
Regulatory Impact Statement: Regulation of smokeless 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 for a regulatory framework, under the Smoke-free Environments Act 1990 (SFEA), for smokeless tobacco and nicotine-delivery products.

The discussion on regulator powers, functions and duties, offences and penalties, and regulation-making powers also applies to e-cigarettes and e-liquid, as these issues were not considered by Cabinet in its substantive consideration of the regulation of e-cigarettes in March 2017.

In addition, the Ministry of Health has revisited whether manufacturers and importers of e-cigarettes and e-liquid should be required to provide annual sales returns, similar to requirements for tobacco products.

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:

- reviewed international approaches to the regulation of smokeless tobacco and nicotine-delivery products
- been informed by earlier consultation on the regulation of e-cigarettes, and meetings held in May-June 2017 with invited tobacco policy stakeholders, including health sector agencies, academics, tobacco companies and vape retailers.

Limits on the options analysed

Consideration of the potential impacts of policy options for the new regulatory regime has been hindered by the lack of information about the likely scale of a regulated market. Smokeless tobacco and nicotine-delivery products are currently illegal to sell, however, people can import these products for their own personal use. The Ministry has no information on their use in this country as consumer products (other than e-cigarettes which were the subject of an earlier Regulatory Impact Statement).

This work does not consider whether additional regulatory requirements should be applied to smoked tobacco products. The Ministry acknowledges that the overall outcome of the proposed regulatory changes is likely to see manufacturers/importers of approved smokeless tobacco, nicotine-delivery and vaping products facing a higher regulatory impost than manufacturers/importers of smoked tobacco products, which have a significantly higher risk profile.

Previous Government decisions

In considering a regulatory framework for e-cigarettes in March 2017, Cabinet agreed that the framework should be sufficiently broad in scope to provide a pathway for emerging tobacco and nicotine-delivery products to be regulated as consumer products in future.

Further work

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

Legislative change would be needed before any decisions could be implemented. This is unlikely to be possible before the end of 2018. Regulations, guidelines etc. would also be needed to give effect to some of the more detailed proposals, such as product safety.

Work with industry stakeholders and technical experts would be necessary to develop some of the detailed proposals, for example, for pre-market approval and product safety requirements.

Further work is also needed, in consultation with industry, to accurately determine costs, including fees and levies, and arrangements for cost recovery.

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

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Executive summary

- 1 A range of smokeless tobacco and nicotine-delivery products are marketed internationally as less harmful alternatives to smoking combustible tobacco. At present, these products are likely unlawful unless approved as nicotine replacement therapies by the Minister of Health under the Medicines Act 1981.
- 2 The scope of smokeless tobacco and nicotine-delivery products considered in this Regulatory Impact Statement (RIS) is those that are primarily intended to be used recreationally as a reduced-harm alternative to tobacco smoking, although they may have a side effect of supporting an individual to quit tobacco smoking. A product that is wholly or principally for smoking cessation is, and should continue to be a medicine (eg, nicotine-replacement therapies are produced and marketed as smoking cessation aids, backed up with efficacy data).
- 3 Characteristics of smokeless tobacco and nicotine-delivery products include:
 - a) the clinical, toxicological and behavioural (eg, impact on tobacco smoking and uptake by young people) risks associated with the majority of products available are unknown as there is little published data
 - b) different product types are likely to have widely varying risk profiles
 - c) categories are unlikely to be discrete – overlaps are evident between vaping and heated tobacco technology
 - d) innovation is rapid with new products emerging and existing products constantly changing.
- 4 The regulatory framework needs to be able to respond to the challenges above. It should be flexible enough to deal with products across a broad spectrum of risk and to respond in a timely way to changing evidence about benefits and risks.
- 5 The Ministry of Health recommends that a pre-market approval process be implemented to ensure the quality, safety and reduced-risk profile of any smokeless tobacco or nicotine-delivery products sold in New Zealand. This provides a pathway to enable products to be lawfully marketed as consumer products, where that is appropriate, while also providing protections for public health.

- 6 In addition to pre-market approval, the Ministry recommends the following regulatory controls be placed on approved smokeless tobacco and nicotine-delivery products:

Tobacco product controls	Proposed controls on smokeless tobacco and nicotine-delivery products
Prohibit sale, and supply in a public area, to under-18s	Prohibit sale, and supply in a public area, to under-18s
Restrict use of vending machines so that products can only be accessed by a salesperson for sale to those aged over 18 years	Restrict sales via vending machines to R18 settings
Prohibit use in legislated smokefree areas	Prohibit use only of products that resemble smoking or vaping (regulator has discretion, as part of the pre-market approval process, to determine whether or not a particular product falls within scope of the prohibition)
Prohibit promotion and advertising	Provide scope for exemptions to be prescribed in regulations, for example, to allow point-of-sale display, broader in-store display, advertising in mainstream media, etc
Standardised packaging	Retain requirement for smokeless tobacco products, but do not extend to nicotine-delivery products (status quo under the SFEA)
Annual returns on sales data	Require, with details appropriate to nicotine-delivery products and vaping products specified in regulations
Product safety (there are some product safety-related regulation-making powers, eg, in relation to harmful constituents)	Require, with details relevant to product categories specified in regulations and/or guidelines, notices etc. Product safety requirements should cover manufacturing, ingredients, labelling, packaging, etc

- 7 This regulatory framework should be incorporated within the Smoke-free Environments Act 1990 and the regulatory responsibility should sit with the Director-General of Health.
- 8 The Ministry proposes that the existing regulatory powers, functions and duties, in the SFEA that apply to tobacco products be applied, with any necessary modifications, to vaping products (e-cigarettes and e-liquid), smokeless tobacco and nicotine-delivery products. Additional requirements will be needed relating to new functions, for example:
- a) any pre-market approval processes for smokeless tobacco and nicotine-delivery products
 - b) product notification requirements for e-cigarettes and e-liquid.
- 9 Similarly, existing regulation-making powers should be applied, with any necessary modifications, to all products covered by the Act. New regulation-making powers will be needed to prescribe, for example:
- a) information requirements and other detail related to product approvals, suspension and withdrawal of approvals
 - b) information requirements related to annual sales returns and reports (for vaping products and nicotine-delivery products)
 - c) classes of products that are exempt from aspects of the prohibitions on promotion and advertising of products
 - d) fees for processing applications for pre-market approvals, and product withdrawals, and for any product notification, certificates, audit, etc.

- 10 The offences and penalties regime should be reviewed. A flexible, modern offences and penalties regime should be developed with appropriate penalty levels, and a wide range of options for the regulator, meaning enforcement action can be commensurate with the severity of misconduct, and the regulator's approach can be flexible according to circumstances.
- 11 The new regulatory regime should be fully cost recovered from industry, consistent with Treasury guidelines. Further work is needed, in consultation with industry, to accurately determine costs, including for initial fees and levies, and to develop a cost-recovery plan.

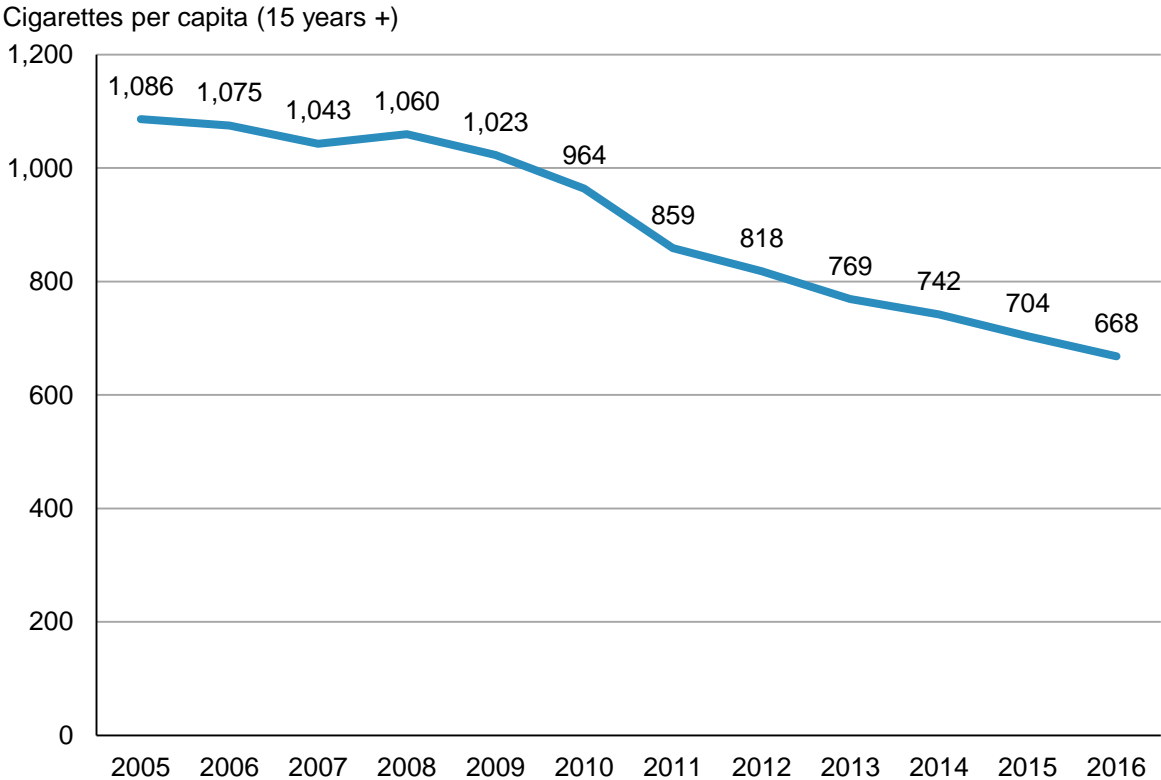
Status quo

Tobacco control in New Zealand

12 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).

13 The following graph shows tobacco consumption (cigarettes per capita, aged 15 years and over) from 2005 to 2016, based on information provided annually by tobacco companies to the Ministry of Health.

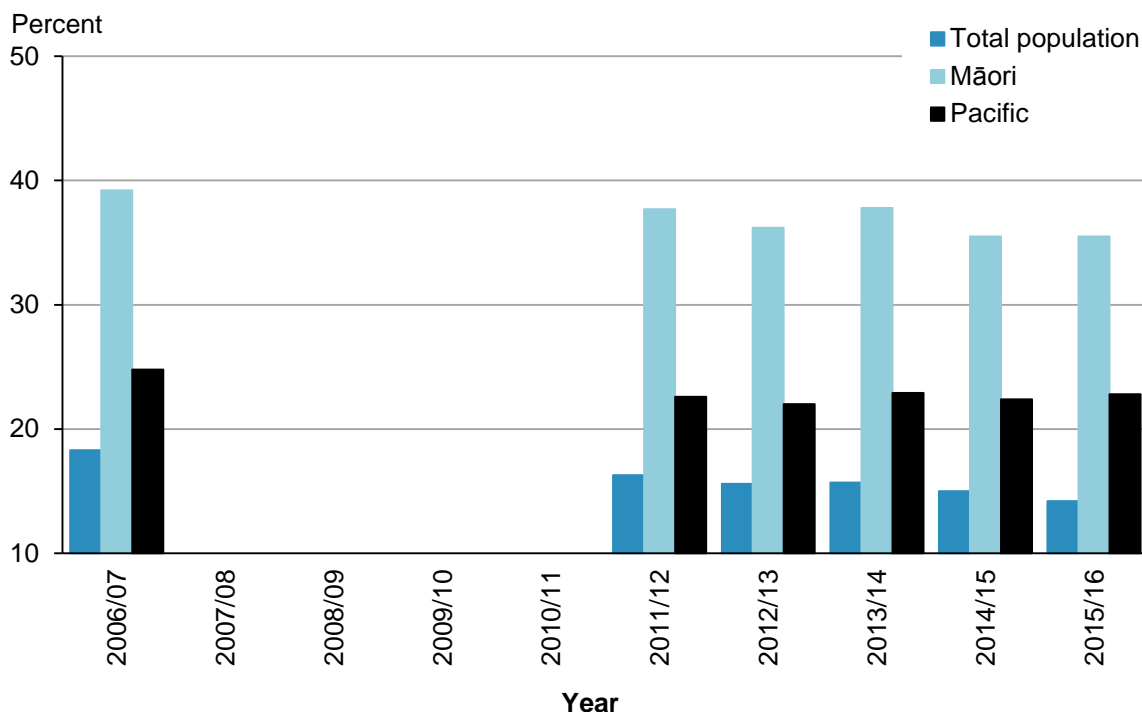
Figure 1: Tobacco consumption



Source: Industry returns

14 The following graph shows prevalence of daily smoking by ethnicity from 2006/07 to 2015/16. The break in data is due to a changed methodology for those years, meaning that data for those years cannot be compared with earlier and subsequent years.

Figure 2: Daily smoking prevalence by ethnicity



Source: New Zealand Health Survey

- 15 New Zealand’s tobacco control programme is comprehensive and based on international best practice, consistent with the Framework Convention on Tobacco Control.
- 16 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.

Current legislative framework

- 17 The sale and supply of smokeless tobacco and nicotine-delivery products as consumer products (rather than medicines) is likely unlawful in New Zealand under the Smoke-Free Environments Act 1990 and/or the Medicines Act 1981.
- 18 The SFEA prohibits the sale of tobacco products for oral use other than smoking. Smokeless tobacco and nicotine-delivery products fall within this prohibition if the nicotine component 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.

- 19 Under the Medicines Act, it is unlawful to sell and supply a product which has not been approved by the Minister of Health (except where it has been prescribed by a doctor) if:
 - it is intended for a therapeutic purpose, for example, to help smokers quit
 - it contains nicotine.
- 20 An amendment to the SFEA (and probably the Medicines Act) would be needed to regulate any of these products as consumer products, if that were considered desirable.
- 21 Other relevant legislation includes the Misuse of Drugs Act 1975, the Fair Trading Act 1986, the Consumer Guarantees Act 1993 and the Hazardous Substances and New Organisms (HSNO) Act 1996 (see Appendix Two).

Definitions

- 22 The SFEA defines a tobacco product as “any product manufactured from tobacco and intended for use by smoking, inhalation, or mastication; and includes nasal and oral snuff; but does not include any medicine (being a medicine in respect of which there is in force a consent or provisional consent given under section 20 or section 23 of the Medicines Act 1981) that is sold or supplied wholly or principally for use as an aid in giving up smoking”.
- 23 Changes will be needed to this and some other definitions in the SFEA to give effect to the proposals in this Regulatory Impact Statement (RIS). In the meantime, working definitions used in this RIS are:
 - a) **smokeless tobacco product:** a product containing tobacco that is consumed in a way which does not involve a combustion process (including chewing tobacco, nasal tobacco, and other tobacco for oral use other than smoking)
 - b) **smoked tobacco product:** a product containing tobacco which may be smoked
 - c) **vaping product:** a device that aerosolises a substance or mixture of substances that is intended for use with the device and which, when heated, produces an aerosol for the purpose of inhalation, and includes a substance or mixture of substances, whether or not it contains nicotine, that is intended to be used with the devices (this includes **e-cigarettes** and **e-liquid**)
 - d) **nicotine-delivery product:** a product, which does not contain tobacco leaf, but that delivers nicotine (and is not a vaping product).

Smokeless tobacco and nicotine-delivery products

- 24 A range of smokeless tobacco and nicotine-delivery products are marketed internationally as less harmful alternatives to smoking combustible tobacco products. Yet the health impacts of these products remains inadequately understood.
- 25 Examples of these products include but are not limited to:
 - a) heated tobacco products
 - b) chewing tobacco, snus, dissolvable tobacco (eg, lollipops), and nasal tobacco
 - c) inhaled nicotine products.Some of these products are described below.

- 26 Technological innovation in these products is rapid with existing products constantly evolving and new products continuously emerging onto the international market.
- 27 Although many smokeless tobacco and nicotine-delivery products are likely to be safer than traditional tobacco smoking, they are not without some degree of health risk. Some of these products may be significantly less harmful than smoked tobacco (similar to e-cigarettes), or only marginally less harmful. For the most part, there is insufficient information to determine where products sit on the harm spectrum, including little information about health risks associated with long-term use of these products.
- 28 There is some concern that smokeless tobacco and nicotine-delivery products may act as a ‘gateway’ to (rather than from) nicotine addiction, attracting non-smokers (particularly young people) who would not otherwise have smoked, and leading on to cigarette smoking. However, views are mixed and the evidence for this is limited.

Heated tobacco products

- 29 Heated tobacco products work by heating tobacco leaf rather than igniting and burning tobacco.
- 30 The precursors of today’s heated tobacco products date from the late 1980s and existing products continue to evolve. There are three types of heated tobacco product:
- The first type has an embedded heat source that can be used to aerosolize nicotine from tobacco leaf directly (eg, RJ Reynold’s *Eclipse*).
 - The second type uses an external heat source to aerosolize nicotine from tobacco leaf directly (eg, Philip Morris International’s (PMI) *IQOS*).
 - The third types use a heated sealed chamber to aerosolize nicotine from tobacco leaf directly (eg, Japan Tobacco International’s (JTI) *Ploom*).

Images of these products are provided below.



Eclipse



IQOS



Ploom

- 31 Heated tobacco products can overlap with vaping products. For example, British American Tobacco’s (BAT) iFuse is a hybrid e-cigarette and heated tobacco product, which has a chamber containing tobacco as well as cartridges containing e-liquid. A heating element aerosolizes the liquid, which passes through the tobacco chamber before being inhaled by the user.
- 32 Heated tobacco products are marketed as less harmful, based on the principle that most of the harm associated with tobacco smoking comes from the combustion process. However, there is little research on the effects of these products, given their rapid evolution in recent years.

- 33 Studies by PMI show that the IQOS product appears to deliver fewer toxicants compared with cigarettes. However, an independent Swiss study showed that aerosol released from IQOS contained a range of toxicants found in tobacco smoking in proportions ranging from 0.2% to 295%, suggesting that it may not be less harmful than smoking tobacco (Auer et al 2017). There is limited data on the British American Tobacco's Glo product and no published studies were found on JTI's Ploom product.
- 34 There is limited information on product use, including whether smokers are likely to switch completely from tobacco smoking or use both types of product, as well as initiation by non-smokers (including young people). Data from a survey undertaken in Japan showed that 7.8% and 8.4% of respondents had 'ever used' Ploom and IQOS, respectively, with highest 'ever use' among current and former smokers. For comparison, the rates of ever using a nicotine-containing e-cigarette was 33.4% (Tabuchi et al 2016).

Chewing tobacco

- 35 Chewing tobacco is made by compressing tobacco leaf and is consumed by placing a portion between the cheek and/or upper lip and gum. The nicotine and flavour are released through crushing the tobacco with the teeth, and the unwanted juices are spat out. Chewing tobacco is one of the oldest methods of consuming tobacco, and versions of this product have been commercially available since the 19th century.
- 36 Evidence indicates that chewing tobacco is a risk factor for oral cancer and precancerous conditions (Foulds et al 2003; Pau et al 2013). Chewing tobacco is still used, predominantly by young males in some parts of the United States. There is limited information on the use of chewing tobacco internationally.

Snus (and moist snuff)

- 37 Snus is made from steam-cured tobacco leaf, and is consumed by placing a portion of the tobacco (which may be packaged in small teabag-like bags) in the cheek or under the lip. The product is similar to moist snuff and dipping tobacco, where the ground tobacco is absorbed in the mouth rather than inhaled.
- 38 Recently, the manufacture of snus has included a range of flavour additives, such as mint, chocolate and fruit. At the same time, snus packaging has changed to include a wide variety of colours and designs to increase appeal, particularly for young people.
- 39 A recent study found that young people are particularly attracted to the packaging and flavoured products, and perceive the product to be less harmful than tobacco smoking (Scheffels and Lund 2017). Snus use has increased dramatically among non-smoking young people in Sweden and Norway since the early 1990s when traditional moist snuff was reintroduced as a new, drier product packed in small sachets (Popova et al 2012).
- 40 There is some evidence that snus does not lead to increased risk of cancer, however, it is possible that snus users have a slightly increased cardiovascular risk compared to those who do not smoke. One study estimated that snus is 90 percent less harmful than smoking cigarettes (Biener et al 2016).

The market for smokeless tobacco and nicotine-delivery products

- 41 The sale of smokeless tobacco and nicotine-delivery products is likely to be unlawful under the Smoke-free Environments Act 1990. Products are, however, available for purchase online. One tobacco company has launched its heated tobacco product in the New Zealand market and a prosecution for unlawful sale is pending.
- 42 The Ministry is unable to ascertain the size of the market for smokeless tobacco and nicotine-delivery products in New Zealand, due to a lack of information. The international market is developing quickly as more products become available and are marketed as safer alternatives to smoking. In Japan, there has been a rapid uptake of Philip Morris' heated tobacco product, IQOS. Some commentators have suggested that this may be because vaping products are unavailable in Japan (Auer 2017).

Interface with illicit drugs

- 43 Some devices which can be used to heat and vaporise tobacco and other forms of nicotine can also be used for illicit drugs. The Misuse of Drugs (Prohibition of Cannabis Utensils and Methamphetamine Utensils) Notice 2014 prohibits the importation of specific drug utensils, including hookahs and water pipes, which are commonly used for tobacco. Such utensils would not be eligible to be approved as smokeless tobacco or nicotine-delivery products.

Challenges in designing a regulatory framework for smokeless tobacco and nicotine delivery products

- 44 There are significant challenges in proposing a regulatory framework for smokeless tobacco and nicotine-delivery products, including:
 - a) the clinical, toxicological, and behavioural (eg, impact on tobacco smoking and uptake by young people) risks associated with the majority of products available are unknown, as there is little published data
 - b) different product types are likely to have widely varying risk profiles – at one end are products with a considerable body of evidence to show that the balance of risks and benefits makes it appropriate that they be regulated as consumer products (ie, e-cigarettes). At the other end is tobacco for smoking, which is likely the most harmful to human health. In between, are products about which we have varying degrees of knowledge about their impact on human health, both direct and indirect (eg, via effects of emissions on bystanders, attractiveness to children and young people, whether they are a 'gateway' to tobacco smoking)
 - c) categories are unlikely to be discreet – already we see overlaps between vaping and heated tobacco technology
 - d) innovation is rapid; new products are emerging and existing products are constantly changing.

Regulatory approaches in other jurisdictions

- 45 In some jurisdictions, the way smokeless tobacco is regulated depends, by default, on how it fits into their existing tobacco control legislation. For example, in New Zealand and Australia, smokeless tobacco is prohibited whereas, in Canada, it is regulated like tobacco for smoking. Other jurisdictions have established regulatory frameworks that provide a pathway for new or novel tobacco and nicotine-delivery products to be lawfully marketed.
- 46 In the United States, distributors of ‘new tobacco products’¹ are required to make a pre-market tobacco application to the Federal Food and Drug Administration (FDA). The applicant must provide toxicological and behavioural (eg, 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.
- 47 The European Union Tobacco Product Directive 2014/40/EU includes processes for the notification of ‘e-cigarettes’, ‘refill containers’, and ‘novel tobacco products’. The United Kingdom’s implementing regulations require producers to give six months’ notification of their intention to market a novel tobacco product, e-cigarette or e-liquid. Notification requirements include the provision of toxicological and behavioural information. Provided notification requirements are met, approval is not required before the product can be marketed.
- 48 More detailed information on these regulatory frameworks is contained in Appendix One.

¹ Definition includes nicotine-delivery products (including e-cigarettes).

Problem definition

- 49 If a smokeless tobacco or nicotine-delivery product were considered appropriate for sale as a consumer product, an amendment to the SFEA would be needed each time to legalise it and regulate it as a consumer product. Cabinet has asked officials to consider alternative pathways for emerging products to be regulated as consumer products in future.

Objectives

- 50 There is no statutory basis for undertaking this work. It has been commissioned by the Associate Minister of Health, who is responsible for the tobacco control portfolio.
- 51 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.
- 52 The overall outcomes sought through changes to the way smokeless tobacco and nicotine-delivery products are regulated is to contribute to the achievement of *Smokefree 2025*. Smokers switching from tobacco smoking to the use of smokeless tobacco and nicotine-delivery products will contribute to the achievement of this goal.²
- 53 The primary objectives of any policy changes are:
- a) **Harm reduction:** to reduce the harm to individual smokers from tobacco smoking, where smokers switch to smokeless tobacco and nicotine-delivery products.
 - b) **Harm prevention:** to prevent harm to the public from greater access to smokeless tobacco and nicotine-delivery products, 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 that the increasingly visible use of smokeless tobacco and nicotine-delivery products will renormalise smoking-like behaviour.
 - c) **Risk proportionality:** tobacco and nicotine-delivery products span a broad spectrum of risks, including clinical, toxicological, and behavioural (eg, impact on tobacco prevalence and uptake by young people) risks.

Tobacco smoking is at the upper end of the risk spectrum. E-cigarettes, estimated by Public Health England to be 95 percent less harmful than smoking, are at the lower end and have been considered by the New Zealand Government as being appropriate for sale as a consumer product, subject to a range of controls under the SFEA.

The regulatory framework should be flexible enough to respond proportionately to the wide range of risks associated with the use of tobacco and nicotine-delivery products.
 - d) **Product safety:** to protect users and non-users from harm as a result of the use of smokeless tobacco and nicotine-delivery products:
 - 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 smokeless tobacco and nicotine-delivery products.

² The use of e-cigarettes, smokeless tobacco and nicotine-delivery products is not considered smoking, although prevalence of the use of these alternative products will be monitored alongside smoking.

e) **Cost and ease of implementation:** for industry and government is reasonable given the potential health harms associated with the use of smokeless tobacco and nicotine-delivery products.

- 54 Some trade-off must be made between objectives 1 and 2 – harm reduction and harm prevention. Making products more accessible for smokers to switch to a safer alternative also increases the likelihood that non-smokers will use new products and potentially also go on to smoke tobacco, increasing their health risks. This is particularly of concern for those who would not otherwise have gone on to smoke, in the absence of the introduction of the new product. The Ministry of Health considers that e-cigarettes set a benchmark and that any products approved in future should have a similar risk to benefit profile as e-cigarettes.
- 55 One study has modelled the impact of e-cigarettes using four different levels of risk ranging from 2.5 percent to 25 percent relative to the risk of smoking (ie, 97.5 percent to 75 percent safer than smoking). Under this model, using a 5 percent risk estimate, there is a net public health benefit associated with e-cigarettes, resulting in 21 percent fewer smoking-attributable deaths and a 20 percent reduction in life years lost (Levy et al 2016).
- 56 For people in this model who would never have started smoking, over 80 percent would have to seriously try e-cigarettes (ie, not just puff on someone else’s device) for net harms to appear, assuming a 5 percent level of health risk associated with e-cigarette use (Levy et al 2016; McRobbie 2016).
- 57 The net benefit of any new product would depend on the level of risk associated with its use. However, it is expected that in order for a product to be approved or suitable to be notified, it should be broadly similar to the harm associated with the use of e-cigarettes.

Options and impact analysis

Criteria for assessing options

- 58 The following objectives are used as criteria for assessing the options for the issues outlined in this section:
- a) harm reduction
 - b) harm prevention
 - c) risk proportionality
 - d) product safety
 - e) cost and ease of implementation.
- 59 The issues considered in this section are:
- a) who decides whether smokeless tobacco and nicotine-delivery products should be lawfully marketed
 - b) what regulatory controls should apply to smokeless tobacco and nicotine-delivery products:
 - i) sale, and supply in a public place, to under 18s
 - ii) use of vending machines
 - iii) use in legislated smokefree areas
 - iv) promotion and advertising
 - v) standardised packaging
 - c) product safety requirements
 - d) provision of annual sales data
 - e) a regulatory vehicle and regulator.
- 60 While these issues comprise an overall package in terms of a regulatory regime for smokeless tobacco and nicotine-delivery products, each issue stands alone. If the Ministry's recommendation under issue 1 (pre-market approval) is not accepted, this does not influence the Ministry's recommendations under subsequent issues.

Issue 1: Who decides whether smokeless tobacco and nicotine-delivery products should be lawfully marketed?

- 61 The Government has recently decided that e-cigarettes and e-liquid should be able to be lawfully sold and distributed in New Zealand. Parliament needs to amend the SFEA to give effect to this decision. Under the status quo, this process would need to be followed in future if a smokeless tobacco or nicotine-delivery product were assessed as being appropriate for regulation as a consumer product under the SFEA. Cabinet has asked officials to consider alternative pathways for emerging tobacco and nicotine-delivery products to be regulated as consumer products in future.
- 62 International models for emerging tobacco and nicotine-delivery products vary. In some countries (eg, Canada) the default position under their tobacco control legislation allows smokeless tobacco products to be marketed. In others (eg, Australia) the sale of such products is, by default, prohibited.
- 63 The United States and the European Union (EU) have implemented processes to provide a pathway for the lawful marketing of smokeless tobacco and nicotine-delivery products. The United States has a pre-market approval requirement and the EU has an extensive notification requirement (although member states may introduce a more robust pre-market approval process).
- 64 The four approaches considered below are:
- a) Option 1: (status quo) an **amendment to the SFEA by Parliament** is needed every time it is determined that a smokeless tobacco or nicotine-delivery product, or class of such products, should be legalised and regulated as a consumer product under the SFEA.
 - b) Option 2: smokeless tobacco and nicotine-delivery products, or classes of such product, are legalised and regulated as consumer products under **regulations made under the SFEA, following a decision by Cabinet**.
 - c) Option 3(a): smokeless tobacco and nicotine-delivery products are legalised and regulated as consumer products by the manufacturer/importer obtaining a **pre-market approval issued by a regulator**.

Manufacturers/importers would be required to submit specified information to a regulator prior to marketing a product. This information would be assessed to determine whether the product meets the requirements for regulation as a consumer product under the SFEA. The regulator must approve the product before it can be marketed. This is similar to the process New Zealand has in place for approving medicines and psychoactive substances.

If this option were to be progressed, detailed requirements for pre-market approval would need to be developed and consulted upon.

- d) Option 3(b): smokeless tobacco and nicotine-delivery products are legalised and regulated as consumer products by the **manufacturer/importer registering the product on an online database and self-certifying that it meets regulatory requirements.**

The regulator would not be required to actively approve the product, although it would have the power to remove a product from the market if it was found that the product did not meet regulatory requirements. This is similar to the self-certification model proposed for natural health products (cf Natural Health and Supplementary Products Bill).

If this option were to be progressed, detailed requirements for product notification/self-certification would need to be developed and consulted upon.

- 65 The EU notification regime is not considered as an option. In its detail, the EU regime has significant information requirements, consistent with what would be expected of a pre-market approval system. The Ministry of Health considers that, if extensive data is required as would be expected with products that are higher than low-risk, or of unknown risk, then the onus is on the regulator to assess that information and it is appropriate that a pre-market approval system, rather than a notification system, be developed.
- 66 The following table compares the options for the decision-maker for smokeless tobacco and nicotine-delivery products.

Table 1: Comparison of options for the decision-maker for smokeless tobacco and nicotine-delivery products

Options	Option 1: status quo (legislative amendment by Parliament)	Option 2: regulations (Executive)	Option 3(a): pre-market approval (regulator)	Option 3(b): self-certification (manufacturer/importer)
	An amendment to the SFEA is needed to allow marketing of smokeless tobacco and nicotine-delivery products or classes of products	Products, or classes of product, are authorised for marketing by Order in Council	Regulator assesses and authorises product as suitable for marketing following application by manufacturer/importer	Manufacturer/importer registers the product on an online database and self-certifies it meets regulatory requirements
Pros	<p>Minimises potential health risks, including addiction, to public from use of smokeless tobacco and nicotine-delivery products</p> <p>Minimises potential for renormalisation of smoking-like behaviour, particularly among young people</p> <p>Very high level of public scrutiny before products can be marketed</p>	<p>Smokers' access to reduced-risk products is improved (potentially greater choice, faster access)</p> <p>Some degree of public scrutiny, eg, public consultation could be required; regulations would be subject to review by Regulations Review Committee, judicial review, publication, disallowance, etc.</p> <p>Harm-reduced products are likely to get to market more quickly than under Option 1</p>	<p>Smokers' access to reduced-risk products is improved (potentially greater choice, faster access)</p> <p>Increased choice may provide options for smokers for whom existing alternative products have not worked</p> <p>Manufacturers and importers can market products provided they meet requirements for approval</p> <p>Users of smokeless products have access to local, legal source</p> <p>Pre-market assessment of products' suitability for marketing provides assurance that the level of risk is acceptable</p> <p>Technical nature of the decision makes it one more appropriately taken at an administrative level</p> <p>Regulator know what products are on the market by manufacturer/ importer to support post-market action (eg, recall) if needed</p> <p>Local manufacturers may benefit in export markets through have a robust local regulatory system</p>	<p>Smokers' access to potentially reduced-risk products is improved (almost certainly greater choice, faster access compared with option 3(a))</p> <p>Increased choice may provide options for smokers for whom existing alternative products have not worked</p> <p>Users of smokeless products have access to local, legal source</p> <p>Business can market products provided they meet regulatory requirements</p> <p>Reduced cost to business (including compliance costs and time to market) compared with Option 3(a)</p> <p>Technical nature of decision makes it one more appropriately taken at an administrative level Regulator has register of products on the market by manufacturer/ importer to support post-market action (eg, recall) if needed</p>

Options	Option 1: status quo (legislative amendment by Parliament)	Option 2: regulations (Executive)	Option 3(a): pre-market approval (regulator)	Option 3(b): self-certification (manufacturer/importer)
	An amendment to the SFEA is needed to allow marketing of smokeless tobacco and nicotine-delivery products or classes of products	Products, or classes of product, are authorised for marketing by Order in Council	Regulator assesses and authorises product as suitable for marketing following application by manufacturer/importer	Manufacturer/importer registers the product on an online database and self-certifies it meets regulatory requirements
Cons	Restricts smokers' access to potentially harm-reduced products through time taken to amend legislation (around 18 months at best)	Restricts smokers' access to potentially harm-reduced products through time taken to make regulations	<p>Restricts smokers' access to potentially harm-reduced products through delayed time to market while products are assessed</p> <p>Non-smokers, including young people, may be attracted to try new products, increasing their health risks</p> <p>Users may buy unapproved product brands online or on the black market</p> <p>Costs of the regime may increase costs to users compared with buying online</p> <p>Upfront costs to government to establish and maintain the approval process, but these could be recovered from industry</p> <p>Cost to business (including compliance costs and delayed time to market compared with Option 3(b) likely to be passed on to customers</p> <p>Increased range of products available may increase complexity for stop-smoking services and smokefree enforcement officers</p>	<p>Non-smokers, including young people, may be attracted to try new products, increasing their health risks</p> <p>Reliance on self-certification that regulatory requirements are met, rather than independent assessment</p> <p>Inadequate to regulate products with a wide spectrum of risk; appropriate for low-risk products</p> <p>Users may buy product brands that are not notified online or on the black market</p> <p>Costs of the regime may increase costs to users compared with buying online</p> <p>Cost to business (including compliance costs) likely to be passed on to customers</p> <p>Likely to be additional post-market costs to government over Option 3(a) associated with managing risks related to inappropriate products that make their way onto the market</p> <p>Increased range of products available may increase complexity for stop-smoking services and smokefree enforcement officers (likely to be more complex under this option than 3(a) as more products are likely to come to market more quickly</p>

67 The following table compares the impact of the options for the decision-maker for smokeless tobacco and nicotine-delivery products against the criteria set out in paragraph 58.

Table 2: Impact assessment of options for the decision-maker for smokeless tobacco and nicotine-delivery products compared with the status quo

Comparison of options with the status quo (ie, amend primary Act)			
Criteria	Option 2: authorise marketing by regulations	Option 3(a): pre-market approval	Option 3(b): self-certification
Harm reduction	Much better	Much better	Better
Harm prevention	Same	Same	Worse
Risk proportionate	Better	Much better	Worse
Product safety	Better	Much better	Better
Cost and ease of implementation	Much better	Better	Better
Conclusion	Recommended		

Conclusion

68 The Ministry of Health recommends option 3(a): the decision about whether to allow smokeless tobacco and nicotine-delivery products to be lawfully marketed is made by a regulator based on information submitted in an application by the manufacturer/importer. An active approval is required before the product can be marketed.

69 Compared with the status quo and option 2, this option better lends itself to the nature of the market, where risks are higher than low-risk or are uncertain, and technology and products are changing rapidly. Compared with option 3(b), it provides considerably more safeguards for public health.

Issue 2: What regulatory controls should apply to smokeless tobacco and nicotine-delivery products?

70 The following table sets out the regulatory requirements that apply to smoked tobacco compared with those Government has recently agreed should apply to e-cigarettes (which have yet to go through Parliament).

Table 3: comparison of regulatory controls for tobacco products with those proposed for e-cigarettes and e-liquid

Regulatory controls	Tobacco	E-cigarettes
Prohibit sale, and supply in a public place, to under-18s	✓	✓
Restrict use of vending machines to R18 settings	✓	✓
Prohibit use in legislated smokefree areas	✓	✓
Prohibit all promotion and advertising:	✓	x
• exempt point-of-sale display for all retailers	x	✓
• exempt in-store display, discounts, etc for R18 retailers	x	✓
• exempt promotion on outside of store for R18 retailers	x	✓
Standardised packaging requirements	✓	x
Require annual returns on sales data	✓	x
Product safety requirements		
• product notification	x	✓
• manufacturing standards	x	✓
• ingredients	x	✓
• labelling	✓	✓
• packaging	✓	✓
• annual testing	✓	tbc
• disclosure of product content and composition	✓	tbc

71 If we apply a principle of risk proportionality, we would expect products that are less harmful to have lesser regulatory controls than smoked tobacco. However, we have a dearth of evidence for the majority of smokeless tobacco and nicotine-delivery products about the direct and indirect health risks to users and bystanders, as well as other concerns, such as the attractiveness of the products to non-smokers, particularly young people.

Sub-issue 2(a): sale and supply of smokeless tobacco and nicotine-delivery products to people under the age of 18 years

72 The sale, and supply in a public place, of tobacco products is prohibited to people under 18 years of age. This also applies to online sales. Cabinet has recently agreed to extend this prohibition to the sale, and supply in a public place, of e-cigarettes.

73 The status quo for smokeless tobacco and nicotine-delivery products varies. Smokeless tobacco products cannot be sold at all, including to under 18 year olds. Nicotine-delivery products do not fall under this prohibition but e-cigarettes will, subject to amendments being made to the SFEA.

- 74 The options considered below are:
- a) Option 1: (status quo) the sale, and supply in a public place, of tobacco products (including smokeless tobacco products) to under 18s is prohibited, including via online sales; this prohibition does not apply to nicotine-delivery products.
 - b) Option 2: exempt any smokeless tobacco products from the prohibition on sale, and supply in a public place, to under 18s.
 - c) Option 3: prohibit sale, and supply in a public place, of all tobacco and nicotine-delivery products to under 18s. This would also apply to online sales.
- 75 Option 3 only affects sale, and supply in a public place, to under 18s. It does not stop whānau from giving reduced-harm products to younger people for any reason, including to provide them with a safer option than tobacco smoking or to support them to quit smoking. Nor does it affect the way nicotine replacement therapy (NRT) is regulated under the Medicines Act. NRT is available to young smokers from the age of 12 years, providing another legal means of access to products to support minors to quit smoking.
- 76 The following table compares the options for the sale and supply in a public place, of smokeless tobacco and nicotine-delivery products to people under 18 years of age.

Table 4: Comparison of options for sale, and supply in a public place, of smokeless tobacco and nicotine-delivery products to under 18s

Options	Option 1: status quo	Option 2:	Option 3:
Sale, and supply in a public place, of tobacco products (including smokeless tobacco) to under 18s is prohibited	No prohibition on nicotine-delivery products (but intended to be applied to e-cigarettes and e-liquid)	Exempt smokeless tobacco products from the prohibition on sale, and supply in a public place, to under 18s	Prohibit sale, and supply in a public place, of <u>all</u> tobacco and nicotine-delivery products to under 18s
Pros	Provides access to potential harm reduced nicotine delivery products to smokers under the age of 18 years Optimises size of market and potential for business growth	Provides access to potential harm reduced products to smokers under the age of 18 years Optimises size of market and potential for business growth	Limits potential risks to health from long-term use of nicotine products, including addiction Limits potential risk of renormalisation of smoking-like behaviour among young people Limits size of market and potential for business growth
Cons	May increase potential risks from long-term use of nicotine products May increase risk of renormalisation of smoking-like behaviour among young people Limits size of market and potential for business growth	May result in disproportionate regulation if the prohibition applies to e-cigarettes, but not other nicotine-delivery products May increase potential risks from long-term use of smokeless tobacco products May increase risk of renormalisation of smoking-like behaviour among young people May result in disproportionate regulation if the prohibition applies to e-cigarettes, but not smokeless tobacco products Limits size of market and potential for business growth	Limits access to potential harm-reduced products to smokers under the age of 18 (although products may be provided to minors in a private place, eg, by parents to give young smokers a less harmful option) Limits size of market and potential for business growth

77 The following table compares the impact of the options for the sale, and supply in a public place, of smokeless tobacco and nicotine-delivery products to under-18s against the criteria set out in paragraph 58.

Table 5: Impact assessment of options for sale and supply of smokeless tobacco and nicotine-delivery products to minors compared with the status quo

Comparison of options with the status quo (ie, sale, and supply in a public place, to under 18s is prohibited for tobacco products, but not nicotine-delivery products)		
Criteria	Option 2: Exempt smokeless tobacco products from the prohibition of sale, and supply in a public place, to under 18s	Option 3: Prohibit sale, and supply in a public place, of <u>all</u> smokeless tobacco and nicotine-delivery products to under 18s
Harm reduction	Much better	Worse
Harm prevention	Worse	Much better
Risk proportionate	Better	Better
Product safety	Same	Same
Cost and ease of implementation	Better	Much better
Conclusion		Recommended

Conclusion

78 The Ministry of Health recommends option 3: a prohibition on the sale, and supply in a public place, of all tobacco and nicotine-delivery products to those under the age of 18 years. This proposal protects young people from any potential long-term health risks associated with the use of nicotine products, including addiction. It also contributes to maintaining an environment in which smoking-like behaviour is not seen as normal or desirable.

Sub-issue 2 (b): use of vending machines for smokeless tobacco and nicotine-delivery products

79 Vending machines can be used to sell tobacco products if they can only be accessed by a salesperson to sell products to those aged 18 years and over. This supports the prohibition on sales to under 18 year olds. The Government intends to restrict the use of vending machines to sell e-cigarettes and e-liquid to R18 settings to support the prohibition on sales to under-18s.

80 Smokeless tobacco products cannot be sold at all, including via vending machines. There are no controls over whether nicotine-delivery products can be sold via vending machines.

81 The following table compares the options for sale via vending machines for smokeless tobacco and nicotine-delivery products.

82 The options considered below are:

- a) Option 1 (status quo): sale of smokeless tobacco products is prohibited (including via vending machines; there are no restrictions on the sale of nicotine-delivery products, including via vending machines)
- b) Option 2: restrict use of vending machines so that products can only be accessed by a salesperson for sale to those over 18 years (current control under the SFEA for tobacco products)
- c) Option 3: restrict sale via vending machines to R18 settings (consistent with Government's decision on e-cigarettes and e-liquid)
- d) Option 4: allow sale of all smokeless tobacco and nicotine-delivery products via vending machines, without restrictions to limit sales to under-18s.

Table 6: Comparison of high-level options for sale via vending machines

Options		Option 1: status quo	Option 2:	Option 3:	Option 4:
	The sale of smokeless tobacco products is prohibited, including via vending machines	There are no restrictions on the sale of nicotine-delivery products via vending machines (but restrictions are intended to be applied to e-cigarettes and e-liquid)	Restrict the use of vending machines so that products can only be accessed by a salesperson for sale to those aged 18 and over	Restrict sale via vending machines to R18 settings	Allow sale of all smokeless tobacco and nicotine-delivery products via vending machines, without restrictions to limit sales to under-18s
Pros	Supports proposed ban on sales to minors	Provides smokers with greater access to potentially reduced-harm products	Supports proposed ban on sales to minors	Supports proposed ban on sales to minors Provides better access for smokers to option 2 Consistent with Cabinet's decisions on e-cigarettes Differentiates between smoked tobacco and reduced-harm products	Increases smokers' access to potentially harm-reduced products
Cons	Reduces smokers' access to potentially reduced-harm products	Would be inconsistent with government's decisions on e-cigarettes and e-liquid	Reduces smokers' access to potentially harm-reduced products, with disproportionate impact on smokers under 18 years Would be inconsistent with government's decisions on e-cigarettes	Reduces smokers' access to potentially harm-reduced products, with disproportionate impact on smokers under 18 years	Increases young people's access to nicotine products (inconsistent with Ministry of Health's recommendation under issue 2(a) above)

83 The following table compares the impact of the options for the sale of smokeless tobacco and nicotine-delivery products via vending machines against the criteria set out in paragraph 58.

Table 7: Impact assessment of options for sale of smokeless tobacco and nicotine-delivery products via vending machines compared with the status quo

Comparison of options with the status quo (ie, sale of smokeless tobacco is prohibited, including via vending machines; there are no restrictions on the sale of nicotine-delivery products via vending machines)			
Criteria	Option 2: Restrict the use of vending machines so that products can only be accessed by a salesperson for sale to those aged 18 and over	Option 3: Restrict the use of vending machines to R18 settings	Option 4: Allow sale of all smokeless tobacco and nicotine-delivery products via vending machines, without restrictions
Harm reduction	Better	Better	Much better
Harm prevention	Worse	Worse	Much worse
Risk proportionate	Better	Much better	Better
Product safety	Same	Same	Same
Cost and ease of implementation	Worse	Worse	Worse
Conclusion	Recommended		

Conclusion

84 The Ministry of Health recommends option 3: restrict use of vending machines so that smokeless tobacco and nicotine-delivery products can only be sold via vending machines in R18 settings, consistent with proposals for e-cigarettes. This supports the proposed prohibition on sale, and supply in a public place, of smokeless tobacco and nicotine-delivery products to those under the age of 18 years.

Sub-issue 2(c): Use of smokeless tobacco and nicotine-delivery products in legislated smokefree areas

85 The 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 from second-hand smoke to employees in indoor workplaces.

86 The Government has agreed to prohibit vaping in legislated smokefree areas, due to concerns that increasingly visible vaping in public areas and around children has the potential to erode cultural norms around the undesirability of smoking-like behaviour.

87 Most local authorities have also designated smokefree outdoor areas, over and above the requirements of the SFEA (Auckland City Council 2016). 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. Local authorities also make their own decisions about whether to prohibit vaping in their smokefree areas.

- 88 Some types of smokeless tobacco and nicotine-delivery products resemble smoking or vaping and their use in legislated smokefree areas could result in confusion, making compliance and enforcement difficult. This concern would not apply to all product types, for example, snus and chewing tobacco.
- 89 The options considered below are:
- a) Option 1: (status quo) the use of smokeless tobacco and nicotine-delivery products in legislated smokefree areas is lawful (the existing legislative prohibition applies to smoking)
 - b) Option 2: prohibit use of smokeless tobacco and nicotine-delivery products that produce harmful emissions in legislated smokefree areas
 - c) Option 3: prohibit use only of products that produce emissions and/or resemble smoking in appearance in legislated smokefree areas
- 90 If either option 2 or 3 is agreed, the Ministry of Health considers that it would be useful to have regulation-making powers prohibit the use of product classes in legislated smokefree areas. It would also be important to give the regulator a power to declare products to be subject to/exempt from the prohibition. The reasons for this are that it is likely that:
- evidence on the harm associated with the emissions from a product/product type will shift over time
 - products will evolve to produce less harmful emissions
 - products will emerge that do not fit neatly into either the prohibited or not prohibited grouping of products given the highly innovative nature of the market.

- 91 The following table compares the options for use of smokeless tobacco and nicotine-delivery products in legislated smokefree areas.

Table 8: Comparison of options for use of smokeless tobacco and nicotine-delivery products in legislated smokefree areas

Options	Option 1: status quo	Option 2:	Option 3:
	Use of smokeless tobacco and nicotine-delivery products in legislated smokefree areas is lawful (provided they do not involve smoking)	Prohibit use only of smokeless tobacco and nicotine-delivery products that contain harmful emissions in legislated smokefree areas	Prohibit use only of products that produce emissions and/or resemble smoking in appearance in legislated smokefree areas
Pros	May provide incentive for smokers to switch to potentially harm-reduced products if they can use smokeless tobacco and nicotine-delivery products where they can't smoke	Minimises risks of harm to the health of bystanders due to inhaling harmful second-hand emissions May encourage smokers to switch if they can use potentially harm-reduced products where they can't smoke May limit potential risk of renormalisation of smoking-like behaviour, particularly among young people	Limits potential risk of renormalisation of smoking-like behaviour, particularly among young people
Cons	May increase risk of renormalisation of smoking-like behaviour, particularly among young people Inconsistent with Government decision to prohibit vaping in legislated smokefree areas Creates difficulties for enforcement if some product types are prohibited and others that appear similar are allowed	Reduced incentive for smokers to switch if they can't use potentially reduced-harm products when they can't smoke Inconsistent with Government decision to prohibit vaping in legislated smokefree areas	Reduced incentive for smokers to switch to particular potentially harm-reduced products if they can't use them where they can't smoke

- 92 The following table compares the impact of the options for using smokeless tobacco and nicotine-delivery products in legislated smokefree areas against the criteria set out in paragraph 58.

Table 9: Impact assessment of options for use of smokeless tobacco and nicotine-delivery products in legislated smokefree areas compared with the status quo

Criteria	Comparison of options with the status quo (ie, use of smokeless tobacco and nicotine-delivery products in legislated smokefree areas is permitted)	
	Option 2: Prohibit use only of products which have harmful emissions in legislated smokefree areas	Option 3: Prohibit use only of smoking/vaping-like products in legislated smokefree areas
Harm reduction	Worse	Worse
Harm prevention	Better	Better
Risk proportionate	Better	Much better
Product safety	Better	Same
Cost and ease of implementation	Better	Better
Conclusion		Recommended

Conclusion

- 93 The Ministry of Health recommends option 3: prohibit use of smoking-like products (ie, devices and products, the use of which resembles smoking or vaping and/or that produce emissions) in legislated smokefree areas. This is consistent with the rules that apply to smoking and are intended to apply to vaping, subject to amendments to the SFEA. This consistency will support cost and ease of implementation, including enforcement. Option 2 would be disproportionate as it would see a prohibition on the use of products that are not visible to the public, for example, snus (if that were to be legalised).
- 94 It will be necessary to have the ability to declare products to either be or not be subject to a prohibition on use in legislated smokefree areas, to deal with uncertainty around the margins about which category products fit into and to deal with changing evidence related to the safety of products over time.

Sub-issue 2(d): promotion and advertising of smokeless tobacco and nicotine-delivery products

- 95 The SFEA prohibits promotion and advertising of tobacco products (including smokeless tobacco). 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’.
- 96 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.
- 97 These prohibitions do not apply to nicotine-delivery products. The Government has, however, agreed to prohibit promotion and advertising of e-cigarettes, with exemptions for:
- a) point-of-sale display for all retailers
 - b) broader in-store display (including window display) for R18 retailers
 - c) giving of free sample, rewards, discounts and co-packaging for R18 retailers
 - d) promotion on the outside of stores for R18 retailers (eg, to name a shop and advise availability of products, which cannot be done with respect to tobacco products).
- 98 Without any legislated controls, the advertising industry would self-regulate the promotion and advertising of products. The Advertising Standards Authority has developed Codes of Practice including the Advertising Code of Ethics, which includes a number of principles, for example, that advertising should not be misleading or deceptive and should be prepared with a due sense of social responsibility.
- 99 Complaints about advertising 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.

100 The options considered below are:

- a) Option 1: (status quo) promotion and advertising of tobacco products (including smokeless tobacco) is prohibited; there are no prohibitions on promotion and advertising of nicotine-delivery products (although the Government has agreed to prohibit promotion and advertising of e-cigarettes and e-liquid, with some exemptions, which requires an amendment to the SFEA).
- b) Option 2: prohibit promotion and advertising of all products, including nicotine-delivery products tobacco (notification of product availability would be permitted).
- c) Option 3: prohibit promotion and advertising of all tobacco and nicotine-delivery products, but provide a power enabling products or product classes to have exemptions from the prohibition based on their risk profile, by regulations or the regulator.

101 The following table compares the options for promotion and advertising, including sponsorship, of smokeless tobacco and nicotine-delivery products.

Table 10: Comparison of options for promotion and advertising, including sponsorship, of smokeless tobacco and nicotine-delivery products

Options	Option 1: status quo	Option 2:	Option 3:
	Promotion and advertising of tobacco products (including smokeless tobacco) is prohibited, but not nicotine-delivery products (industry self regulates)	Prohibit promotion and advertising of all products (notification of product availability would be allowed)	Prohibit promotion and advertising of all tobacco and nicotine-delivery products, but provide a <u>regulation-making power</u> to enable products or product classes to have exemptions
Pros	<p>Increases smokers' awareness of nicotine-delivery products as a safer alternative to smoking</p> <p>Provides potential for nicotine-delivery products to be seen as 'normal' consumer products</p> <p>Limits potential for downplay of risks to non-smokers</p> <p>Minimises uptake by non-smokers of smokeless tobacco</p> <p>Limits potential for long-term health risks, including addiction, from smokeless tobacco products</p> <p>Limits risk of renormalisation of smoking-like behaviour</p>	<p>Minimises potential for products to be seen as 'normal' consumer products</p> <p>Limits potential for downplay of risks to non-smokers</p> <p>Minimises uptake by non-smokers</p> <p>Limits potential for long-term health risks, including addiction</p> <p>Minimises risk of renormalisation of smoking-like behaviour</p>	<p>Minimises potential for products to be seen as 'normal' consumer products</p> <p>Limits potential for downplay of risks to non-smokers</p> <p>Minimises uptake by non-smokers</p> <p>Limits potential for long-term health risks, including addiction</p> <p>Minimises risk of renormalisation of smoking-like behaviour</p> <p>Potential to apply controls more closely related to risk profile of product</p> <p>Greater flexibility to amend controls as more evidence becomes available</p>
Cons	<p>Limits smokers' awareness of potentially less harmful alternatives to smoking</p> <p>Gaps in regulatory coverage potentially create confusion for users and regulators</p> <p>Restricts potential for market growth</p> <p>Restricts freedom of expression in relation to commercial activity</p>	<p>Limits smokers' awareness of potentially less harmful alternatives to smoking</p> <p>Restricts potential for market growth</p> <p>Restricts freedom of expression in relation to commercial activity</p>	<p>Limits smokers' awareness of potentially less harmful alternatives to smoking</p> <p>Restricts potential for market growth</p> <p>Restricts freedom of expression in relation to commercial activity</p>

102 The following table compares the impact of the options for promotion and advertising of smokeless tobacco and nicotine-delivery options against the criteria set out in paragraph 58.

Table 11: Impact assessment of options for promotion and advertising of smokeless tobacco and nicotine-delivery products compared with the status quo

Comparison of options with the status quo (ie, prohibition on promotion and advertising of tobacco products (including smokeless tobacco), but no prohibition on nicotine-delivery products (except for e-cigarettes and e-liquid subject to amendments to the SFEA))		
Criteria	Option 2: Prohibit promotion and advertising of all tobacco and nicotine-delivery products (notification of product availability would be allowed)	Option 3: Prohibit promotion and advertising of all tobacco and nicotine-delivery products, but provide a power to enable products or product classes to have exemptions (by regulations)
Harm reduction	Worse	Better
Harm prevention	Much better	Better
Risk proportionate	Better	Much better
Product safety	Worse	Better
Cost and ease of implementation	Much better	Better
Conclusion	Recommended	

Conclusion

103 The Ministry of Health recommends option 3: prohibiting promotion and advertising, including sponsorship, but providing a regulation-making power to exempt product classes from some of the provisions, for example, to allow point-of-sale display. The main advantage of this option is that regulatory controls can be more closely targeted to the actual risk profile of the product or product class and changes can be made more readily as evidence changes.

Sub-issue 2(e): require standardised packaging for smokeless tobacco and nicotine-delivery products

104 The SFEA requires standardised packaging for tobacco products (including smokeless tobacco). The detailed requirements, which are set out in regulations, will come into force in March 2018. The Government has not applied standardised packaging requirements to e-cigarettes and e-liquid, although product safety requirements related to labelling and packaging are likely to standardise packaging for e-cigarettes and e-liquid to some extent.

105 If standardised packaging requirements were to be applied to nicotine-delivery products, the regulations setting out the detailed requirements would need to differ from those set out for tobacco products (eg, the health messages and graphic warnings would need to reflect the risks associated with the particular product or product class).

106 Options considered are:

- a) Option 1: (status quo) standardised packaging is required for tobacco products (including smokeless tobacco), but not nicotine-delivery products (the Government has not applied standardised packaging requirements to e-cigarettes and e-liquid, however, product safety requirements may lead to some standardisation of labelling and packaging)
- b) Option 2: extend standardised packaging requirements to include nicotine-delivery products
- c) Option 3: exempt smokeless tobacco products from standardised packaging requirements (although product safety requirements may lead to some standardisation of labelling and packaging).

107 The following table compares the options for standardised packaging for smokeless tobacco and nicotine-delivery products.

Table 12: Comparison of options for standardised packaging

Options	Option 1: status quo Required for tobacco products, including smokeless tobacco but not for nicotine-delivery products	Option 2: Extend standardised packaging requirements to nicotine-delivery products	Option 3: Exempt smokeless tobacco products from standardised packaging requirements
Pros	<p>Acknowledges likely lower risk associated with nicotine-delivery products compared with tobacco products</p> <p>Increases smokers' awareness of nicotine-delivery products as a safer alternative to smoking</p> <p>Eliminates potential for packaging being used to circumvent any promotion and advertising prohibitions on smokeless tobacco products</p> <p>May encourage market growth and/or businesses to grow their market share in nicotine-delivery products</p>	<p>Eliminates potential for packaging being used to circumvent any promotion and advertising prohibitions on nicotine-delivery products</p> <p>Promotes potential market growth and/or businesses to grow their market share</p>	<p>Acknowledges likely lower risk associated with nicotine-delivery products and smokeless tobacco products compared with smoked tobacco products</p> <p>Increases smokers' awareness of smokeless tobacco and nicotine-delivery products as a potentially safer alternative to smoking</p>
Cons	<p>Fails to recognise that some harm is associated with nicotine-delivery products, eg, addiction</p> <p>Restricts potential for market growth</p> <p>Restricts freedom of expression in relation to commercial activity</p>	<p>May be disproportionate if nicotine-delivery products are safer than tobacco products, including smokeless tobacco</p> <p>Lacks consistency with decision made to exempt e-cigarettes and e-liquid</p> <p>Restricts potential for market growth in nicotine-delivery products</p> <p>Restricts freedom of expression in relation to commercial activity</p>	<p>Fails to recognise that some harm is associated with smokeless tobacco and nicotine-delivery products</p> <p>Blunt tool to deal with potentially reduced harm associated with smokeless tobacco and nicotine-delivery products (which will have varied risk profiles)</p>

108 The following table compares the impact of the options for standardised packaging against the criteria set out in paragraph 58.

Table 13: Comparison of the impact of the options for standardised packaging with the status quo

Comparison of options with the status quo (standardised packaging required for tobacco products but not for nicotine-delivery products)		
Criteria	Option 2: Extend standardised packaging requirements to nicotine-delivery products	Option 3: Exempt smokeless tobacco and nicotine-delivery products from standardised packaging requirements
Harm reduction	Worse	Better
Harm prevention	Better	Worse
Risk proportionate	Better	Worse
Product safety	Better	Worse
Cost and ease of implementation	Worse	Better
Conclusion	Maintain status quo	

Conclusion

109 The Ministry of Health recommends option 1 (status quo): standardised packaging requirements should apply to all tobacco products (including smokeless tobacco), but not to nicotine-delivery products. This is consistent with decisions taken for e-cigarettes and some standardisation is likely to be applied to all products as a result of product safety requirements for labelling and packaging.

Issue 3: product safety requirements

- 110 There are inherent risks associated with the use of smokeless tobacco and nicotine-delivery products, relating primarily to the toxicants that are present. The nature of these risks will vary between product types and are, at this stage, largely unknown for most product types given the lack of published data.
- 111 There are few mandatory product safety controls on tobacco products (including smokeless tobacco). Devices sold in New Zealand should comply with the Electricity (Safety) Regulations 2010. Regulatory requirements for nicotine 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 use of nicotine in smokeless tobacco and nicotine-delivery products.
- 112 Industry may self-regulate against a range of existing standards and consumers have recourse against faulty products, false advertising etc under the Consumer Guarantees Act and the industry self-regulated system of advertising standards. The Ministry of Health considers this is inadequate on its own for products that have a higher than low-risk, or unknown risk, to human health.

- 113 Part 2 of the SFEA has some provisions related to tobacco product safety. Its purpose includes “to reduce some of the harmful effects of tobacco products on the health of users by monitoring and regulating the presence of harmful substances in the products and in tobacco smoke”. Specific provisions related to product safety (the detail of which may be set out in regulations) cover:
- a) health information or warning signs
 - b) labelling and health messages
 - c) limits on harmful constituents
 - d) annual testing for constituents
 - e) ability of the Director-General of Health to require further testing.
- 114 In addition, the Government has recently agreed to set product safety requirements for e-cigarettes and e-liquid, covering:
- a) product notification
 - b) manufacturing standards
 - c) quality and safety of ingredients
 - d) labelling
 - e) packaging.
- 115 The provisions in the SFEA would go some way towards providing the powers needed to set out comprehensive product safety requirements for smokeless tobacco and nicotine-delivery products, but additional powers would likely be needed.
- 116 Options considered below are:
- a) Option 1: (status quo) no specific regulatory controls (Consumer Guarantees and Fair Trading Acts apply)
 - b) Option 2: identify existing product safety standards for adoption under the Fair Trading Act (Commerce Commission enforces)
 - c) Option 3(a): make regulations/notices/guidelines etc under the SFEA without product registration (Ministry of Health regulates)
 - d) Option 3(b): make regulations/notices/guidelines etc under the SFEA with product registration (Ministry of Health regulates).
- 117 The following table compares the options for regulating product safety for smokeless tobacco and nicotine-delivery products.

Table 14: Comparison of options for regulating product safety for smokeless tobacco and nicotine-delivery products

Options	Option 1: status quo	Option 2:	Option 3(a):	Option 3(b):
	No specific product safety controls	Adopt existing product safety standards under the Fair Trading Act (Commerce Commission enforces)	Make regulations/notices/ guidelines etc. under the SFEA <u>without</u> product registration (Ministry of Health regulates)	Make regulations/notices/guidelines, etc under the SFEA <u>with</u> product registration (Ministry of Health regulates)
Pros	No costs to manufacturers, importers or retailers to implement and comply No cost to government to enforce	Risks to health mitigated Smokers have access to products they can have confidence in, which may encourage them to switch	Risks to health mitigated Smokers have access to products they can have confidence in, which may encourage them to switch Ministry of Health is government agency with the best understanding of regulating products to reduce risks to health (eg, medicines, psychoactive substances) SFEA has some provisions already to allow product safety requirements to be set by regulation	As for Option 3(a) Self-certification associated with product registration would facilitate compliance Regulator has register of products by manufacturer/importer to facilitate post-market activity (eg, recall of products found to be causing harm) Consistent with decisions for e-cigarettes and e-liquid
Cons	Nicotine, which has addictive and toxic properties, is unregulated except where it is regulated as a medicine or HSNO thresholds are met Other constituents of products, some of which may be harmful, are unregulated Uneven playing field for industry – some businesses will meet best-practice standards; others will sell cheaper, lower-quality products Experience suggests it is unlikely consumers would seek redress under the Consumer Guarantees Act	Costs to industry to implement, which may be passed on to consumers Costs to government to implement and enforce Difficulty in identifying international best practice standards to adopt Enforcement is passive, in response to complaints and product failures	Costs to industry to implement, which may be passed on to consumers Costs to government to implement and enforce	As for Option 3(a) but greater costs to industry associated with more active regulation

- 118 The following table compares the impact of the options for setting product safety requirements against the following criteria:
- a) risk proportionality
 - b) product safety
 - c) cost and ease of implementation.

Table 15: Impact assessment of options for regulating product safety for smokeless tobacco and nicotine-delivery products compared with the status quo

Comparison of options with the status quo (no specific product safety controls)			
Criteria	Option 2: Adopt product safety standards under the Fair Trading Act	Option 3(a): Make regulations/notices/guidelines under the SFEA <u>without</u> product registration	Option 3(b): Make regulations/notices/guidelines under the SFEA <u>with</u> product registration
Risk proportionate	Better	Better	Better
Product safety	Better	Better	Much better
Cost and ease of implementation	Worse	Worse	Worse
Conclusion			Recommended

Conclusion

119 The Ministry of Health recommends option 3(b): making regulations, notices, guidelines etc. under the SFEA with product registration. It is unclear whether appropriate existing standards could be identified under option 2 for any products that might be regulated as consumer products in future. Options 3(a) and 3(b) provide for greater flexibility which is a better response to this rapidly innovating market. Option 3(b) allows for more active regulation and particularly provides the regulator with the ability to deal with any post-market concerns, such as recall of products found to be unsafe.

120 Further work would be needed with industry and expert stakeholders to develop and cost detailed proposals for product safety.

Issue 4: provision of annual sales data

- 121 The SFEA requires tobacco manufacturers and importers who sell tobacco products (including smokeless tobacco) to provide the Director-General of Health, by 31 January each year, a return showing:
- a) by class of tobacco product, or brand of tobacco product of any class, or variant of a brand of tobacco product of any class, (as the regulations may require) the weight of tobacco and of each additive used in the manufacture of the tobacco products sold by the manufacturer or importer during the previous year; and
 - b) the quantity of each brand, and of each variant of a brand, of tobacco product sold by the manufacturer or importer during the previous year; and
 - c) the recommended price of each brand, and of each variant of a brand, of tobacco product sold by the manufacturer or importer during the previous year.

- 122 Sales data is analysed and published on the Ministry of Health’s website. It supports the Ministry’s ability to monitor the impact of policy changes, giving some insight into shifts in product supply and use as a response to regulatory changes. The Government did not consider this requirement for e-cigarettes.
- 123 The requirements set out in the SFEA for tobacco are not relevant to vaping products (eg, e-cigarettes) and other nicotine-delivery products. New detailed requirements would need to be specified for these products.
- 124 Options considered are:
- a) Option 1: (status quo) annual sales data is required for tobacco products (including smokeless tobacco), but not for nicotine-delivery products, including e-cigarettes and e-liquid.
 - b) Option 2: extend requirement for annual sales data to nicotine-delivery products, including e-cigarettes and e-liquid, with the detailed requirements to be set out in regulations.
- 125 The following table compares the options for the provision of annual sales data.

Table 16: Comparison of options for annual sales data

Options	Option 1: status quo Required for tobacco products (including smokeless tobacco), but not for nicotine-delivery products	Option 2: Extend requirement to provide annual sales data to nicotine-delivery products (including e-cigarettes and e-liquid)
Pros	Reduces costs to business	Data collected provides information on changing sales patterns between product types to monitor policy changes Cost effective for government to collect information directly from business
Cons	Hampers government’s ability to monitor policy shifts if there is no data on shifting sales patterns between product types	Increases costs to business

- 126 The following table compares the impact of the options for the provision of annual sales data against the against the following criteria:
- a) harm prevention
 - b) cost and ease of implementation

Table 17: Impact assessment of options for provision of annual sales returns compared with the status quo

Comparison of options with the status quo (annual sales returns required for smokeless tobacco products but not for nicotine-delivery products)	
Criteria	Option 2: extend requirement to provide annual sales data to nicotine-delivery products, including e-cigarettes and e-liquid (whether or not they contain nicotine)
Harm prevention	Much better
Cost and ease of implementation	Worse
Conclusion	Recommended

Conclusion

- 127 The Ministry of Health recommends option 2: the provision of annual sales data for nicotine-delivery products, including e-cigarettes/e-liquid. This will provide a full picture of changes in the market to support monitoring of the impact of policy changes. We propose a regulation-making power to set the information requirements for vaping products and nicotine-delivery products. The detail would be worked through in consultation with industry and other stakeholders.

Issue 5: A regulatory vehicle/regulator for smokeless tobacco and nicotine-delivery products

- 128 Any framework for deciding on whether or how to regulate smokeless tobacco and nicotine-delivery products needs to have the flexibility to cover products across a broad spectrum of risks, including clinical, toxicological, and behavioural (eg, impact on tobacco smoking and uptake by young people) risks.
- 129 There are existing regulatory frameworks at either end of the risk spectrum, ie, 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 under the SFEA or development of a new Act to replace the SFEA.
- 130 The Ministry of Health considers that regulation under consumer protection legislation would not be sufficiently robust to manage the safety risks associated with smokeless tobacco and nicotine-delivery products. It is unlikely that suitable standards could be identified for adoption under the Fair Trading Act Experience. Reliance on the Consumers Guarantees Act (CGA) alone would result in partial coverage where industry adheres to existing voluntary standards, however, this could result in an uneven playing field where some businesses meet best-practice standards and others sell cheaper, lower-quality products. Experience suggests that consumers would be unlikely to seek redress under the CGA. The Ministry's preference is for a regulatory scheme that is actively enforced.
- 131 Regulation under the Psychoactive Substances Act would similarly be disproportionate as that regime is designed to cover products at the high end of the risk spectrum. It would be unsuitable to cover products across a broad spectrum of risks.
- 132 The options considered below for a regulatory vehicle/regulator for smokeless tobacco and nicotine-delivery products are:
- a) Option 1: (status quo) smokeless tobacco products remain unlawful under the SFEA; nicotine-delivery products are likely covered by the Medicines Act; decisions to legalise/ regulate as consumer products are taken on a case-by-case basis and given effect by amending the SFEA
 - b) Option 2: incorporate within the SFEA (Ministry of Health administers)
 - c) Option 3: develop a new Act to replace the SFEA (Ministry of Health administers).
- 133 The following table compares the high-level options for a regulatory vehicle/regulator for smokeless tobacco and nicotine-delivery products.

Table 18: Comparison of options for a regulatory vehicle/regulator for smokeless tobacco and nicotine-delivery products

Options	Option 1: status quo Smokeless tobacco products unlawful under SFEA; nicotine-delivery products likely come under Medicines Act; decisions taken and Act amended on case-by-case basis	Option 2: Incorporate within the SFEA	Option 3: Develop new legislation to replace the SFEA
Pros	High level of scrutiny and decision-making	Smokeless tobacco and nicotine-delivery products are intended as safer alternatives to tobacco smoking and on the face of it fit within the scope of the SFEA 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 smokeless tobacco and nicotine-delivery products
Cons	Slow process – regulatory change lags considerably behind shifting evidence and public expectations	Extent of changes may mean significant amendment, complicating the Act and making it more difficult to interpret	Time and cost in developing a new Act Existing tobacco products may fit poorly, unless regulatory controls were recalibrated to reflect their level of risk relative to other products (including e-cigarettes)

134 The following table considers the options against the assessment criteria set out in paragraph 58 above.

Table 19: Impact assessment of options for a regulatory vehicle for smokeless tobacco and nicotine-delivery products compared with the status quo

Comparison of options with the status quo (ie, smokeless tobacco products unlawful under SFEA; nicotine-delivery products likely come under Medicines Act; decisions taken and Act amended on case-by-case basis)		
Criteria	Option 2: Incorporate within the SFEA	Option 3: Develop bespoke legislation
Harm reduction	Better	Better
Harm prevention	Better	Better
Risk proportionate	Better	Much better
Product safety	Better	Better
Cost and ease of implementation	Much better	Better
Conclusion	Recommended	

Conclusion

135 The Ministry of Health recommends option 2: to include regulatory controls for smokeless tobacco and nicotine-delivery products under the SFEA, administered by the Ministry of Health. An amendment to the SFEA is, at this stage, a more practicable option compared with the development of a new Act. More detailed analysis of the amendments needed to the SFEA may suggest that a new Act is a better option.

Consultation

- 136 As part of its 2016 consultation on the regulation of e-cigarettes, the Ministry of Health asked whether there were other products that should be regulated as consumer products at the same time as e-cigarettes. A number of submitters thought that there were and named a wide range of potential products.
- 137 More recently, the Ministry of Health held targeted discussions on the regulation of smokeless tobacco and nicotine-delivery products with tobacco sector stakeholders including health sector agency staff, academics, the tobacco companies which have a presence in New Zealand, and a number of vape retailers. Views varied widely.

Process for providing authorisation to market

- 138 A few stakeholders, including academics and two tobacco companies, thought that no smokeless tobacco product should ever be regulated as a consumer product and that New Zealand should maintain its existing prohibitions. However, most of these stakeholders were open to regulating nicotine-delivery products as consumer products.
- 139 Most stakeholders seemed to favour a pathway based on pre-market approval. Some of those favouring a pre-market approval process noted that their rationale for this preference is that it is better to set the regulatory bar higher in the first instance as it is easier to relax overall requirements than to strengthen them once products are on the market.
- 140 One tobacco company preferred a notification/self-certification process as it considered the US pre-market approval process was too strict.
- 141 There was a strong view by academics and the health sector in particular that there should be processes in place to ensure that evidence on the risks and benefits of products was independently assessed (eg, independent advisory committees). Some stakeholders were particularly concerned about independent assessment if a notification/self-certification system was adopted.
- 142 Some considered that provisions should be made for approving classes of products in some cases (eg, for products that have been used for decades with well-known risks and benefit, such as snus).
- 143 Many stakeholders suggested that it may not be worth considering legalising existing smokeless tobacco products, as newer products are cleaner and more likely to be used in New Zealand. In particular, some academics and a couple of tobacco companies suggested that oral tobacco products, such as snus, should not enter the New Zealand market as there is no market for them.

- 144 Health sector staff and academics suggested that products should only be regulated as consumer products if they were significantly less harmful than smoked tobacco. Suggestions for the benchmark for approving products ranged between 75% and 95% less risk than smoked tobacco products. A few stakeholders suggested using health outcomes as an indicator for approval rather than risk.
- 145 When asked what principles or objectives should be applied for regulating smokeless tobacco and nicotine-delivery products, stakeholders suggested:
- a) reducing harm / improving health
 - b) promoting smoking cessation
 - c) ensuring that new products prevent and reduce smoking-related harm to Māori, Pasifika and other populations with relatively high smoking prevalence.

Regulatory controls

- 146 Most stakeholders thought that the existing tobacco controls were largely suitable for smokeless tobacco products. There was a strong view, particularly among two tobacco companies, vape retailers and some academics, that ‘tobacco is tobacco’, that is, tobacco products should be treated the same whether they are smoked or not.
- 147 One tobacco company noted that the tobacco components of some smokeless tobacco products could be re-purposed for smoking, and that excise rates should not encourage this and/or contribute to illicit trade.
- 148 There was recognition by some that, if existing tobacco controls were applied, some of them would need to be modified for some products, for example:
- a) the warnings would need to be different for smokeless tobacco
 - b) a ban on use in smokefree areas wouldn’t make sense for all product types
 - c) the advertising and promotion restrictions should be looser for products that are proven to be less harmful so that smokers are aware of them and encouraged to switch.
- 149 Some stakeholders did not think exemptions should be made for any tobacco products, however, the vast majority of stakeholders considered that a distinction should be made between smoked and smokeless tobacco. There was a general view that nicotine-delivery products should be treated as a separate class of product to tobacco products.

Likely response to the proposals

- 150 Overall, the proposals are likely to be broadly supported. In general, the public health sector, vape retailers and two of the three tobacco companies expressed a preference for the prohibition on smokeless tobacco to remain. While this is not recommended, there was a general view that a pre-market approval system was the next best option. One tobacco company would prefer a notification/self-certification model, but this was not supported by others. The proposed prohibition on sales to minors is likely to be universally supported, together with a ban on the use of smoking-like products in smokefree areas. Views on the potential for products to be exempt from some of the advertising prohibitions on tobacco will be mixed, and unlikely to be supported by the majority of the public health sector.

Conclusions and recommendations

- 151 There are significant challenges in proposing a regulatory regime for smokeless tobacco and nicotine-delivery products, including:
- a) the clinical, toxicological, and behavioural (eg, impact on tobacco smoking and uptake by young people) risks associated with the majority of products available are unknown as there is little published data
 - b) different product types are likely to have widely varying risk profiles
 - c) categories are unlikely to be discreet – overlaps are evident between vaping products and heated tobacco technology
 - d) innovation is rapid with new products emerging and existing products constantly changing.
- 152 The regulatory framework needs to be able to respond to the challenges above. It should be flexible enough to respond to products across a broad spectrum of risk and to respond in a timely way to changing evidence about benefits and risks.
- 153 The Ministry of Health considers that e-cigarettes/e-liquid, as a class of product, set a benchmark. Any smokeless tobacco or nicotine-delivery product should not be able to be lawfully marketed under the SFEA unless it is significantly less harmful than smoked tobacco and is likely, based on evidence, to contribute towards the achievement of *Smokefree 2025*.
- 154 The Ministry of Health’s recommendations are to:
- a) implement a pre-market approval process to enable smokeless tobacco and nicotine-delivery products to be regulated as consumer products
 - b) prohibit the sale, and supply in public areas, of nicotine-delivery products to people under the age of 18 years
 - c) restrict the use of vending machines to R18 settings
 - d) prohibit the use of smoking/vaping-like products in smokefree areas
 - e) give the regulatory a power to declare products to be/not to be subject to the prohibition on use in smokefree areas
 - f) prohibit promotion and advertising of smokeless tobacco and nicotine-delivery products, but provide a regulation-making power to enable exemptions from the prohibitions for a product class (eg, to allow point-of-sale display, broader in-store display, etc)
 - g) extend the requirement to provide annual sales returns to all products regulated under the SFEA, including e-cigarettes and e-liquid, with the detailed requirements for nicotine-delivery products and vaping products (including e-cigarette and e-liquid) to be set out in regulations

- h) make provisions in the SFEA for product safety controls for smokeless tobacco and nicotine-delivery products to be set, including for:
 - i) manufacturing standards
 - ii) quality and safety of ingredients
 - iii) labelling
 - iv) packaging
- i) extend the existing regulatory powers, functions and duties in the SFEA that apply to tobacco products, where relevant, to cover all products regulated under the Act (vaping products and approved smokeless tobacco and nicotine-delivery products) and prescribe additional requirements related to new functions, for example:
 - i) any pre-market approval processes for smokeless tobacco and nicotine-delivery products
 - ii) product notification requirements for e-cigarettes and e-liquid
- j) extend existing regulation making powers, where relevant, and include new regulation-making powers in the SFEA to prescribe, for example:
 - i) information requirements and other detail related to product approvals, suspension and withdrawal of approvals
 - ii) information requirements related to annual sales returns and reports (for vaping products and nicotine-delivery products)
 - iii) products that are prohibited for use in legislated smokefree areas
 - iv) classes of products that are exempt from aspects of the prohibitions on promotion and advertising of products
 - v) fees for processing applications for pre-market approvals, and product withdrawals, and for any product notification, certificates, audit, etc
- k) review the offences and penalties regime. A flexible, modern offences and penalties regime should be developed with appropriate penalty levels, and a wide range of options for the regulator, meaning enforcement action can commensurate with the severity of conduct, and the regulator's approach can be flexible according to circumstances
- l) fully cost recover from industry, with the exception of policy advice and enforcement. Further work is needed, in consultation with industry, to accurately determine costs and establish fee levels.

Implementation plan

Legislative change

- 155 Implementation of the proposals requires an amendment 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 a system for the pre-market approval of products

- 156 If the Government agrees to proceed with pre-market approval of smokeless tobacco and nicotine-delivery products, further work would be needed to design and cost proposals.
- 157 It is expected that manufacturers and importers would provide information to the regulator to support an application to market a smokeless tobacco or nicotine-delivery product. Detailed information requirements would be set out in regulations and would likely include:
- a) reports, investigations, etc. into the safety of the product (including relative to smoking tobacco)
 - b) reports, investigations, etc. on the impact of the product on public health (including for vulnerable populations – ie, those with high prevalence of tobacco smoking or at high risk of tobacco smoking), for example on:
 - i) smokers' behaviour
 - ii) relapse in ex-smokers
 - iii) uptake by non-smokers, particularly young people
 - c) detailed description of the product, including the means by which nicotine is absorbed, and the mechanism by which emissions or vapour is generated (where relevant)
 - d) ingredients and emissions information (where relevant).
- 158 Other aspects of the regime would include:
- a) a prohibition on sales to under 18s, advertising restrictions, monitoring of sales patterns, and product safety requirements
 - b) establishment of technical advisory groups to support the regulator in its decision-making
 - c) ability for the regulator to set conditions as a pre-requisite for giving approval (eg, to require in-market monitoring of consumer behaviour)
 - d) a process to appeal regulator decisions
 - e) processes for the suspension and withdrawal of product approvals
 - f) the potential for export certification if requested

- g) post-market activities (eg, monitoring, compliance, adverse reactions monitoring)
 - h) the payment of regulatory fees and levies
 - i) protection from liability for the regulator, his or her delegate, and advisory committee personnel.
- 159 Further work would be needed, in consultation with industry, on requirements when a product is modified and the type of modifications that would trigger a new product application (eg, a modification that impacts on the quality, safety or performance of the product).
- 160 The following principles should apply to the performance of any functions, powers and duties under the Act:
- a) regulation of products should be proportionate to the risks associated with their use
 - b) product information should be accurate, true to label, and tell consumers about any risks, including side-effects, of using the product
 - c) regulatory activity and decision-making should aim to assist in preventing or reducing the impact of smoking, particularly on young people and populations with high smoking prevalence.
- 161 If government decides on a notification/self-certification model, information requirements would be significantly scaled back from those proposed for a pre-market approval model, the regulatory function within the Ministry of Health would be smaller, and the fees and levies set at a lower level. A similar process would be needed to develop the detailed requirements, in consultation with industry.
- 162 If government decides that products should be considered and legalised by way of regulations under the Smokefree Environments Act 1990, then there would be no particular implementation requirements. Standard policy processes would be followed.

Development of product safety controls

- 163 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 smokeless tobacco and nicotine-delivery products
 - e) regulatory controls should be proportionate to the risks associated with the use of smokeless tobacco and nicotine-delivery products
 - f) cost and ease of implementation to industry and government.

- 164 Specific proposals to minimise costs to industry include:
- a) use of existing standards (if suitable international best-practice standards can be identified)
 - b) engagement with industry stakeholders in the developmental process.

Fees/charges (including e-cigarettes and e-liquid)

- 165 The cost of importing finished smokeless tobacco and nicotine-delivery products would be related to either a marketing approval or product notification (options 3(a) and 3(b) of Issue 1 above). The cost to manufacturers/importers of e-cigarettes and e-liquid would be the costs related to product notification.
- 166 The regulator would be responsible for managing the assessment and approval process for smokeless tobacco and nicotine-delivery products as well as the notification of e-cigarettes and e-liquid (vaping products), together with surveillance, auditing and enforcement.
- 167 At this stage, it is not possible to be clear about the costs associated with establishing and running the regime, as there is no accurate information on the likely demand for the regulatory activities.
- 168 The Ministry considers that the number of applications to approve smokeless tobacco and nicotine-delivery products would be very small, probably fewer than ten in the first year. However, it is possible that product notifications for e-cigarettes and e-liquids could number several thousand (we understand that, as at March 2017, over 100,000 notifications had been made across the European Union, including more than 10,000 in France alone).
- 169 There are two options for cost recovery:
- a) Option 1: Full cost recovery (including set-up costs, which may need to be met up-front by the Crown and recovered over time through fees), including enforcement activities. This is the model applied to psychoactive substances.
 - b) Option 2: Partial cost recovery (including set-up costs), but not charging for enforcement activity (however, post-market safety activities including compliance, audit, and monitoring should be recovered). This is the model currently applied to medicines.

170 The following table provides the Ministry’s assessment of the outputs for the new regulatory scheme:

Output	Type of good	Recommendation
Policy advice	Public – to maintain independence of advice to the Minister	Crown pays
Assessment and approval of smokeless tobacco and nicotine-delivery products	Private – the benefits can be directly attributed to those wanting to market their products	Industry pays, fee for service
Product notification of vaping products (e-cigarettes and e-liquid)	Private – the benefits can be directly attributed to those wanting to market their products	Industry pays, fee for service
Standards setting	Industry – use by one industry participant does not impose a loss of benefit on others	Industry pays, levies
Compliance, audit, surveillance and monitoring	Industry – use by one industry participant does not impose a loss of benefit on others	Industry pays, levies
Enforcement (investigations, sanctions, prosecutions)	Industry – use by one industry participant does not impose a loss of benefit on others. A case can be made that the costs of enforcement are a public good and that charging fees or levies could be counter-productive (eg, if a party would incur costs if they reported non-compliance).	Industry pays, levies

* in this table, industry refers to manufacturers and importers of notified e-cigarettes and e-liquid and those seeking pre-market approval / holders of a pre-market approval for smokeless tobacco and nicotine-delivery products.

171 The Ministry recommends option 1: full cost recovery, with the exception of policy advice. All other costs should be met by industry through fees and charges, including set-up costs which would need to be met up-front by the Crown and recouped over a specified period of time (eg, five years) from industry.

172 Further work is needed, in consultation with industry stakeholders, to clarify expected numbers of regulated products and to develop detailed costings, fees and levies, and proposals for cost recovery.

173 It is proposed that fees and levies would be reviewed five years after the scheme commences. At that time, the regulator would have more information on which to accurately set fees.

Regulatory powers, functions and duties, offences, penalties (including e-cigarettes and e-liquid)

174 The existing regulatory powers and duties in the Smoke-free Environments Act 1990 (SFEA) for tobacco products (including smokeless tobacco) should be extended to vaping products and nicotine-delivery products, where relevant. New Powers and duties will be needed for new functions, including the notification/self-certification regime for vaping products and, if the Ministry of Health’s recommendations are accepted, the pre-market approval regime for smokeless tobacco and nicotine-delivery products.

- 175 After considering similar legislation in New Zealand (eg, the Natural Health and Supplementary Products Bill) and comparable overseas legislation (eg, in Canada, United Kingdom and United States), the Ministry recommends additional powers, functions and duties to apply to smokeless tobacco and nicotine-delivery products, and vaping products as follows:
- a) a duty to monitor market developments, including to detect which consumer groups purchase and use the products (is it smokers, non-smokers; if smokers, do they switch or dual use; if non-smokers, is there evidence of a gateway effect, particularly for young people)
 - b) power to require manufacturer's or importer's disclosure of modifications, research and developments to products since notified or approved
 - c) power to issue guidance, and codes of practice after consultation with stakeholders
 - d) power to publish statements/notices about the product, including that a product has a prohibited constituent or misleading labelling or advertising
 - e) power to require product withdrawals from the New Zealand market on reasonable grounds that the manufacturer or importer has provided incomplete, false or misleading information, advertising or labelling, or that the product is likely to cause harm to human safety or health
 - f) power to suspend a product notification (for vaping products only)
 - g) power to cancel or reinstate a product notification (for vaping products only)
 - h) duty to declare a product has been notified/approved or suspended or withdrawn, and publish this
 - i) duty to maintain a register/s of vaping products and smokeless tobacco and nicotine-delivery products, and further prescribe the details of the registers in Regulations. Certain parts of the register/s would be published on the Ministry of Health's website. The core components would include: product type and description of constituents; importer/manufacture of the product; product suspensions or withdrawal information (where relevant); and adverse reaction information and statements about the product issued by the regulator
 - j) power to appoint advisory committee/s of technical specialists to advise the regulator, and to remunerate them in accordance with the Cabinet Fees Framework
 - k) power to impose fees for cost recovery, prescribed by Regulations (recommended by the Minister to the Governor-General, with prior consultation with industry stakeholders).

Recommended enforcement officer powers and duties

- 176 Additional powers are recommended as follows:
- a) to issue warning letters or compliance notices on behalf of the Director-General
 - b) to seize products (without a warrant) on reasonable grounds the Act has been contravened
 - c) to obtain a warrant to enter a dwelling place, or rely on other applicable statutory powers.

177 The Ministry recommends applying the preceding paragraph to tobacco products and herbal products for smoking, if that can be done within the scope of the proposed Amendment Bill.

Recommended duties applying to manufacturers and importers

178 Companion duties should apply to manufacturers and importers who have notified vaping products or had products approved under the amended SFEA. Apart from those already mentioned in the SFEA, the Ministry intends that duties should include:

- a) to notify or disclose product modifications, research, test results, developments to products since approved or notified
- b) as part of annual returns, to provide information on consumer preferences
- c) a duty to report all suspected or known serious, adverse reactions to the product, and to operate a system for collecting these suspected adverse effects.

Offences and penalties

179 The maximum penalty ranges for offences in the SFEA may not provide sufficient deterrent to manufacturers and importers to comply with the proposed new regulatory requirements.

180 Further work to design a flexible, modern offences and penalties regime aligned with similar legislation (such as the Food Act 2014) is needed. The enforcement tools would be designed to allow the regulator a wide range of options, meaning enforcement action can be commensurate with the severity of misconduct, and the regulator's approach can be flexible according to circumstances. This would be undertaken in consultation with the Ministry of Justice.

Recommended protections for people carrying out functions under the SFEA

181 Section 19 currently protects enforcement officers appointed under s 14 who do any act in pursuance or intended pursuance of their functions, duties or powers under the Act from civil or criminal liability unless he or she acted in bad faith or without reasonable care. The Ministry recommends giving the Director-General or his or her delegate/s, similar protections when carrying out regulator functions under the SFEA.³

Regulation-making powers (including e-cigarettes and e-liquid)

182 The SFEA has extensive regulation-making powers related to tobacco products. The Ministry of Health proposes to extend these to vaping products and nicotine-delivery products where relevant. New regulation-making powers will also be needed. The scope of these will depend on the decisions taken by Cabinet.

³ The immunity chief executives of government departments have in s 86 of the State Sector Act 1988 is limited to civil immunity, may not relate to the specific statutory functions over and above chief executive functions, and has a different threshold test to that in s 19.

- 183 New regulation-making powers will be needed, including to prescribe:
- a) information requirements and other detail related to product approvals, suspension and withdrawal of approvals
 - b) information requirements related to annual sales returns and reports (for vaping products and nicotine-delivery products)
 - c) classes of products that are exempt from aspects of the prohibitions on promotion and advertising of products
 - d) fees for processing applications for pre-market approvals, and product withdrawals, and for any product notification, certificates, audit, etc.

Enforcement

- 184 At present, smokeless tobacco and nicotine-delivery products used in New Zealand can be bought online from overseas suppliers, however, there is no information available to quantify this.
- 185 The preferred regulatory option for product safety would see the Ministry of Health responsible for enforcement of regulatory controls under the SFEA. Further work is needed to determine the scope and cost associated with this work, including how any regulatory requirements would be enforced.
- 186 Enforcement of any regulatory controls related to the sale, distribution and advertising of smokeless tobacco and nicotine-delivery products, as well as use in smokefree areas would be undertaken by smokefree officers appointed by the Director-General of Health under the Smoke-free Environments Act 1990.

Monitoring, evaluation and review

- 187 The Ministry of Health will continue to monitor developing evidence on smokeless tobacco and nicotine-delivery products, including their safety and potential impacts on smoking prevalence in New Zealand.
- 188 Use of e-cigarettes is monitored via the Health Promotion Agency's biennial Health and Lifestyles Survey and Youth Insights Survey. These questions could be extended to provide information on smokeless tobacco and nicotine-delivery products.
- 189 Currently, there are no mechanisms in place to monitor the market for nicotine-delivery products. The proposal to require annual sales returns would provide information on what is available on the market, once fully implemented. It would not, however, provide information on what people are using, especially if they are importing products for their own personal use.
- 190 The Ministry is reviewing its approach to the monitoring of tobacco and related product use in New Zealand and intends to develop a framework for assessing the impact of the overall tobacco control programme.
- 191 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

Country	Legal framework	Market authorisation	Sales to under 18s	Smokefree areas	Advertising, promotion, display	Product safety
United Kingdom: implementing the EU Tobacco Product Directive (TPD)	Provides a regulatory framework for novel and smokeless tobacco products to be lawfully marketed.	Regulations require a six-month notification of intention to market a novel tobacco product. Notification requirements include the provision of toxicological and behavioural information. No approval is required provided notification requirements are met.	Sales prohibited to people under 18.	There is no prohibition on novel and smokeless tobacco product use in legislated smokefree areas in the UK.	Regulations include a requirement for health warnings on smokeless and novel tobacco products.	TPD outlines that novel tobacco products are subject to the safety requirements for smokeless or smoking tobacco products, depending on which product definition they fall under.
Canada	Lawful. The Tobacco Act 1997 ⁴ applies to all tobacco products (including heated tobacco product), and regulatory controls apply.	No notification or marketing authorisation requirements.	Sales prohibited to people under 18.	Differs across provinces. Provincial legislation regulates smoke-free spaces.	Imposes tobacco product-related prohibitions, including on advertising that appeals to young people, 'lifestyle' advertising, sponsorship, give-aways. Restricts sales promotions to R18 settings. Advertising and point-of-sale promotion must be consistent with regulations.	No specific product safety requirements for novel tobacco products – generic consumer products legislation is relied upon.

⁴ An Amendment Bill proposing that devices be incorporated into the tobacco product definition was adopted by the Senate on 2 June 2017. The Bill is now before the House of Commons and Royal assent is expected before the end of 2017.

Country	Legal framework	Market authorisation	Sales to under 18s	Smokefree areas	Advertising, promotion, display	Product safety
United States	The Federal Food and Drug Administration (FDA) regulates all tobacco products, including novel and future tobacco products.	FDA requires a Pre-Market Tobacco Application for novel and future tobacco products. The applicant must provide toxicological, behavioural, and physiological 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.	Sales prohibited to people under 18. Products sold in vending machines can only be made available in R18 settings.	Differs across states. State legislation covers smokefree places.	Requires that all tobacco products and advertisements for them include an addictiveness warning label statement. Provides regulations on advertising, and restrictions to individuals under 18. Prohibits distribution of free samples.	A new product cannot be marketed unless a manufacturer demonstrates that the product meets the relevant public health standard and has an approval from the FDA to market the product.

Appendix Two: Legislative framework covering smokeless tobacco and nicotine-delivery products

- 192 In addition to the Smokefree Environments Act 1990 and the Medicines Act 1981, a range of other legislation is relevant smokeless tobacco and nicotine-delivery products, including the Misuse of Drugs Act 1975, the Fair Trading Act 1986, the Consumer Guarantees Act 1993 and the Hazardous Substances and New Organisms Act 1996.
- 193 The **Misuse of Drugs Act** (MoDA) regulates the recreational use of illegal psychoactive substances, such as cannabis, cocaine, opiates, methamphetamine etc. Nicotine is excluded from the scope of MoDA.
- 194 Currently, any device or utensil re-purposed or modified as a tool with which to take drugs could become regulated as a drug utensil under the MoDA. The Misuse of Drugs (Prohibition of cannabis utensils and Methamphetamine Utensils) Notice 2014, issued under the MoDA, identified such products and prohibits them for sale, supply or import. Some devices, for example, vaporisers are now being marketed for use with a variety of substances including dry herb (tobacco or cannabis), wax and oil.
- 195 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.
- 196 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.
- 197 Devices 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.
- 198 Under the **Hazardous Substances and New Organisms Act** (HSNO), 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 (ie, 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.