotine. Any long-term adverse effects are, however, likely to be minimal in comparison to continued tobacco use.<sup>17</sup>
- 37 Inaccurate **labelling of nicotine levels** has been a concern with e-liquids: a wide variance has been found in the nicotine levels of different e-cigarettes and between actual contents and disclosed ingredients. For example, a United States study found that nicotine levels varied between 85 and 121 percent of what was listed on the label.<sup>18</sup>
- 38 An increasing number of people have tried e-cigarettes but very few go on to regular vaping, especially among those who have never smoked. This suggests that the **nicotine addiction** potential of currently available e-cigarettes is low. This may change in the future as e-cigarette technology evolves and nicotine delivery and user satisfaction improves.<sup>3</sup>

- 39 E-liquid is available in numerous **flavours**, which are important for user satisfaction. The flavours used are considered safe for oral ingestion, but the effects of heating these and then inhaling them are unknown. *In vitro* studies that have examined the effects of vapour on human cells have found flavoured e-liquids to be more damaging than unflavoured liquids, although both are substantially less harmful to cells than tobacco smoke.<sup>19 20</sup> Some flavours appear to have a higher degree of risk (eg, diacetyl<sup>21</sup> which gives a buttery flavour, and cinnamon<sup>22</sup>), and may be best avoided.
- 40 Analyses of e-cigarette vapour has detected a range of **other toxicants** (eg, metal and silicate particles, carbonyl compounds, tobacco-specific nitrosamines).<sup>22-35</sup> Where these are present they are typically at levels many times lower than found in tobacco smoke and under the limits that are generally considered safe for occupational exposure.<sup>36</sup> Operation of e-cigarettes at high temperatures can generate high levels (as high as found in cigarette smoke) of aldehydes,<sup>37,38</sup> which have carcinogenic potential. This however creates an unpleasant taste (commonly known as a 'dry puff'), which vapers recognise and avoid.<sup>38,39</sup>
- 41 The reduction in exposure to toxicants in e-liquid and vapour, relative to smoking, observed in *in vitro* studies has been demonstrated in *in vivo* studies: significantly lower levels of tobacco-specific nitrosamines and other carcinogens have been found in the urine of vapers compared with smokers,<sup>40,41</sup> and significant reductions in the levels of toxicants and carcinogens in smokers who switched to vaping.<sup>42-44</sup>
- 42 The findings to date suggest that, overall, e-cigarettes expose users to considerably lower levels of toxicants and carcinogens (in range and concentration) than smoking. However there remains a possibility that the long-term inhalation of toxicants and carcinogens, even at low levels will cause harm.
- 43 It remains difficult to predict the **long-term health effects** of vaping. The Royal College of Physicians<sup>3</sup> found that some of the carcinogens, oxidants and other toxins detected in e-cigarette vapour may increase the risks of lung cancer, chronic obstructive pulmonary disease, cardiovascular disease and other smoking-related diseases, but that the magnitude of such risks is likely to be substantially lower than those of smoking, and extremely low in absolute terms. It will take decades to accumulate evidence about long-term risks. In the meantime, smokers are exposed to the known health risks of tobacco smoking.

### **Harm has been caused by malfunctioning devices**

- 44 Harm caused by the **malfunction of e-cigarettes** has been reported (eg, burns caused by e-cigarettes exploding).<sup>45</sup> In many cases, this has been due to a malfunctioning or over-heated battery. Around 80 percent of e-cigarette fires occur when the battery is being charged. <sup>61</sup> Using an incorrect charger can increase the risk of over-charging the battery, which can result in explosion. <sup>60</sup>

### **There are no known direct health risks to bystanders from e-cigarette emissions**

- 45 So far, there are no robust data showing that second hand vapour causes harm to bystanders.<sup>3</sup>
- 46 Studies have demonstrated that second-hand vapour can expose non-users to nicotine and other toxicants, but at levels that are many times lower than those found in second-hand smoke.<sup>46,47</sup> To date, there are no case reports of harm caused by exposure to second-hand vapour, however, if any risks to health are present, they would not become evident for some years.

- 47 Third-hand exposure (exposure to substances from vapour that are deposited on surfaces) is even less likely to cause harm.

### **It appears likely that e-cigarettes can help smokers quit smoking**

- 48 A recent Cochrane review on the use of e-cigarettes for smoking reduction and cessation found that e-cigarettes may help smokers to stop smoking, and the included studies did not find any serious side effects associated with their use for up to two years.<sup>48</sup> These findings were unchanged from a 2014 Cochrane review.<sup>49</sup>
- 49 A 2016 review by Public Health England also concluded that e-cigarettes are significantly (95 percent) less harmful to health than smoked tobacco, and have the potential to help smokers quit smoking.<sup>50</sup> Similarly, a report by the Royal College of Physicians concluded that, for all the potential risks involved, harm reduction through smokers completely switching to e-cigarettes has huge potential to prevent death and disability from tobacco use, and to hasten progress to a tobacco-free society.<sup>3</sup> However, not all reviews are in agreement with these findings.<sup>51</sup>
- 50 Overall the quality of the research is low, however, this is an active area of research. There are a large number of ongoing studies that will add to the evidence on the effectiveness of e-cigarettes as a smoking-cessation support over the next few years.

### **There are concerns increased e-cigarette use could undermine tobacco control**

- 51 A number of other concerns about widespread e-cigarette use have been raised. One is that vaping may make cigarette smoking appear to be a normal activity (ie, to renormalise smoking) and undermine tobacco control. Another is that the easy availability of e-cigarettes may result in more people becoming addicted to nicotine, which may act as a gateway to tobacco smoking. This has been raised as a particular concern with respect to young people.
- 52 To date there are no robust data to show that the increase in e-cigarette use has had a negative impact on tobacco control. For example, smoking prevalence, among both adults and young people, has continued to fall in the United Kingdom as e-cigarette use has increased.<sup>52</sup> However, it is also important to recognise that the United Kingdom has comprehensive, evidence-based tobacco control measures in place, including taxation, standardised packaging, smokefree environments and smokefree cars, which mitigate these concerns being realised.
- 53 Population surveys show that young people are experimenting with e-cigarettes. In the United Kingdom, data from a 2013 survey showed that 4.5 percent of 16 to 18 year olds had tried an e-cigarette.<sup>53</sup> The rates of any use of an e-cigarette in the last 30 days by United States high-school students increased from 1.5 percent in 2011 to 16 percent in 2015.<sup>54</sup>
- 54 As with adults, experimentation with e-cigarettes is most common in smokers. For example, in Canada around 73 percent of young smokers (aged 15-19) reported ever using an e-cigarette, compared with 14 percent of never smokers.<sup>55</sup> Regular use of e-cigarettes is much lower than ever use. In 2014, for example, 1.6 percent of young people in the United Kingdom reported using e-cigarettes on at least a monthly basis. In 2015 this proportion was 1.7 percent.<sup>56</sup> Regular use of e-cigarettes was almost exclusively confined to current and ex-smokers.

- 55 Dual use (ie, smoking and vaping) has been raised as a concern as some studies have found lower quit rates in dual users than in smokers who did not use e-cigarettes, although this is largely explained by study design.<sup>48</sup> Dual use may be part of the transition from smoking to vaping. It may also be an adverse consequence of advertising, where smokers are led to believe that they can reduce their health risks by replacing some of their cigarettes with vaping. The health benefits of such an approach are unclear, but the greatest benefits to health are associated with complete cessation of smoking.

## **Emerging tobacco and nicotine-delivery products**

- 56 A range of products are marketed internationally as less harmful alternatives to smoking combustible tobacco products. Some of these are relatively new on the international market, such as heat-not-burn cigarettes. Other products are not new, for example, snus (teabag-like pouches of tobacco which slowly release nicotine when tucked under the lip or in the cheek) and American chewing tobacco. These products have diverse risk profiles.
- 57 Tobacco companies are investing a considerable amount in research and development in alternative tobacco and nicotine-delivery products. One tobacco company (Philip Morris International) publicly states that it is building its future on smoke-free products that are a much better choice than cigarette smoking.
- 58 Products are expected to continue to evolve rapidly and new products will emerge over time.

## **The regulatory framework for alternative tobacco and nicotine-delivery products**

- 59 The sale, and supply in a public place, of these products is unlawful in New Zealand under the SFEA. There is no mechanism, other than amending the Act, to regulate any of these products as consumer products if that were to be considered desirable.
- 60 Other relevant legislation includes those Acts outlined for e-cigarettes in paragraphs 20-24. There will be a more significant interface with the Misuse of Drugs Act for some product types than there is for e-cigarettes, for example, vaporisers are now being marketed for use with a variety of substances including dry herb, wax and oil. Consideration will be needed to ensure that the proposed changes do not promote illicit drug use, while removing barriers to accessing products that are safer than tobacco smoking.

## **The market for alternative tobacco and nicotine-delivery products**

- 61 There is, at present, no market in New Zealand for alternative nicotine-delivery products other than e-cigarettes. Many products are much newer than e-cigarettes to international markets and their sale, and supply in a public place, would be unlawful under the Smoke-free Environments Act 1990. Products are, however, widely available on-line and one tobacco company appears to be gearing up to launch its heat-not-burn product in the New Zealand market.

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# Regulatory approaches in other jurisdictions

## E-cigarettes

- 62 Overseas jurisdictions have taken a range of positions on the regulation of e-cigarettes, from banning their sale to regulating them as medicines, tobacco products and/or consumer products.
- 63 Appendix One summarises the regulatory approaches to e-cigarettes in Australia, the United Kingdom, Canada and the United States. Like New Zealand, many of these jurisdictions have recently reviewed their regulatory approach to e-cigarettes and are in the process of implementing controls on sale and supply, advertising and product safety for nicotine and/or non-nicotine e-cigarettes.

## Emerging tobacco and nicotine-delivery products

- 64 The United States and the European Union have regulatory frameworks that provide a pathway for new tobacco products to be lawfully marketed.
- 65 In the United States, distributors of new tobacco products are required to make a Pre-Market Tobacco Application to the Federal Food and Drug Administration (FDA). The applicant must provide toxicological and behavioural (e.g. impact on tobacco smoking and uptake by non-smokers, including young people) information. The product can be marketed only after the FDA has evaluated it as being ‘appropriate for the protection of public health’ and issued a marketing approval.
- 66 In considering whether a product is appropriate for the protection of the public health, the FDA takes the following into account:
- a. risks and benefits to the population as a whole, including users and non-users of tobacco products
  - b. increased or decreased risk that existing users of tobacco products will stop using such products
  - c. increased or decreased likelihood that those who do not use tobacco products will start using such products.
- 67 The European Union Tobacco Product Directive 2014/40/EU includes processes for the notification of e-cigarettes and novel tobacco products. The United Kingdom’s implementing regulations require producers to give 6 months notification of their intention to market a novel tobacco product. Notification requirements include the provision of toxicological and behavioural information.

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# Problem definition

## E-cigarettes

- 68 The regulatory provisions in the Smoke-free Environments Act 1990 and the Medicines Act 1981, which pre-date the emergence of e-cigarettes, are not adequate to control them. The legal status of e-cigarettes is complex and the laws are not routinely enforced because of a lack of clarity and difficulty meeting evidential standards for a prosecution.
- 69 Users can easily access nicotine e-cigarettes through legal Internet sales and illegal local sales. Little information is available about the local market, but it is apparent that sales and use are growing rapidly and this is expected to continue. Some mechanism for monitoring the local market will be needed as part of the ongoing monitoring of the impact of any policy changes.
- 70 Currently, the sale and supply of **nicotine** e-cigarettes are prohibited, while smoked tobacco can be sold legally. The evidence on whether e-cigarettes help people quit smoking is not yet settled. However, indications are that they almost certainly help with quitting smoking, and there is no doubt that they are significantly less harmful than smoked tobacco if people switch completely.
- 71 **Non-nicotine** e-cigarettes and e-liquid are lawfully available, except for ‘toy tobacco products’ which cannot be supplied to minors under the SFEA. There are no specific regulatory requirements, although consumers are protected by generic consumer products laws covering faulty products, false advertising etc.
- 72 A key problem is the lack of evidence, especially about long-term use, that would lead us to definitively conclude how e-cigarettes should be regulated. Many of the concerns raised in the literature and/or by commentators are not supported by current evidence.

73 The following table outlines the Ministry of Health’s broad assessment of the state of the evidence, which has informed the options and impact analysis below.

Issue	Comment
Vaping is significantly less harmful for smokers than smoked tobacco if they switch completely.	Strong evidence, although the risks of long-term use are as yet unknown (long-term use is unlikely to be risk-free, but likely to be much less harmful than long-term tobacco smoking).
Vaping supports smokers to quit.	Highly likely. To date, the quality of the evidence at a population level is low, although many studies are underway which will provide more information over the next few years. The United Kingdom medicines regulator has approved an e-cigarette (an electronic inhaler, <i>E-Voke</i> ) as a smoking cessation tool.
Nicotine is a toxic and addictive substance.	There is potential for the nicotine used in e-liquid to result in accidental poisoning, however any risks can be managed with child-resistant closures, and controls on maximum available concentrations and volumes of nicotine e-liquid. E-cigarettes currently available do not seem to be highly addictive, but this may change as technology improves.
Bystanders’ health will be adversely affected by exposure to second-hand vapour.	No evidence to-date that e-cigarette emissions cause direct harm to the health of bystanders. It appears unlikely they will cause significant harm, however, more research is needed.
There is a ‘gateway effect’ (of particular concern with young people) whereby people become addicted to nicotine through e-cigarette use, which leads to tobacco smoking.	Theoretical risk; evidence appears to be trending against this hypothesis, however, ongoing monitoring should continue. New Zealand has a comprehensive tobacco control programme which militates against this.
Increasing visibility of vaping in public will renormalise smoking-like behaviour.	Theoretical risk with no evidence, however, ongoing monitoring should continue. New Zealand has a comprehensive tobacco control programme which militates against this.
E-cigarette use in public places will make it difficult to enforce smokefree areas as it may not be clear whether someone is smoking or vaping.	Increasingly, e-cigarettes are visibly distinct from tobacco cigarettes, which should militate against this.

## Emerging tobacco and nicotine-delivery products

74 At present, if a new tobacco or nicotine-delivery product were assessed as being appropriate for sale as a consumer product, an amendment to the SFEA would be needed to legalise it and regulate it as a consumer product.

75 It is conceivable that in the future there will be many more alternative nicotine-delivery products that, like e-cigarettes, are less harmful than combustible tobacco and it may be acceptable that they be marketed as consumer products. It is likely that a broad range of different technologies will be used and technological innovation will be rapid.

76 It is impracticable that case-by-case decisions about whether and how to regulate emerging tobacco and nicotine-delivery products, which are to a large extent technical in nature, be made by Parliament. Rather, an approach whereby Parliament sets the parameters of whether and how emerging tobacco and nicotine-delivery products can be regulated as consumer products, and the case-by-case decision-making is made at an administrative level, would better fit the nature of this market. Such a framework should:

- a. contain a high-level public interest test which new products must meet
- b. be flexible enough to respond to products across a broad span of risk



- c. establish a marketing authorisation process or processes (e.g. self-certification, notification, pre-market approval)
- d. provide an ability to set requirements for product safety, as appropriate for a particular product or product class (e.g. related to ingredients, emissions, labelling)
- e. provide for a legal age for sale, and supply in a public place
- f. regulate promotion and advertising, and use in legislated smokefree areas (where applicable).

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# Objectives

- 77 In March 2011, Government adopted the *Smokefree 2025* goal to reduce smoking prevalence and tobacco availability to minimal levels, making New Zealand essentially a smokefree nation by 2025. The overall outcome sought through changes to the way e-cigarettes are regulated is to contribute to the achievement of *Smokefree 2025*.
- 78 The objectives of any policy changes are:
- a. **Harm reduction:** to reduce the harm to individual smokers from tobacco smoking, where smokers switch completely to e-cigarettes.
  - b. **Harm prevention:** to prevent harm to the public from greater access to e-cigarettes, including through unintended consequences on tobacco control initiatives:
    - i. policies should minimise the risk of initiation of nicotine use by non-smokers (particularly children and young people)
    - ii. policies should minimise the risk of adversely impacting on tobacco control.
  - c. **Product safety:** to protect users and non-users from harm as a result of e-cigarette use:
    - i. products should be safe when used as intended
    - ii. products should be true to label
    - iii. consumers should be supported to make informed choices about the use of e-cigarettes.
  - d. **Risk proportionality:** regulations should be proportionate to the risk associated with the use of e-cigarettes.
  - e. **Cost and ease of implementation:** for industry and government is reasonable given the potential health harms associated with e-cigarette use.
- 79 For e-cigarettes, the objective of harm reduction is given more weight than that of harm prevention. The evidence is clear that e-cigarettes are significantly less harmful to health than smoked tobacco, but they are not risk free. Therefore, the main aim is to support smokers to switch completely from tobacco smoking to vaping, while taking precautions to limit any risk that non-smokers will become regular users.
- 80 Evidence from the United Kingdom, where nicotine e-cigarettes are sold as consumer products, shows that regular e-cigarette use is confined to smokers and ex-smokers. Concerns that non-smokers will take up vaping in large numbers and that tobacco control will be set back through the increased availability of e-cigarettes seem unlikely to be realised.
- 81 The long-term health risks to vapers are also unknown but are likely to be many times less than the risks associated with tobacco smoking. Data on short-term use shows it is likely that the benefits to smokers of regulating e-cigarettes as consumer products outweighs the risks to smokers themselves and the wider population. We propose to deal with this uncertainty through ongoing monitoring of the evidence that emerges. A proposed review, five years after any legislative changes commence will provide an opportunity to recalibrate this policy, if that is indicated.

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# Options and impact analysis

## Criteria for assessing options

- 82 The following objectives are used as criteria for assessing the options for issues 1–6 below:
- harm reduction
  - harm prevention
  - risk proportionality
  - cost and ease of implementation.

## Issue 1: Regulate nicotine e-cigarettes and e-liquid as consumer products under the SFEA

- 83 **Nicotine** e-cigarettes and e-liquid are regulated under the Medicines Act and the Smoke-free Environments Act (**non-nicotine** e-cigarettes and e-liquid are unregulated and freely available).
- 84 The sale and supply of nicotine e-cigarettes and e-liquid are unlawful, unless the products are approved under the Medicines Act. To date, no applications have been made to Medsafe to approve an e-cigarette (although an application to approve *Voke*, a cigarette-like inhaler, as a support for smoking cessation is currently being considered). In time, e-cigarettes approved under the Medicines Act may become available for smoking cessation purposes. Access (eg, by prescription, pharmacist-only, over-the-counter) would be determined by the regulatory approval process.
- 85 In addition, the SFEA prohibits the sale or distribution of any tobacco product for oral use other than smoking. E-liquid is captured by this provision if it contains nicotine manufactured from tobacco. This prohibition would not apply to products approved under the Medicines Act.
- 86 Users obtain nicotine e-cigarettes and e-liquid through illegal local sales and legal Internet purchases (Medsafe allows up to three-months' supply of nicotine e-liquid to be imported for personal use).
- 87 Existing laws are complex and difficult to enforce. As a result, the Ministry of Health has been unable to effectively enforce the law. If the status quo were to be retained, some legislative amendments would be desirable to clarify the law and facilitate enforcement.

88 The following table compares the proposal to regulate **nicotine** e-cigarettes and e-liquid as consumer products against the status quo:

**Table 1: Comparison of options to regulate nicotine e-cigarettes and e-liquid as consumer products**

Options	Option 1: status quo	Option 2:
	Sale and supply of nicotine e-cigarettes and e-liquid generally unlawful, without a product approval under the Medicines Act Laws difficult to enforce	Legalise the sale and supply of nicotine e-cigarettes and e-liquid, with appropriate regulatory controls as considered under issues 2–6 below
Pros	May reduce likelihood that non-smokers, including young people, will use nicotine e-cigarettes, potentially leading to nicotine addiction Minimises any risks that increasingly visible vaping will renormalise smoking-like behaviour (ie, vaping and/or smoking) and set back tobacco control	Increases smokers' access to nicotine e-cigarettes for harm reduction or smoking cessation via legal local sales Potential for fewer smoking-related demands on the public health system, to the extent that smokers switch to e-cigarettes and reduce their health risks Opportunity to regulate product safety so that smokers have access to e-cigarettes and e-liquid that they can be confident in Potential to reduce spend on nicotine replacement therapy products Supports potential for local business growth
Cons	Smokers' lawful access to nicotine e-cigarettes and e-liquid as a harm-reduction or smoking cessation tool is limited People continue to buy nicotine e-cigarettes and e-liquid online, with no assurance of quality Some businesses continue to sell nicotine e-cigarettes and e-liquid unlawfully and enforcement remains problematic, unless the law is clarified	Risk that non-smokers, including young people, will experiment with nicotine e-cigarettes, potentially resulting in nicotine addiction Risk that increasingly visible vaping will renormalise smoking-like behaviour and set back tobacco control Loss of tobacco excise revenue, to the extent that smokers switch to e-cigarettes

89 The following table compares the legalisation of nicotine e-cigarettes and e-liquid with the status quo against the assessment criteria set out in paragraph 67:

**Table 2: Impact assessment of options to legalise nicotine e-cigarettes and e-liquid compared with the status quo**

Comparison of options with the status quo	
Criteria	Option 2: legalise sale and supply
Harm reduction	Much better
Harm prevention	Better (subject to range of regulatory controls as considered below)
Risk proportionate	Much better
Cost and ease of implementation	Much better (subject to range of regulatory controls as considered below)
Conclusions	Recommended (subject to range of regulatory controls as considered below)

## Conclusion

90 The Ministry of Health recommends option 2, to legalise the sale and supply of e-cigarettes and e-liquid. This option is a much better fit against the criteria than the status quo. In particular it supports harm reduction through increasing smokers' access to

a much safer alternative to tobacco smoking. The potential risks associated with increasing access to e-cigarettes can be mitigated by the controls proposed below; overall there is the potential for a regulatory framework that better fits the overall criteria than the status quo (eg, through restricting young people's access and improving product safety).

# Issue 2: Sale and supply of nicotine and non-nicotine e-cigarettes and e-liquid to people under 18 years of age

- 91 The sale, and supply in a public place, of tobacco products is prohibited to people under 18 years of age. There are no age restrictions on the sale and supply of e-cigarettes and e-liquid. It appears, however, that many specialist vape shops have a voluntary ban on sales to under-18s.
- 92 The following table compares the options for the sale and supply of **nicotine and non-nicotine** e-cigarettes and e-liquid to people under 18 years of age.

**Table 3: Comparison of options for sale and supply of nicotine and non-nicotine e-cigarettes and e-liquid to minors**

Options	Option 1: status quo: Allow sale and supply of e-cigarettes and e-liquid to all age groups	Option 2: align with SFEA Prohibit sale, and supply in a public place, of <b>nicotine and non-nicotine</b> e-cigarettes and e-liquid to minors	Option 3: Prohibit sale, and supply in a public place, of only <b>nicotine</b> e-cigarettes and e-liquid to minors
Pros	Optimises size of market and potential for business growth	Limits potential risks to health from long-term e-cigarette use, including addiction  Limits potential risk of renormalisation of smoking-like behaviour among young people  Allows access by minors who smoke, eg, via parents in a private place	Some limits on potential health risks from long-term e-cigarette use, including addiction  Allows access to nicotine e-cigarettes by minors who smoke, eg, via parents in a private place
Cons	May increase potential risks from long-term e-cigarette use, including addiction  May increase risk of renormalisation of smoking-like behaviour among young people	Limits size of market and potential for business growth (although it appears that most specialist retailers do not sell to under-18s)	Somewhat smaller impact on size of market and potential for business growth than option 2

93 The following table compares the impact of the options for the sale and supply of e-cigarettes and e-liquid to under-18s against the criteria set out in paragraph 67.

**Table 4: Impact assessment of options for sale and supply of nicotine and non-nicotine e-cigarettes and e-liquid to minors compared with the status quo**

Comparison of options with the status quo		
Criteria	<b>Option 2: align with SFEA</b> Prohibit sale, and supply in a public place, of nicotine and non-nicotine e-cigarettes and e-liquid to minors	<b>Option 3:</b> Prohibit sale, and supply in a public place, of nicotine e-cigarettes and e-liquid to minors
Harm reduction	Same	Same
Harm prevention	Much better	Better
Risk proportionate	Better	Better
Cost and ease of implementation	Worse	Worse
Conclusion	Recommended	

**Conclusion**

94 The Ministry of Health recommends option 2, prohibiting the sale, and supply in a public place, of nicotine and non-nicotine e-cigarettes and e-liquid to under-18s. This option is the best fit overall against the criteria. In particular, it best supports harm prevention by restricting young people’s access to e-cigarettes. Option 2 is also expected to be less costly and easier to implement than option 3 as retailers and enforcement staff do not need to be concerned with whether a product being sold or supplied contains nicotine or not, which is difficult to prove.

# Issue 3: Use of vending machines for nicotine and non-nicotine e-cigarettes and e-liquid

- 95 Requirements on the use of vending machines for tobacco products are that they must be restricted to R18 settings and be manually operated by a salesperson. This supports the prohibition on sales to under 18 year olds. At present, there are no restrictions on the use of vending machines for e-cigarettes and e-liquid.
- 96 The following table compares the options for the use of vending machines for e-cigarettes and e-liquid.

**Table 5: Options for the use of vending machines for nicotine and non-nicotine e-cigarettes and e-liquid**

Option	Option 1: status quo	Option 2: align with SFEA	Option 3:
	No restrictions	Restrict vending machines to R18 settings and require manual operation by salesperson	Prohibit use of vending machines
Pros	Increases smokers' access to nicotine e-cigarettes and e-liquid	Supports proposed ban on sale, and supply in public places, to minors	Supports proposed ban on sale, and supply in a public area, to minors
Cons	Increases young peoples' access to e-cigarettes (inconsistent with recommendation under Issue 2)	Reduces smokers' access to nicotine e-cigarettes and e-liquid	Reduces smokers' access to nicotine e-cigarettes and e-liquid Disproportionate to regulation of tobacco

- 97 The following table compares the impact of the options for the use of vending machines for e-cigarettes and e-liquid against the criteria set out in paragraph 67.

**Table 6: Impact assessment of the options for the use of vending machines for nicotine and non-nicotine e-cigarettes and e-liquid compared with the status quo**

Comparison of options with the status quo		
Criteria	Option 2: align with SFEA	Option 3:
	Restrict vending machines to R18 settings and require manual operation by salesperson	Prohibit use of vending machines
Harm reduction	Same	Same
Harm prevention	Better	Better
Risk proportionate	Much better	Better
Ease and cost of implementation	Worse	Worse
Conclusion	Recommended	

## Conclusion

- 98 The Ministry of Health recommends option 2, restricting the use of vending machines to R18 settings and requiring manual operation by a salesperson. In particular this supports the harm prevention criteria by supporting a potential restriction on sale and supply to minors. It is preferred over option 3 as greater restrictions on access to e-cigarettes compared with tobacco are difficult to justify on the basis of risk proportionality.



## Issue 4: Promotion and advertising

- 99 There is little information available on the impact of advertising on consumer decision-making on e-cigarettes. One randomised trial studying the effect of advertising on young people in the United States found that exposure to e-cigarette advertisements may enhance curiosity and limited trial of e-cigarettes in those who have never used them.<sup>63</sup> Another study found that e-cigarette exposure is associated with current e-cigarette use among middle and high school students in the United States, with greater exposure to advertising associated with higher odds of e-cigarette use.<sup>64</sup>
- 100 A study of English children (aged 11-16 years) found that advertisements for e-cigarettes do not seem to increase the appeal of tobacco smoking. However, flavoured, compared with non-flavoured, e-cigarettes elicited greater interest in buying and trying e-cigarettes.<sup>65</sup>
- 101 E-cigarettes have been advertised in New Zealand on television, billboards, point-of-sale promotions (including in pharmacies), letterbox drops and on websites. Submitters to the Ministry of Health's recent public consultation on e-cigarettes provided examples of overseas advertisements where it is difficult to distinguish between e-cigarettes and tobacco cigarettes, as well as advertisements which glamorise e-cigarette use.
- 102 E-cigarettes and e-liquid products that contain nicotine and/or make a therapeutic claim fall under Medicines Act requirements for advertising.
- 103 There are no specific advertising-related controls on non-nicotine e-cigarettes and e-liquid. The advertising industry self regulates. The Advertising Standards Authority has developed Codes of Standards including the Advertising Code of Ethics, which includes a number of principles, for example, that advertisements should not be misleading or deceptive and should be prepared with a due sense of social responsibility.
- 104 Complaints about advertisements are heard by the Advertising Standards Complaints Board, with a right of appeal to an appeals' board. If a complaint is upheld, the advertiser, advertising agency and media are requested to withdraw the advertisement.
- 105 Under the SFEA, a tobacco product advertisement is defined as 'any words, whether written, printed, or spoken, including on film, video recording, or other medium, broadcast or telecast, and any pictorial representation, design, or device, used to encourage the use or notify the availability or promote the sale of any tobacco product or to promote smoking behaviour'.
- 106 The SFEA advertising prohibitions include display of products, free samples, rewards (eg, loyalty points), discounts (eg, on old stock), co-packaging and sponsorship, as well as requirements for standardised packaging. The rules for notifying product availability in stores are set out in regulations under the SFEA.
- 107 The options considered below are:
- Option 1: status quo (no restrictions on promotion and advertising)
  - Option 2: prohibit promotion and advertising, consistent with the SFEA
  - Option 2(a): prohibit promotion and advertising, with an exemption for all retailers (including Internet retailers) for point-of-sale display (ie, display of products at the cash register or behind the counter)
  - Option 2(b): prohibit promotion and advertising, with an exemption for specialist vape shops for in-store display, free samples, rewards, discounts and co-packaging, window

display and promotion on the outside of the store (eg, via trading names) where settings are R18 (including Internet retailers)

- Option 2(c): prohibit promotion and advertising with an exemption from the standardised packaging requirements that apply to tobacco products.

108 Options 2(a) to 2(c) are not mutually exclusive. Options 2 to 2(c) would require regulations to be made to define terms where relevant, such as ‘point-of-sale display’ and ‘specialist vape shop’ and to set out the parameters of what would be acceptable.

109 The following table compares the options for promotion and advertising of **nicotine and non-nicotine** e-cigarettes and e-liquid.

**Table 7: Comparison of options for promotion and advertising of nicotine and non-nicotine e-cigarettes and e-liquid**

Options	Option 1: status quo	Option 2: align with SFEA	Option 2(a):	Option 2(b):	Option 2(c):
	No restrictions (industry self regulates)	Prohibit promotion and advertising, including sponsorship (notification of product availability would be allowed)	Prohibit with exemption for <b>all retailers</b> for point-of-sale display of products	Prohibit with exemption for <b>specialist vape shops</b> for in-store display, free samples, rewards, discounts and co-packaging, window displays and promotion on the outside of the store (where settings are R18)	Prohibit with exemption from standardised packaging requirements
Pros	Increases smokers' awareness of e-cigarettes as a safer alternative to smoking Promotes potential for market growth and/or businesses to grow their market share	Minimises potential for e-cigarettes to be seen as 'normal' consumer products Limits potential for downplay of risks to non-smokers Minimises uptake by non-smokers Limits potential for long-term health risks Minimises risk of renormalisation of smoking-like behaviour	Increases smokers' awareness of safer option to tobacco smoking Increases potential for market growth	Provides smokers opportunity to explore options that may best suit them May encourage vapers to try new products which may be safer or more effective Minimises potential for e-cigarettes to be seen as a normal consumer product Increases potential for market growth and/or businesses to grow their market share	Eliminates potential for packaging to be used to circumvent promotion and advertising prohibition (if imposed)
Cons	May downplay risks of vaping for non-smokers May increase risk of uptake by non-smokers May increase risk of renormalisation of smoking-like behaviour May increase the likelihood of people continuing to smoke and vape	Limits smokers' awareness of less harmful alternative to smoking Restricts potential for market growth Restricts freedom of expression in relation to commercial activity	Increases potential that non-smokers may experiment with e-cigarettes Increases potential for e-cigarettes and e-liquid being seen as normal consumer products Restricts freedom of expression in relation to commercial activity	May increase likelihood of non-smokers trying e-cigarettes Potential difficulty defining 'specialist vape shop' Restricts freedom of expression in relation to commercial activity	Restricts branding by manufacturers, thus restricting freedom of expression in relation to commercial activity Makes it difficult for users to make choices between different brands and products

110 The following table compares the impact of the options for promotion and advertising against the criteria set out in paragraph 67.

**Table 8: Impact assessment of options for promotion and advertising of nicotine and non-nicotine e-cigarettes and e-liquid compared with the status quo**

Criteria	Comparison of options with the status quo			
	<b>Option 2: align with SFEA</b> Prohibit promotion and advertising, including sponsorship (notification of product availability would be allowed)	<b>Option 2(a):</b> Prohibit with exemption for all retailers for point-of-sale display of products	<b>Option 2(b):</b> Prohibit with exemption for specialist vape shops for in-store display, free samples, rewards, discounts and co-packaging, window displays and promotion on the outside of the store (where settings are R18)	<b>Option 2(c):</b> Prohibit with exemption from standardised packaging requirements
Harm reduction	Much worse	Worse	Worse	Worse
Harm prevention	Much better	Better	Better	Better
Risk proportionate	Better	Much better	Much better	Much better
Cost and ease of implementation	Worse	Worse	Worse	Worse
Conclusion		Recommended	Recommended	Recommended

## Conclusion

- 111 The Ministry of Health recommends options 2 (a), 2 (b) and 2 (c), prohibiting promotion and advertising, but with some exemptions. These recommendations aim to strike a balance between the harm reduction and harm prevention criteria; smokers/vapers need information to support them to shift to safer or more effective products, but some restrictions on advertising are necessary to protect non-smokers. It is difficult to justify a complete prohibition (option 2) on the basis of risk proportionality.

## Issue 5: Vaping in smokefree areas

- 112 The Smoke-free Environments Act (SFEA) prohibits tobacco smoking in indoor workplaces and certain public areas, including schools and early childhood centres, aircraft, passenger service vehicles etc. The rationale for this prohibition is the known significant health risks to employees from smoking in indoor workplaces.
- 113 Most local authorities have also designated smokefree outdoor areas, over and above the requirements of the SFEA.<sup>62</sup> The rationale for smokefree outdoor areas is primarily that decreasing the visibility of smoking helps to denormalise it, which supports efforts towards developing a smokefree society.
- 114 Bylaws could be made under the Local Government Act 2002 or the Health Act 1956. The SFEA explicitly states that nothing in Part 1 (smokefree workplaces and public areas) of that Act limits or affects the ability of local authorities to make bylaws providing greater protection from tobacco smoke than provided for in the SFEA. However, only one council (Whanganui) has made bylaws, and this policy is currently under review.<sup>62</sup> Others rely on non-regulatory approaches, such as contracts for the use of council-owned land, signage and public education. A recent review of its policy by Auckland Council concluded that the use of bylaws would be expensive, difficult to enforce, and unnecessary to implement its smokefree public places policy.<sup>62</sup>
- 115 There are no legislated restrictions on where people can vape. However, many employers have prohibited vaping in the workplace as part of their smokefree policies. Examples include Air New Zealand, Parliament, the Ministry of Health and district health boards. One local authority (Wellington City Council) has included vaping in its smokefree outdoor-areas policy.
- 116 International approaches vary. For example:
- The majority of states in Australia and Canada that have recently considered the regulation of e-cigarettes have prohibited vaping in smokefree areas.
  - United Kingdom governments have not legislated to prohibit vaping in smokefree areas. Public Health England has issued guidelines to assist employers, businesses and local authorities to decide their own environmental vape policies.
- 117 The options considered below are:
- a. Option 1: status quo (no restrictions on vaping in legislated smokefree areas)
  - b. Option 2: align with the SFEA (prohibit vaping in legislated smoke-free areas)
  - c. Option 3: non-regulatory option (issue guidelines to support employers, businesses and local authorities to determine their own policies).
- 118 Option 3 could also be implemented in combination with option 2, to enable a distinction to be drawn between vaping indoors and outdoors, thus prohibiting indoor vaping, while discouraging local authorities from prohibiting vaping in their smokefree outdoor areas.
- 119 A legislative prohibition on councils including vaping in their smokefree areas has not been considered as a feasible option. This would seem to be disproportionate. Only one local authority (Wellington City Council) appears to have included vaping in its smokefree policy. The Council's policy statement suggests that advice on the Ministry of Health's website discouraging e-cigarette use in areas where smoking is not permitted may be part of its rationale for the inclusion of e-cigarettes in its smokefree policy.

120 The following table compares the options for using nicotine and non-nicotine e-cigarettes in smokefree areas.

**Table 9: Comparison of options for using nicotine and non-nicotine e-cigarettes in legislated smokefree areas**

Options	Option 1: status quo	Option 2: align with SFEA	Option 3: non-regulatory option
		Prohibit vaping in areas that are smokefree under the SFEA	Issue guidance to support local decision-making
Pros	<p>May provide incentive for smokers to switch if they can vape where they can't smoke</p> <p>Businesses able to tailor policies to suit customer preferences/target market</p> <p>No costs on business to implement</p> <p>No cost to government to implement or enforce</p>	<p>Employees and bystanders are not exposed to e-cigarette emissions</p>	<p>As for option 1</p> <p>May reduce costs to business and local authorities by providing information to support decision-making, including clarity on the legal position</p>
Cons	<p>May encourage 'dual use' – smokers smoke where they can, but otherwise vape, reducing incentives to quit</p> <p>May provide a trigger for ex-smokers to return to smoking or take up vaping</p> <p>Constrains business owners' choices on best use of their premises</p> <p>May be some cost to businesses to determine own policies, particularly if consultation required</p> <p>May appear inconsistent and confusing if vaping is allowed in some places but not others, including outdoor areas which fall under local authorities' smokefree policies</p> <p>Employees and bystanders exposed to e-cigarette emissions</p> <p>Potential to renormalise smoking-like behaviour</p>	<p>May expose vapers to second-hand smoke if required to vape outside alongside smokers</p> <p>May reduce incentives on smokers to switch to vaping</p> <p>Constrains business owners' and employers' choices on the best uses of their premises</p>	<p>As for option 1</p>

121 The following table assesses whether the options for vaping in legislated smokefree areas meet the criteria set out in paragraph 67.

**Table 10: Impact assessment of the options for using nicotine and non-nicotine e-cigarettes in smokefree areas compared with the status quo**

Comparison of options with the status quo		
Criteria	Option 2: align with SFEA	Option 3:
	Prohibit vaping in legislated smoke-free areas	Issue guidance to support local decision-making
Harm reduction	Worse	Same
Harm prevention	Better	Same
Risk proportionate	Worse	Same
Cost and ease of implementation	Worse	Better
Conclusion		Recommended

## Conclusion

122 The Ministry of Health recommends option 3, issuing guidance to support employers, businesses and local authorities to make their own decisions about whether or not to allow vaping in their premises/smokefree areas (the status quo). On balance, it would be difficult to justify a prohibition on vaping in legislated smokefree areas on the basis of risk proportionality.



## Issue 6: Product safety

- 123 Devices sold in New Zealand should comply with the Electricity (Safety) Regulations 2010. There are no mandatory product safety controls on non-nicotine e-liquid. Medicines requirements should apply to nicotine e-liquid (and nicotine in other forms), however, this is currently sold unlawfully in New Zealand without an approval under the Medicines Act. Regulatory requirements for nicotine also exist under the HSNO Act, where threshold criteria are met. This would most likely apply to imports of bulk nicotine and is largely irrelevant to the day-to-day sale and supply of nicotine e-liquid for use in e-cigarettes, which also carries some risk of poisoning.
- 124 Industry may self-regulate against a range of existing standards and consumers may have recourse against faulty products, false advertising etc under the Consumer Guarantees Act and the industry self-regulated system of advertising standards.
- 125 There are inherent risks associated with the use of e-cigarettes, as discussed in paragraphs 31 to 55 above). These risks relate primarily to the toxicants present in e-liquid, however there is also some risk with malfunctioning devices (related to the batteries overheating and exploding). The risks associated with e-cigarette use can be mitigated with a range of controls on product safety including requirements for:
- a. manufacturing standards for devices and e-liquids
  - b. quality and safety of ingredients
  - c. labelling and packaging requirements.
- 126 Internationally, a range of generic manufacturing standards for consumer products exist that may be appropriate for aspects of the manufacture of e-cigarettes and e-liquid. A number of e-cigarette-specific standards, which may also be appropriate, have also been developed, for example:
- a. the British Standards Institute has developed a standard for the manufacture, importation, testing and labelling of vaping products<sup>57</sup>
  - b. the European Union has established a technical committee to develop standards for the safety aspects of both e-cigarettes and e-liquid.<sup>58</sup>
- 127 Safety requirements can be implemented with or without product notification and/or pre-market approval requirements. A light-touch system would require the importer or manufacturer to notify products to the regulator via a web-based system, prior to marketing. This would include certification that the product complies with regulatory requirements. Such a system is being implemented in New Zealand for natural health products. A more robust notification system is being implemented in the United Kingdom for nicotine e-cigarettes and novel tobacco products, in accordance with the European Union's Tobacco Product Directive.
- 128 The advantage of notification as a minimum requirement is that the regulator knows what products are on the market and who is responsible if any action is required, for example, to remedy a breach of the rules or to recall an unsafe product. However, there would be a cost to industry. The cost would depend on how robust the overall requirements associated with notification were.
- 129 An alternative would be a pre-market approval system, which New Zealand has for medicines and psychoactive substances and the United States has implemented for new tobacco products.

130 The following table compares the high-level options for regulating product safety for **nicotine and non-nicotine** e-cigarettes and e-liquid. Regulations and/or tertiary legislative instruments (eg, notices, guidelines) would need to be developed to progress options 2, 3 or 3 (a). As these options create new responsibilities for enforcement bodies, there would be a need for reprioritisation or additional funding to provide capacity to implement any new regulatory requirements. There is no proposal to regulate personal imports of products.

131 The following table compares the options for regulating product safety for nicotine and non-nicotine e-cigarettes and e-liquid

**Table 11: Comparison of options for regulating product safety for nicotine and non-nicotine e-cigarettes and e-liquid**

Comparison of options with the status quo				
Options	Option 1: status quo	Option 2:	Option 3:	Option 3(a):
	No specific regulatory controls (Consumer Guarantees Act (CGA) applies)	Identify existing product safety standards for adoption under the FTA (Commerce Commission and Customs undertake activities)	Make regulations/notices/guidelines under the SFEA <u>without</u> product notification / self-certification (Ministry of Health regulates)	Make regulations/notices/guidelines under the SFEA <u>with</u> product notification / self-certification (Ministry of Health regulates)
Pros	No costs to manufacturers, importers or retailers to implement and comply No cost to Government to implement and enforce No impact on consumers' ability to purchase products they want	Risks to health mitigated Smokers have access to locally-sold products they can have confidence in, which may encourage them to switch	As for option 2 Ministry of Health is government agency with the best understanding of regulating products to reduce risks to health (eg, medicines, natural health products, psychoactive substances)	As for option 3 Enforcement would be proactive Self-certification would facilitate compliance Notification would facilitate regulator to take action against any breaches
Cons	Nicotine, which has addictive and toxic properties, is unregulated (except where HSNO thresholds are met) Other constituents of e-liquid, some of which may be harmful, are unregulated Child-resistant closures are optional Uneven playing field for industry – some businesses meet best-practice standards; others sell cheaper, lower-quality products Experience suggests it is unlikely that consumers will seek redress under the CGA	Costs to industry to implement (depends on specific controls), which may be passed on to consumers Costs to government and industry to implement and enforce May reduce consumer choice if some products are removed from the market Difficulty in identifying international best standards to adopt Consumers may continue to access poor quality products over the Internet Enforcement is passive, in response to complaints and product failures	As for option 2 Regulator wouldn't know what products are on the market, whether they comply or who is responsible for compliance Enforcement would be in response to complaints and product failures/harm to health	As for option 2, but greater cost to industry associated with notification/more active regulation

- 132 The following criteria are used for assessing the high-level options for product safety:
- a. effectiveness in minimising harm associated with e-cigarette use
  - b. risk proportionality
  - c. cost and ease of implementation.

133 The following table considers the options against the assessment criteria set out above.

**Table 12: Impact assessment of the high-level options for regulating product safety for nicotine and non-nicotine e-cigarettes and e-liquid compared with the status quo**

Comparison of options with the status quo			
Criteria	<b>Option 2:</b> Product safety standards (FTA)	<b>Option 3:</b> Regulations (SFEA) <u>without</u> product notification)	<b>Option 3(a):</b> Regulations (SFEA) <u>with</u> product notification
Effectiveness in minimising harm	Better	Better	Much better
Risk proportionate	Better	Better	Much better
Cost and ease of implementation	Worse	Worse	Much worse
Conclusion	Recommended		

## Conclusion

- 134 The Ministry of Health recommends option 3(a). On balance, option 3(a) is preferred over the other options as it provides a vehicle for active regulation of risks. It will be more costly than the other options, but these greater costs are proportionate to the risks involved and can be kept to a minimum through the design of the regulatory system.
- 135 Further work would be needed with industry and expert stakeholders to develop and cost detailed proposals for product safety.

## Issue 7: Future-proofing the legislative changes

- 136 The emerging tobacco and nicotine-delivery products that have come to the Ministry of Health's attention to date are, on the face of it, unlawful under the SFEA. If an assessment of risks and benefits shows that any of these products, now or in the future, are more appropriately regulated as consumer products, then the process to implement this would involve Cabinet decisions, followed by a Parliamentary process to amend the SFEA. While this process provides for a high level of scrutiny and decision-making, it is also cumbersome, costly and time-consuming.
- 137 Tobacco and nicotine-delivery product technology is changing rapidly and emerging products are capable of delivering a variety of substances in different forms (e.g. nicotine leaf and liquid, cannabis leaf, cannabis oil etc). Not all products are cigarette-like – products such as chewing tobacco and snus, which have been around for many years, also span a broad spectrum of risk and some of these product types may also be more appropriately regulated as consumer products.
- 138 Any framework for deciding on whether or how to regulate emerging tobacco and nicotine-delivery products, therefore, needs to have the flexibility to cover products across a broad spectrum of risks, including clinical, toxicological, and behavioural (e.g. impact on tobacco smoking and uptake by young people) risks.
- 139 There are existing regulatory frameworks at either end of the risk spectrum, i.e. consumer protection legislation, which is very light-touch, and the Psychoactive Substances Act, which has a very high regulatory hurdle. Other options identified are incorporation of a regulatory framework within the SFEA or development of a bespoke legislative framework.
- 140 The options considered below for a regulatory vehicle for emerging tobacco and nicotine-delivery products are:
- a. status quo
  - b. consumer protection legislation (MBIE administers)
  - c. Psychoactive Substances Act (Ministry of Health administers)
  - d. incorporate a new framework under the SFEA (Ministry of Health administers)
  - e. develop bespoke legislation (consideration would be needed of which department would be appropriate to administer a new Act).

141 The following table compares the high-level options for a regulatory vehicle for emerging tobacco and nicotine-delivery products.

**Table 13: Comparison of options for a regulatory vehicle for emerging tobacco and nicotine-delivery products**

Options	Option 1: status quo	Option 2:	Option 3:	Option 4:	Option 5:
	Products unlawful under SFEA; decisions taken and Act amended on case-by-case basis	Rely on existing consumer protection legislation	Include within the scope of the Psychoactive Substances Act	Incorporate a new regulatory framework under the SFEA	Develop bespoke legislation
Pros	High level of scrutiny and decision-making	Low cost for business and government	High regulatory hurdle in Act is appropriate for products at the high-risk end of the spectrum	Opportunity to build on e-cigarettes framework (at low-risk end of spectrum) Emerging tobacco and nicotine-delivery products fits best with legislation regulating existing tobacco products Existing legislative vehicle on 2017 legislation programme to amend SFEA	Opportunity to develop bespoke purpose, principles and modern risk-based regulatory framework best suited to emerging tobacco and nicotine-delivery products
Cons	Slow process – regulatory change lags considerably behind shifting evidence and public expectations	Not sufficiently robust to manage the safety risks associated with emerging tobacco and nicotine-delivery products No existing safety standards for emerging tobacco and nicotine-delivery products which could be adopted Enforcement is passive, in response to complaints and failures	High regulatory hurdle inappropriate for products at the low-risk end of the spectrum Relatively high costs to business and government associate with approving products Would require a legislative amendment to bring nicotine into scope of the Act	May be philosophically at odds with traditional approach to tobacco control, which has focused on an end-game (harm reduction is not a principle that has been used)	Time and cost in developing a new Act Would need to interface smoothly with SFEA

142 The following table considers the options against the assessment criteria set out above.

**Table 14: Impact assessment of options for a regulatory vehicle for emerging tobacco and nicotine-delivery products compared with the status quo**

Comparison of options with the status quo				
Criteria	<b>Option 2:</b> Rely on existing consumer protection legislation	<b>Option 3:</b> Include within scope of the Psychoactive Substances Act	<b>Option 4:</b> Incorporate a new regulatory framework under the SFEA	<b>Option 5:</b> Develop bespoke legislation
Harm reduction	Worse	Worse	Better	Better
Harm prevention	Worse	Worse	Better*	Better*
Risk proportionate	Worse	Worse	Better	Better
Cost and ease of implementation	Worse	Worse	Much better	Better
Conclusion	Recommended			

\* subject to detailed regulatory requirements which will be considered in a future regulatory impact statement. It is assumed, at this stage, that they will be consistent with requirements for e-cigarettes

## Conclusion

- 143 The Ministry of Health recommends option 4, to include a new regulatory framework under the SFEA which would be administered by the Ministry of Health. Regulation under existing consumer legislation or inclusion within the scope of the Psychoactive Substances Act would not provide a sufficiently flexible risk-based regulatory framework to cover the broad spectrum of emerging tobacco and nicotine-delivery products. An amendment to the SFEA is a more practicable option compared with the development of a new Act.
- 144 A significant amount of further work is needed to develop and cost detailed proposals for the regulation of emerging tobacco and nicotine-delivery products.

## Issue 8: Excise duty on nicotine e-liquid

- 145 Excise duties are an important part of government strategies to reduce tobacco consumption. The case for an excise duty on nicotine e-liquid is much less clear cut. E-cigarettes have a much lower risk-profile than tobacco smoking and do not impact on the health budget in the way harm caused by tobacco smoking does.
- 146 Design and implementation issues are likely to be highly complex. Any duties would need to be set at a level that does not disincentivise smokers to switch, or increase inequalities in smoking prevalence and smoking-related disease.
- 147 There is little information about the nicotine e-liquid market in New Zealand on which to base any estimates of the impact of excise duties (nicotine e-liquid cannot currently be lawfully sold as a consumer product).
- 148 To date, there are very few studies on the responsiveness of nicotine e-liquid demand to price changes. There is also little international experience to draw upon. A handful of jurisdictions in the United States have implemented some form of excise duty on nicotine e-liquid. Others have it under consideration.
- 149 Further work would be needed before options for an excise or excise-equivalent duty on nicotine e-liquid could be proposed.



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# Consultation

- 150 Between 2 August and 12 September 2016, the Ministry of Health consulted publicly on:
- a. legalising nicotine e-cigarettes and e-liquid as a consumer product, under the SFEA, with appropriate controls on both nicotine and non-nicotine e-cigarettes and e-liquid, including:
    - i. prohibiting their sale and supply to those under the age of 18 years
    - ii. restricting the use of vending machines
    - iii. restricting advertising and marketing
    - iv. prohibiting vaping in legislated smokefree areas
    - v. whether any of the other regulatory controls on tobacco products should apply (eg, standardised packaging, discounted pricing etc)
  - b. the need for regulatory controls on product safety
  - c. whether to impose some form of excise or excise-equivalent duty on nicotine e-liquid.
- 151 The Ministry received 250 submissions. Of these, 130 were from individuals and the remainder from organisations. Eighty-one individuals identified themselves as vapers. The organisations identified as being from the health sector, academia, or as vape and/or tobacco businesses.
- 152 There was a general view that regulation should be risk proportionate, and particularly that regulatory controls should be less stringent than controls on smoked tobacco.
- 153 The vast majority of submitters (98 percent) agreed that the sale and supply of nicotine e-cigarettes and e-liquid should be allowed, with appropriate controls. There was no significant difference between vapers and non-vapers.
- 154 Submitters also overwhelmingly agreed (87 percent) that there should be a prohibition on the sale, and supply in a public place, of all e-cigarettes and e-liquid to persons under the age of 18 years; again there was no significant difference between vapers and non-vapers. Submitters were also generally supportive of restrictions on the use of vending machines, primarily to maintain a prohibition on sales to under-18s.
- 155 The majority of submitters (53 percent) supported restrictions on advertising, and expressed a general view that any restrictions should be less stringent than those on smoked tobacco. There was a significant difference in the proportion of vapers who agreed there should be advertising controls compared with non-vapers (37 percent vs 64 percent). On the more specific questions:
- a. less than one-third of submitters (31 percent) agreed that there should be a prohibition on point-of-sale display of products (14 percent of vapers and 44 percent of non-vapers)
  - b. less than one-half of submitters agreed that there should be a ban on free samples (48 percent) and discounts (30 percent), again differences were observed between vapers and non-vapers (free samples: 26 percent vs 66 percent; discounts: 1 percent vs 55 percent)

- c. almost half (48 percent) of submitters agreed that there should be some restrictions on sponsorship. Again, there was a significant difference in agreement between vapers and non-vapers (27 percent vs 64 percent).
  - d. there was moderate support for standardised packaging for e-cigarettes (48 percent overall), although it appeared that this question was unclear to submitters.
- 156 Under half of submitters (44 percent) supported a ban on vaping in legislated smokefree areas. Non-vapers were more likely than vapers to support a ban (59 percent vs 23 percent).
- 157 There were few substantive submissions on the need for product safety controls. Issues considered important were quality of ingredients, nicotine concentration and maximum volume of nicotine liquid available for sale, child-resistant packaging and labelling. A standards-based approach was generally preferred.
- 158 Most submitters who responded to a question on whether there were other (existing or potential) nicotine-delivery products that should be included in the regulatory controls considered that all nicotine-delivery products (e.g. snus, e-shisha, inhalers and oral sprays) should be included. There were divergent views on whether heat-not-burn cigarettes should be included. A few submitters considered that the legislation should be designed with future innovations in mind and proposed establishing a regulatory framework to evaluate nicotine-delivery products based on their risk profile and utility as a smoking-cessation aid.
- 159 The majority of submitters (84 percent) did not support the imposition of an excise or excise-equivalent duty on nicotine e-liquid.
- 160 The full summary of submissions is available on the Ministry of Health's website: [www.health.govt.nz/publication/consultation-electronic-cigarettes-analysis-submissions](http://www.health.govt.nz/publication/consultation-electronic-cigarettes-analysis-submissions)

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# Conclusions

- 161 A key difficulty in proposing a regulatory regime for e-cigarettes is the lack of evidence that would lead us to definitely conclude how e-cigarettes should be regulated. Governments around the world are grappling with this problem.
- 162 The Ministry of Health’s preferred options are set out below. The set of proposals seeks to maximise the potential benefits of e-cigarettes for smokers by increasing consumers’ access to nicotine e-cigarettes. However, we seek to balance this with protections for the public, as well as smokers themselves, from the risks that may be associated with e-cigarette use.
- 163 The Ministry of Health’s preferred options are to:
- a. regulate nicotine and non-nicotine e-cigarettes and e-liquid as consumer products under the Smoke-free Environments Act 1990 (with the exception of products that make a therapeutic claim which should continue to be regulated as medicines)
  - b. prohibit the sale, and supply in public areas, of nicotine and non-nicotine e-cigarettes and e-liquid to people under the age of 18 years
  - c. restrict the use of vending machines for nicotine and non-nicotine e-cigarettes and e-liquid to R18 settings and require that they be manually operated by a salesperson
  - d. prohibit advertising and marketing of nicotine and non-nicotine e-cigarettes and e-liquid, with exemptions for:
    - i. point-of-sale display for all retailers, in accordance with any regulations that may be prescribed
    - ii. in-store display, free samples, rewards, discounts and co-packaging for specialist vape shops, window displays and promotion on the outside of the store (where settings are R18), in accordance with any regulations that may be prescribed
  - e. develop guidelines to support business owners, local authorities and employers to develop and implement vaping policies for their smokefree areas
  - f. make provisions in the SFEA for product safety controls for e-cigarettes and e-liquid, including:
    - i. product notification
    - ii. manufacturing standards
    - iii. quality and safety of ingredients
    - iv. labelling
    - v. packaging.
  - g. provide a pathway in the SFEA to enable emerging tobacco and nicotine-delivery products to be regulated as consumer products in the future

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# Implementation plan

## Legislative change

- 164 Implementation of the proposals requires amendments to the Smoke-free Environments Act 1990 and the making of regulations under that Act. The amendment bill has a priority 5 on the 2017 legislation programme (referral to a select committee in 2017).

## Development of product safety controls

- 165 The Ministry of Health proposes to work with industry stakeholders and relevant experts to develop detailed proposals for product safety regulation. This work should be informed by relevant policy objectives as follows:
- a. harm prevention
  - b. products should be safe when used as intended
  - c. products should be true to label
  - d. consumers should be supported to make informed choices about the use of e-cigarettes
  - e. regulatory controls should be proportionate to the risks associated with the use of e-cigarettes.
  - f. cost and ease of implementation to industry and government.
- 166 Specific proposals to minimise costs to industry include:
- a. use of existing standards (if suitable international best-practice standards can be identified)
  - b. a self-certified, product notification process
  - c. engagement with industry stakeholders in the developmental process.

## Enforcement

- 167 At present, it seems likely that a good proportion of the e-cigarettes and e-liquid used in New Zealand is bought over the Internet from overseas suppliers, however, there is no information available to quantify this. The legalisation of nicotine e-cigarettes and e-liquid would be expected to result in a shift towards more locally-bought products, but it is likely that many individuals will still choose to purchase from offshore websites.
- 168 The preferred regulatory option for product safety would see the Ministry of Health responsible for enforcement of those requirements. Further work is needed to determine the scope and cost associated with this work, including how any regulatory requirements would be enforced.

169 Enforcement of any regulatory controls related to the sale and supply and advertising of e-cigarettes and e-liquid, as well as vaping in smokefree areas would be undertaken by smokefree officers appointed by the Director-General of Health under the Smoke-free Environments Act 1990. Costs would be met from within existing baselines.

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# Monitoring, evaluation and review

- 170 The Ministry of Health will continue to monitor emerging evidence on e-cigarettes, and other emerging tobacco and nicotine-delivery products, including their safety and potential impacts on smoking prevalence in New Zealand.
- 171 Use of e-cigarettes is monitored via the Health Promotion Agency's biennial Health and Lifestyles Survey and Youth Insights Survey.
- 172 The Youth Insights Survey is a nationwide survey of Year 10 students, conducted every two years. It collects data on smoking-related knowledge, attitudes and beliefs. In 2012 and 2014, it collected information on e-cigarette use. Information on ever using an e-cigarette was reported in both years, and in 2014, those who had ever used an e-cigarette also reported their reasons for first trying one.
- 173 The Health and Lifestyles Survey is a nationwide survey, conducted every two years, of the health attitudes and behaviours of adults aged 15 years and over. In 2014, it collected information on ever using and current use of an e-cigarette, reasons for use and brand recognition.
- 174 Currently, there are no mechanisms in place to monitor the market for e-cigarettes and e-liquid. The proposal for product notification would provide information on what is available on the market, once fully implemented. More work will be done on this as part of considering imposition of an excise duty.
- 175 There are a number of registered studies that will provide more evidence about the effectiveness of e-cigarettes for smoking cessation. The majority of these commenced in the last two years and results are unlikely to be available for another two years. One of the largest trials to be conducted to date will be undertaken in New Zealand by the University of Auckland.
- 176 The Ministry proposes that any legislative changes be reviewed within five years of commencement given the developing nature of the evidence, and that this requirement be prescribed in legislation.

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# Appendix One: Comparison of international regulatory frameworks for e-cigarettes

Country	Legal framework	Sales to under 18s	Smokefree areas	Advertising, promotion, display	Product safety
Australia	<p>Nicotine is classed as a poison under Commonwealth legislation (with exemptions if a product is approved for therapeutic use, for a smoked tobacco product, or for use in animals):</p> <ul style="list-style-type: none"> <li>• sale of nicotine e-cigarettes is prohibited in all states</li> <li>• to-date no nicotine e-cigarette has been approved by the Therapeutic Goods Authority</li> <li>• individuals can import nicotine e-cigarettes for personal use (up to 3 months' supply) under certain conditions.</li> </ul>	<p>Sale of <b>nicotine</b> e-cigarettes is unlawful, except when approved as a medicine.</p> <p>Sale of <b>non-nicotine</b> e-cigarettes to under-18s is subject to different state laws:</p> <ul style="list-style-type: none"> <li>• prohibited in Queensland, NSW, ACT</li> <li>• legislation to prohibit pending in Victoria</li> <li>• prohibited in Western Australia (to all age groups as imitation tobacco products)</li> <li>• not prohibited in South Australia, Northern Territory and Tasmania (laws have not been updated to take account of e-cigarettes).</li> </ul>	<p>Restrictions on vaping in smokefree areas vary from state to state:</p> <ul style="list-style-type: none"> <li>• prohibited in all legislated smokefree areas in Queensland, ACT</li> <li>• legislation to prohibit pending in Victoria</li> <li>• prohibited in a car with a passenger aged under 16 years in NSW</li> <li>• no restrictions in other states (laws have not been updated to take account of e-cigarettes).</li> </ul>	<p>Federal restrictions on advertising of therapeutic products apply.</p> <p>State-level restrictions vary:</p> <ul style="list-style-type: none"> <li>• Queensland, NSW, and ACT prohibit advertising and promotion, and display at retail outlets</li> <li>• legislation pending in Victoria will prohibit advertising and promotion, and display at retail outlets</li> <li>• no restrictions in other states (laws have not been updated).</li> </ul>	<p>TGA requirements apply to nicotine e-cigarettes (regulated as medicines).</p>

Country	Legal framework	Sales to under 18s	Smokefree areas	Advertising, promotion, display	Product safety
United Kingdom	<p>Revised European Union (EU) Tobacco Products Directive sets out new regulations which include nicotine e-cigarettes.</p> <p>EU rules don't apply to therapeutic products, which are regulated under national rules (Medicines and Healthcare Products Regulatory Authority has approved a novel cigarette-like nicotine inhaler called Voke and an e-cigarette called e-voke).</p> <p>Member states can decide how to regulate non-nicotine e-cigarettes.</p>	As per EU directive: prohibits sales of nicotine e-cigarettes to under 18s.	<p>Not included in EU directive.</p> <p>No prohibition – Public Health England has issued guidance to assist businesses and employers determine their own vaping policies.</p>	<p>As per EU directive: cross-border forms of sponsorship and advertising prohibited; other forms of advertising allowed, eg, cinemas, local buses.</p> <p>However, the Scottish Government has legislated for comprehensive advertising restrictions for nicotine and non-nicotine e-cigarettes, except at point-of-sale.</p>	<p>As per EU directive; controls include:</p> <ul style="list-style-type: none"> <li>• nicotine concentration no higher than 20 mg/ml</li> <li>• volume limitations on nicotine e-liquid containers</li> <li>• labelling requirements</li> <li>• health warning re addictiveness of nicotine</li> <li>• licensing of flavours</li> <li>• standards to be met for devices and liquids, including child-resistant closures</li> <li>• products must be notified 6 months prior to marketing.</li> </ul>
Canada <sup>1</sup>	<p>E-cigarettes containing nicotine are regulated as drugs/drug delivery devices under the <i>Food and Drugs Act</i>.</p> <p>Nicotine e-cigarettes require market authorisation from Health Canada before they can be imported, marketed or sold (to date no product has been approved).</p> <p>Non-nicotine e-cigarettes that do not make health claims are legal and are regulated at the provincial level.</p>	The majority of provinces prohibit e-cigarette sales to under-19s (one province has an under-18 ban).	The majority of provinces prohibit vaping in enclosed workplaces and public places, similar to smoking.	<p>The majority of provinces have taken some sort of legislative approach and many of these appear to be in the process of making regulations. Most have some sort of restriction, eg:</p> <ul style="list-style-type: none"> <li>• general ban on promotion at retail, but availability and price information allowed</li> <li>• exemptions for vape shops</li> <li>• prohibition where accessible by minors</li> <li>• prohibition if visible from outside.</li> </ul>	<p>Several provinces have regulation-making powers:</p> <ul style="list-style-type: none"> <li>• related to labelling, eg, for health warnings</li> <li>• to determine unit quantities</li> <li>• to ban flavours.</li> </ul> <p>One state has regulation-making powers to determine product standards.</p> <p>No regulations are yet in place.</p>

<sup>1</sup> On 22 November 2016 the Canadian Government introduced amendments to the Tobacco Act to regulate the manufacture, sale, labelling and promotion of e-cigarettes. This would include prohibiting sales to young people, restricting some forms of advertising, prohibiting sales in vending machines and setting standards for product characteristics (eg, regarding performance, appearance, substances and emissions). Products making a therapeutic claim would continue to be regulated as medicines.

Country	Legal framework	Sales to under 18s	Smokefree areas	Advertising, promotion, display	Product safety
United States	US Food and Drug Administration is implementing product safety regulations for nicotine e-cigarettes.	Sale of nicotine e-cigarettes prohibited to under-18s. Non-nicotine e-cigarette laws differ from state to state.	Vaping in smokefree areas differs from state to state.	Differs from state to state. Federal prohibition on distributing free samples	New regulations include: <ul style="list-style-type: none"> <li>• manufacturer registration</li> <li>• ingredients listing</li> <li>• pre-market review and authorisation of products</li> <li>• health warnings on packaging and advertisements</li> <li>• ban on distributing free samples.</li> </ul>