

Coversheet: Supporting smokers to switch to significantly less harmful alternatives

Advising agencies	Ministry of Health
Decision sought	Proposals for the regulation of vaping and smokeless tobacco products
Proposing Ministers	Hon Jenny Salesa

Summary: Problem and Proposed Approach

<p>Problem Definition</p> <p>What problem or opportunity does this proposal seek to address? Why is Government intervention required?</p> <p>The regulatory controls in the Smoke-free Environments Act 1990 were designed primarily for tobacco products that are smoked. They are inadequate for vaping and smokeless tobacco products, which are less harmful to users.</p> <p>There is an opportunity, through better regulation (and public information), to support smokers to switch to significantly less harmful alternatives, substantially reducing the risks to their health and those around them.</p>
<p>Proposed Approach</p> <p>How will Government intervention work to bring about the desired change? How is this the best option?</p> <p>Improved regulation is necessary to clarify the law and, more substantively, to:</p> <ul style="list-style-type: none"> • improve the safety of vaping and smokeless tobacco products on the New Zealand market and manage any adverse effects that occur with the use of these products • reduce the likelihood that vaping and smokeless tobacco products, which have associated health risks (including the potential for addiction), can be accessed by children and young people. <p>Overall, the proposal seeks to strike a balance between the objectives of supporting smokers to switch to significantly less harmful products and protecting children and young people from any risks associated with an increased availability of vaping and smokeless tobacco products. On balance, the proposals are on the precautionary side, reflecting concerns about uptake by young people.</p>

Section B: Summary Impacts: Benefits and costs

Who are the main expected beneficiaries and what is the nature of the expected benefit?

The expected beneficiaries are New Zealand citizens, particularly smokers, and the regulated industry.

For smokers, the availability of products which meet safety standards will be increased. This may encourage more smokers to consider switching to vaping.

For industry, there will be clarity in the law that applies to the sale and supply of vaping and smokeless tobacco products.

For the broader population, the proposals are expected to contribute towards the achievement of Smokefree 2025. The potential of vaping products to help improve public health depends on the extent to which they can act as a route out of smoking for New Zealand’s 550,000 daily smokers, without providing a route into smoking for children and non-smokers.

Where do the costs fall?

The costs fall primarily on the regulated industry which would need to meet product safety requirements. Some suppliers will need to remove some existing products from the market and meet the increased costs associated with meeting higher product safety requirements. This will not be the case for all suppliers, however, the Ministry of Health (the Ministry) does not have the information to assess the size of this impact.

There will also be costs for all manufacturers and importers associated with product notification, which is proposed to be fully cost-recovered. The Ministry has undertaken preliminary costings, but associated fees and levies will need to be determined in consultation with the regulated industry.

Some consumers may lose access to products they have been using and any additional costs are likely to be passed on to consumers.

Expanding legislated “smokefree” areas to include vaping may impact some vapers who, in future, may not be able to vape where they can now (although many businesses are already voluntarily vape-free).

What are the likely risks and unintended impacts, how significant are they and how will they be minimised or mitigated?

The proposal seeks to balance the objectives of supporting smokers to switch to significantly less harmful alternatives with protecting children and young people from any risks associated with vaping in particular. On balance, the proposals are somewhat precautionary and favour the latter objective.

A potential unintended consequence if the right balance is not struck is that we fail to achieve the potential of vaping and other reduced-harm products to contribute towards Smokefree 2025.

On the other hand, there are some concerns that young people who do not smoke may become regular or daily vapers, increasing the risks to their health. There is, to date, no robust evidence to support this concern.

Monitoring is in place to assess the extent to which:

- smokers switch to less harmful products
- young people (who do not smoke) take up vaping on a regular or daily basis.

This information will support future changes to liberalise or take a more conservative approach to the regulation of reduced-harm products, if that proves necessary.

Identify any significant incompatibility with the Government’s ‘Expectations for the design of regulatory systems’.

None identified.

Section C: Evidence certainty and quality assurance

Agency rating of evidence certainty?

There are limitations on the extent to which the problem can be accurately defined and the impacts of the proposals assessed and quantified. This reflects a lack of information on the long-term effects of vaping and using many types of smokeless tobacco product, as well as the local market.

It will be important to monitor the impact of the policy changes and make adjustments in future as necessary.

To be completed by quality assurers:

Quality Assurance Reviewing Agency:

Ministry of Health

Quality Assurance Assessment:

The Impact Statement has been reviewed by the Ministry's Papers and Regulatory Committee, which considers that it meets the quality assurance criteria.

Reviewer Comments and Recommendations:

Stage 1 Cost Recovery Impact Statement

Regulation of vaping and smokeless tobacco products

Status quo

- At present the product safety provisions for tobacco, as set out in the Smoke-free Environments Act 1990 (SFEA), are inadequate; they only extend to products/parts of products manufactured from tobacco, to smoke (not vapour), and to harmful constituents.
- The proposal is to insert into the SFEA an express power to set product safety requirements for vaping and smokeless tobacco products (smoked tobacco is outside the scope of this work, but may be included in any subsequent work towards achieving Smokefree 2025). This would allow for product safety requirements or standards to be set or adopted in regulations.
- The proposal would also establish a product notification process; that is, a web-based system administered by the Ministry whereby manufacturers and/or importers notify products prior to marketing and self-certify that regulatory requirements are met.
- It is proposed that a new power be included to recover the costs associated with product notification as part of the amendments to the SFEA. This would result in a new fee/levy being charged.

Policy Rationale: Why a user charge? And what type is most appropriate?

Product notification is a light-touch system, based on manufacturers and importers self-certifying that regulatory requirements are met.

The main advantage of product notification is that the regulator (the Ministry) would know what products are on the market and who is responsible if any action is required, for example, to remedy a breach of regulations or recall an unsafe product.

The Ministry considers that product notification is a proportionate response, placing the responsibility on the supplier to establish the safety/compliance of their products before introducing them into the New Zealand market. It is suitable for low-risk products, where the regulator's emphasis is on post-market monitoring.

The regulator would be responsible for establishing and managing the product notification system, as well as surveillance and enforcement. Funding would be needed for:

- establishing the new regulatory scheme
- implementing IT systems
- regulator staffing
- specialist services (eg, testing).

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. The Ministry considers that product notifications could number several thousand (mainly vaping products; very few notifications would likely relate to smokeless tobacco products, at least initially).

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 vaping products.

The Ministry considers it appropriate that manufacturers and importers, who would be required to notify the products, meet the costs of product notification to reduce reliance on funding from general taxation as industry is a significant beneficiary of the regulatory scheme.

There are two options for cost recovery:

Option 1: full cost recovery (including establishment costs, which will need to be met up-front by the Crown and recovered over time through fees and levies), including enforcement activities. This is the model applied to psychoactive substances.

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.

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.

High level cost recovery model (the level of the proposed fee and its cost components)

The costs to establish the regulatory scheme, which include human resources and the IT build for the product notification system, are estimated as follows:

	2019/20	2020/21	2021/22
CAPEX	\$450,000	\$600,000	n/a
OPEX	\$180,000	\$230,000	\$60,000

More detailed work, including that needed to determine fees and levies, will be undertaken in consultation with the regulated industry.

Consultation

Consultation will be undertaken with the regulated industry as the detailed cost recovery model is developed.

Impact Statement: Supporting smokers to switch to significantly less harmful alternatives

Section 1: General information

Purpose
<p>The Ministry is solely responsible for the analysis and advice set out in this Regulatory Impact Statement, except as otherwise explicitly indicated. This analysis and advice has been produced for the purpose of informing final decisions to proceed with a policy change to be taken by Cabinet.</p>
Key Limitations or Constraints on Analysis
<p>There are limitations on the extent to which the problem can be accurately defined and the impacts of the proposals assessed and quantified. This reflects a lack of studies showing the benefits and risks of the long-term use of vaping and most smokeless tobacco products for users and the wider population. There is also a lack of information about the local market.</p> <p>The literature on vaping products is growing, but at this stage the evidence is not conclusive. However, it is clear that vaping is significantly less harmful than smoking and it appears likely that vaping can help people to stop smoking.</p> <p>A range of smokeless tobacco products is marketed internationally as less harmful alternatives to smoking combustible tobacco products. The health impact of most of these products is inadequately understood.</p> <p>Provided the regulatory controls are robust, the risks – known and theoretical – associated with vaping and the use of smokeless tobacco products can be mitigated.</p> <p>Public consultation and targeted stakeholder engagement on the regulation of vaping and smokeless tobacco products was undertaken in the second half of 2016 and early 2017. This consultation was undertaken prior to the District Court’s decision (<i>Philip Morris (NZ) Ltd v Ministry of Health</i> [2018] NZDC4478) that Philip Morris’s tobacco stick (HEETS) could be lawfully imported for sale, sold, and distributed in New Zealand. The Ministry subsequently sought advice from Crown Law on the effect of the Judge’s decision on section 29(2) of the SFEA.</p> <p>The Ministry now considers that all oral tobacco products, other than those that are chewed or ‘parked’ in the mouth, are able to be lawfully sold in New Zealand, subject to the regulatory controls set out in the SFEA. This impacts the problem definition and scope of options that were under consideration in 2016 and 2017.</p> <p>The Ministry considers it unlikely, however, that the outcome would be substantially different if it were to consult again. Further, the Ministry does not consider it to be in the public’s interest to delay legislative change by undertaking a further round of consultation. Rather, stakeholders can have their say during the select committee process and during the development of any regulations.</p>

Responsible Manager

Jill Lane
Director
Service Commissioning
Ministry of Health
October 2018

Section 2: Problem definition and objectives

2.1 What is the context within which action is proposed?

Tobacco smoking in New Zealand

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. In 2016/17, 13.8 percent of adults were daily smokers. Māori are more likely (32.5 percent) to smoke daily than the rest of the population, and Māori women (35.5 percent) are more likely to smoke than Māori men (29.1 percent). Pasifika also have high rates of daily smoking (21.8 percent).

New Zealand’s tobacco control programme

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

The SFEA establishes the overarching statutory framework to control the supply and use of tobacco products. A broad suite of tobacco control initiatives (both regulatory and non-regulatory) has been implemented over the past two to three decades to achieve the objectives of the SFEA and to meet Government’s wider tobacco control policy aims. These include:

- excise duties on tobacco products
- legislated smokefree areas
- prohibitions on sales to under 18-year-olds
- prohibitions on advertising and the retail display of products
- support for smokers to quit
- standardised packaging, including graphic warnings.

Vaping and smokeless tobacco products

Vaping products are electrical devices that produce a vapour, rather than smoke, by heating a solution (vaping liquid) which the user inhales. Vaping liquids are available with or without nicotine and are usually flavoured. The liquids and devices can be sold separately.

A wide range of smokeless tobacco products are used internationally as alternatives to smoked tobacco, for example:

- heated tobacco products (devices that heat, rather than burn, manufactured tobacco sticks)
- snus (tobacco, often in small sachets, that is placed in the cheek or under the lip), chewing tobacco and dissolvables.

Evidence for the risks and benefits of vaping and smokeless tobacco products

The evidence for the risks and benefits of the majority of smokeless tobacco and vaping products is still emerging. Debates have focused on:

- the role of vaping and smokeless tobacco products in harm reduction and helping people to reduce, or stop, smoking
- whether vaping normalises smoking and acts as a gateway to tobacco smoking for children and young people
- the safety of products (primarily toxicity).

1. *The role of vaping and smokeless tobacco in harm reduction and smoking cessation*

There is scientific consensus that vaping is significantly (around 95 percent) less harmful than smoking.¹ It is likely that vaping also helps smokers to quit smoking but the evidence is graded as low quality, primarily because there are only two randomised controlled trials to draw from.² A number of studies are underway and more evidence on the effectiveness of vaping products as a smoking-cessation support will be available this year.

Compared with vaping products, there is little literature on the risks and benefits of smokeless tobacco products, including their role in harm reduction and smoking cessation.

However, there is evidence that Swedish-style snus, a low-nitrosamine smokeless oral tobacco product is significantly (>90 percent) less harmful than tobacco smoking and less harmful (to varying degrees) than the use of other oral smokeless tobacco products (none of which may be lawfully sold in New Zealand).

2. *Vaping as a gateway to smoking*

There is a concern in the literature, and by many commentators, that experimentation by young people may lead to regular vaping and then to smoking (ie, vaping acts as a gateway to smoking).

Two major reviews were published in 2018 that address this issue. The National Academy of Sciences³ and Public Health England⁴ both considered the same evidence and concluded that there is an association between ever using a vaping product and ever smoking at a later point in time.

Both reports acknowledge that the studies included in the reviews have a number of limitations and that it is not possible to conclude from these studies that vaping is causing smoking. Rates of smoking have continued to decline over the same period that vaping products have become increasingly available. This is the case in New Zealand, the United Kingdom and the United States.

There is also a strong relationship between regular vaping and previous smoking in adults and young people. For example, the 2017 ASH Year 10 (14 to 15 year olds) survey reports that 0.8 percent of those who have never smoked vape daily, compared with 14.6 percent of regular (at least monthly) smokers and 21 percent of daily smokers.⁵

In 2017, the British Medical Association (BMA)⁶ concluded that current data on vaping and smoking does not support a gateway effect, noting that smoking has continued to decline over the period of time that vaping has increased. However, the BMA also notes that the United Kingdom's regulatory controls to prevent uptake by children and young people (including a ban on sales to under-18s and restrictions on advertising) are likely to have played an important role.

3. *Product safety*

Combustion causes most of the harm associated with tobacco smoking. By definition, products that are not smoked are highly likely to be much less harmful than smoking.

Vaping products are electrical devices that produce a vapour, rather than smoke, by heating a liquid (or other substance) which the user inhales.

Vaping products either lack many of the toxicants found in cigarette smoke or, where

1 Public Health England. 2015. E-cigarettes: an evidence update.

2 Hartmann-Boyce J, McRobbie H, Bullen C, et al. 2016. Electronic cigarettes for smoking cessation and reduction. Cochrane Database Syst Rev: CD010216.

3 National Academies of Sciences. 2018. Public Health Consequences of E-cigarettes.

4 McNeill A, Brose LS, Calder R et al. 2018. Evidence review of e-cigarettes and heated tobacco products 2018: a report commissioned by Public Health England.

5 Action on Smoking and Health. 2018. 2017 ASH Year 10 Snapshot results – e-cigarettes.

6 British Medical Association. 2017. E-cigarettes: Balancing risks and opportunities.

present, these are typically lower than in tobacco smoke and at levels considered a negligible risk to health.⁷ Where toxicants have been found to be present at high levels, this was due to vaping product use outside of normal operation (eg, high levels of some toxicants can be generated at extremely high temperatures).^{8,9}

A wide range of flavours are used in vaping products. Although these are generally considered safe when ingested orally, little is known about the risks of inhaling these. There is some evidence that some flavours, for example, cinnamon¹⁰ and diacetyl,¹¹ which gives a buttery flavour (and has been prohibited in the European Union), have a greater degree of toxicity than others.

The most commonly reported adverse effects associated with short-term use of vaping products include mouth and throat irritation and dry cough, typically mild to moderate in severity.

Nicotine is toxic at certain exposure levels and there are a small number of reports of nicotine poisoning in children, including from vaping liquid.^{12,13,14} However, evidence from short and long-term use of nicotine replacement therapy suggests that the use of small quantities of nicotine is associated with few risks.¹⁵ The addiction potential of nicotine in vaping products appears to be low, at least with current technology.

The long-term effects of vaping are difficult to predict and will not be known for many years. Long-term exposure to some of the toxins detected may be associated with increased health risk. However the magnitude of such risks is likely to be substantially lower than those of smoking, and extremely low in absolute terms.¹⁶

The vapour contains particles that have been identified as evidence of potential risk to others. To date, there are no case reports of harm caused by exposure to second-hand vapour. However, if any risks are present, they would not become evident for some years.¹⁷

A range of **smokeless tobacco products** are marketed internationally as less harmful alternatives to smoking combustible tobacco products. Examples of smokeless tobacco products include heated tobacco, shisha, chewing tobacco, snus, dissolvables and nasal tobacco. Compared with vaping products, there is relatively little research on the risks and benefits of many of these smokeless tobacco products.

Heated tobacco products, which may be lawfully sold in New Zealand following the recent District Court ruling, work by heating tobacco leaf to much lower temperatures than regular cigarettes. They do not combust. They are marketed as less harmful than smoking, based on the principle that most of the harm associated with smoking comes from the combustion process. However, to date there is relatively little research on the risks and benefits of heated tobacco products.

Heated tobacco products can overlap with vaping products. For example, one hybrid product has a chamber containing tobacco as well as a cartridge containing vaping liquid.

⁷ Burstyn I. 2014. Peering through the mist: systematic review of what the chemistry of contaminants in electronic cigarettes tells us about health risks. *BMC Public Health* 14: 18.

⁸ Jensen RP, Luo W, Pankow JF, et al. 2015. Hidden formaldehyde in e-cigarette aerosols. *N Engl J Med* 372: 392–4 and
⁹ Farsalinos KE, Voudris V, Poulas K. 2015. E-cigarettes generate high levels of aldehydes only in 'dry puff' conditions. *Addiction* 110: 1352–6.

¹⁰Bahl V, et al. 2012. Comparison of electronic cigarette refill fluid cytotoxicity using embryonic and adult models. *Reprod Toxicol* 34: 529–37.

¹¹Kreiss K, et al. 2002. Clinical bronchiolitis obliterans in workers at a microwave-popcorn plant. *N Engl J Med* 347: 330–8.

¹² Shawn L, Nelson LS. 2013. Smoking cessation can be toxic to your health. *Emerg Med* 45: 7–9.

¹³Gill N, Sangha G, Poonai N, et al. 2015. E-cigarette liquid nicotine ingestion in a child: case report and discussion. *CJEM* 1–5
doi:10.1017/cem.2015.10.

¹⁴Gupta S, Gandhi A, Manikonda R. 2014. Accidental nicotine liquid ingestion: emerging paediatric problem. *Arch Dis Child* 99: 1149.

¹⁵ Le Houezec J, McNeill A, Britton J. 2011. Tobacco, nicotine and harm reduction. *Drug Alcohol Rev* 30: 119–23.

¹⁶ Royal College of Physicians. 2016. Nicotine without smoke: Tobacco harm reduction.

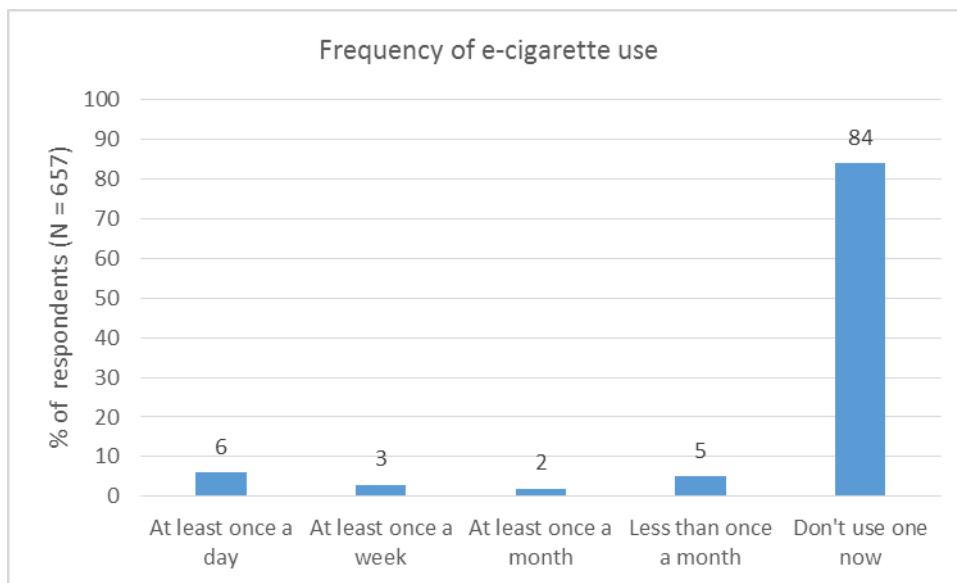
¹⁷ *ibid.*

Vaping in New Zealand

Vaping has been increasing rapidly in New Zealand, a pattern seen in other countries. The Health and Lifestyles Survey (HLS) and Youth Insights Survey (YIS) provide population estimates on vaping.

In 2016, one in six (17 percent) New Zealanders had tried vaping. Males (20 percent) were more likely to report that they had ever tried vaping compared with females (14 percent). People aged 15 to 24 years (30 percent) and 25 to 34 years (27 percent) were more likely to report they had ever tried vaping than older people. Those aged 35 to 54 years (16 percent) were more likely to report ever vaping than those aged 55 years and over (6 percent).

Most people (84 percent) reported that they do not vape now, with 6 percent reporting use at least once a day, 3 percent at least once a week, 2 percent at least once a month and 5 percent less than once a month.



Source: Preliminary analysis on 2016 Health and Lifestyles Survey (HLS) E-cigarette Questions

The number of young people (14 to 15 year olds) who had ever tried vaping more than tripled between 2012 and 2016, with 27.7 percent of young people having ever tried vaping in 2016, up from 20 percent in 2014 and 7.1 percent in 2012.

45.8 percent of young Māori had ever tried vaping in 2016, compared with 22.2 percent of non-Māori. In 2016, 33.4 percent of young males, and 21.8 percent of young females had ever tried vaping.¹⁸

After adjusting for a range of covariates that might correlate with ever e-cigarette use in 2014, ever-use remained strongly associated with smoking status.

Among all young people who had ever tried vaping, the most frequently cited reason for first trying was curiosity (64.5 percent), followed by getting a recommendation from another person (24.2 percent). Curiosity was the most commonly cited reason irrespective of smoking status.

There is emerging evidence that young adulthood (typically defined as 18-24 years old) also represents a vulnerable time for the initiation, development, and establishment of smoking behaviours. High smoking prevalence among New Zealand young adults, coupled with a low and declining smoking prevalence among adolescents indicates that significant initiation may

¹⁸ The Youth Insights Survey 2016

be occurring after the age of 17 years. Recent longitudinal data support this, with 7 percent of never-smoking 18 to 19 year olds becoming regular smokers.¹⁹

The vaping products market

The global market for vaping products in 2015 was estimated at almost US\$10 billion. About 56 percent of this was accounted for by the United States and 12 percent by the United Kingdom.²⁰ There is an absence of information to estimate the size and value of the New Zealand market. The Ministry sought information through a consultation process held in late 2016, however, the information received did not give a good sense of the market, beyond a very small number of individual businesses. It is, however, apparent that there is strong growth in the vaping retail market in New Zealand cities.

Use of smokeless tobacco in New Zealand

Prior to the recent District Court decision (*Philip Morris (NZ) Ltd v Ministry of Health* [2018] NZDC4478) only nasal tobacco was considered lawful for sale in New Zealand. A very small amount of nasal tobacco is imported each year, as reported to the Ministry.

The Court's decision has led to Philip Morris marketing its heated tobacco product in New Zealand. Other tobacco companies are expected to follow suit.

Any increase in the availability of smokeless tobacco will begin to show from 2019, in the annual tobacco returns that manufacturers and importers are required to provide to the Ministry each January.

2.2 What regulatory system, or systems, are already in place?

Vaping products manufactured from tobacco and smokeless oral tobacco products are regulated under the SFEA. The Ministry had understood that these products could not be lawfully sold pursuant to section 29(2) of the SFEA.

In *Philip Morris (NZ) Ltd v Ministry of Health* [2018] NZDC4478, the Court found that Philip Morris's tobacco stick (HEETS) may be lawfully imported for sale, sold and distributed. The Ministry considers the implications from this judgment are that the sale of oral tobacco products, other than those that are chewed or 'parked' in the mouth, is lawful, subject to the regulatory controls in the SFEA.

Some vaping liquids will also trigger thresholds set under the Hazardous Substances and New Organisms Act 1996 (HSNO). These products require a HSNO approval in addition to meeting any requirements under the SFEA. No vaping product approvals have been issued under HSNO.

Products that make a therapeutic claim (eg, to support smoking cessation) must also meet requirements under the Medicines Act 1981. The Medicines Act also regulates the importation of nicotine.

19 Edwards R, Carter K, Peace J, Blakely T. An examination of smoking initiation rates by age: results from a large longitudinal study in New Zealand. *Aust N Z J Public Health*. 2013;37(6):516-519. doi:10.1111/1753-6405.12105.

20 World Health Organization. 2016. Conference of the Parties to the WHO Framework Convention on Tobacco Control (Seventh Session): Electronic Nicotine Delivery Systems and Electronic Non-Nicotine Delivery Systems (ENDS/ENNDS). Available at: <http://www.who.int/fctc/cop/cop7/Documentation-Main-documents/en/> (accessed: 27 September 2016).

2.3 What is the policy problem or opportunity?

Vaping and using many forms of smokeless tobacco product are significantly less harmful than smoking. The law is complex and has been designed primarily to regulate tobacco products that are smoked. Businesses are seeking clarity on the law and looking to the Government to implement risk-proportionate regulation of smokeless tobacco and vaping products.

In addition to solving problems with the existing regulatory framework, there is an opportunity, through improving the way smokeless tobacco and vaping products are regulated, to support smokers to switch to significantly less harmful alternatives. This will contribute to the achievement of Smokefree 2025.

2.4 Are there any constraints on the scope for decision making?

This work has been undertaken in the context of tobacco control and New Zealand's Smokefree 2025 goal.

The development of a risk-proportionate regulatory framework for the products regulated under the SFEA would ideally include consideration of how smoked tobacco products, such as cigarettes, are regulated. However, only vaping and smokeless tobacco products are included within scope. Consideration of the regulatory controls on smoked tobacco products may be included in any future work on an action plan for Smokefree 2025.

There are no interdependencies with other pieces of work.

Related work is, however, being explored including:

- developing a group standard under HSNO for vaping liquids which trigger HSNO thresholds
- developing product safety requirements for other vaping liquids and devices (which would be voluntary pending amendment of the SFEA)
- setting tailored packaging requirements for vaping and smokeless tobacco products (standardised packaging requirements currently apply) in regulations under the SFEA.

2.5 What do stakeholders think?

Stakeholders include:

- health sector agencies, health practitioners and researchers
- vapers
- smokers
- vaping product manufacturers, importers and retailers
- tobacco product manufacturers, importers and retailers.

There is broad agreement that the existing legislative framework is inadequate and that reform is needed to clarify the law and implement risk-proportionate regulatory controls across the product types that are regulated under the SFEA. Where stakeholders differ is on what risk-proportionate controls would look like. Areas of contention are display of products in retail settings, advertising, and use in legislated smokefree areas.

In August and September 2016, the Ministry consulted publicly on:

- legalising nicotine e-cigarettes and e-liquid as consumer products, under the SFEA, with appropriate controls on both nicotine and non-nicotine e-cigarettes and e-liquid, including:
 - prohibiting their sale and supply to those under 18 years of age
 - restricting the use of vending machines
 - restricting advertising and marketing
 - prohibiting vaping in smokefree areas
 - whether any of the other regulatory controls on tobacco products should apply (eg, standardised packaging, discounted pricing etc)
- the need for regulatory controls on product safety
- whether to impose some form of excise duty on nicotine e-liquid.

The Ministry received 250 submissions. Of these, 130 were from individuals and the remainder from organisations. Eighty-one individuals identified themselves as vapers. The organisations identified as being from the health sector, academia, or as vape and/or tobacco firms.

There was a general view that regulation should be risk proportionate, and particularly that regulatory controls should be less stringent than controls on smoked tobacco products.

The vast majority of submitters (98 percent) agreed that the sale and supply of nicotine e-cigarettes and e-liquid should be allowed, with appropriate controls. There was no significant difference between vapers and non-vapers.

Submitters also overwhelmingly agreed (87 percent) that there should be a prohibition on the sale, and supply in a public place, of all e-cigarettes and e-liquid to persons under the age of 18 years; again there was no significant difference between vapers and non-vapers. Submitters were also generally supportive of restrictions on the use of vending machines, primarily to maintain a prohibition on sales to under-18s.

The majority of submitters (53 percent) supported restrictions on advertising, and expressed a general view that any restrictions should be less stringent than those on smoked tobacco

products. There was a significant difference in the proportion of vapers who agreed that there should be advertising controls compared with non-vapers (37 percent and 64 percent respectively). On more specific questions:

- less than one-third of submitters (31 percent) agreed that there should be a prohibition on point-of-sale display of products (14 percent of vapers and 44 percent of non-vapers)
- less than one-half of submitters agreed that there should be a ban on free samples (48 percent) and discounts (30 percent); again differences were observed between vapers and non-vapers (free sample: 26 percent vs 66 percent; discounts: 1 percent vs 55 percent)
- almost half (48 percent) of submitters agreed that there should be some restrictions on sponsorship. Again, there was a significant difference in agreement between vapers and non-vapers (27 percent vs 64 percent)
- there was moderate support for standardised packaging for e-cigarettes (48 percent overall), although it appeared that this question was unclear to submitters.

Under half of submitters supported a ban on vaping in legislated smokefree areas. Non-vapers were more likely than vapers to support a ban (59 percent vs 23 percent).

There were few substantive submissions on the need for product safety controls. Issues considered important were quality of ingredients, nicotine concentration and maximum volume of nicotine liquid available for sale, child-resistant packaging and labelling. A standards-based approach was generally preferred.

The majority of submitters (84 percent) did not support the imposition of an excise duty on nicotine liquid.

The full summary of submissions is available on the Ministry's website: <https://www.health.govt.nz/publication/consultation-electronic-cigarettes-analysis-submissions>.

The Ministry subsequently held targeted discussions on the regulation of smokeless tobacco products with stakeholders, including health sector agency staff, academics, the tobacco companies which have a presence in New Zealand, and a number of vape retailers. Most of these stakeholders favoured pre-market approval as a mechanism to enable new products to be lawfully sold, with processes to ensure that evidence on the risks and benefits of products was independently assessed.

Health sector staff, academics and the majority of vape retailers suggested that products should only be regulated as consumer products if they were significantly less harmful than smoked tobacco (ie, similar to vaping products), otherwise they should remain unlawful.

There was a strong view, particularly among some academics, vape retailers and two tobacco companies, that all tobacco products should be treated the same, whether they are smoked or not. There was a general view that nicotine products that do not contain tobacco should be treated differently from tobacco products.

Section 3: Options identification

3.1 What options are available to address the problem?

Issue 1: extend coverage of the SFEA to all nicotine vaping liquid and vaping and smokeless tobacco product devices and components

The SFEA does not fully apply to vaping and smokeless tobacco products; only the nicotine components that are manufactured from tobacco are regulated, meaning that nicotine that is not manufactured from tobacco (eg, synthetic nicotine), nicotine-free vaping liquids and devices can be sold to minors and used to circumvent laws prohibiting the advertising, promotion and sponsorship of tobacco products.

The options considered below are:

Option 1: status quo (only products manufactured from tobacco are regulated)

Option 2: all nicotine vaping liquid is regulated (whether or not it is manufactured from tobacco)

Option 3: all nicotine and nicotine-free vaping liquid is regulated

Option 4: all nicotine and nicotine-free vaping liquids, and devices and other components of vaping and smokeless tobacco products are regulated.

Table 1: Comparison of options for the scope of products regulated under the SFEA

Options	Option 1: status quo: Nicotine products manufactured from tobacco are regulated	Option 2: All nicotine products are regulated	Option 3: All nicotine products and nicotine-free vaping liquids are regulated	Option 4: All product parts are regulated, including devices and components
Pros	From a business perspective products (other than those manufactured from tobacco) can, for example, be advertised.	All addictive products are covered to protect non-smokers, particularly young people from the risks associated with their use. Facilitates enforcement as it is difficult to tell if the nicotine is manufactured from tobacco, even with laboratory testing.	Nicotine-free vaping liquids cannot be used to get around prohibitions on advertising for example. Facilitates enforcement as enforcement officers cannot tell if a liquid contains or does not contain nicotine.	Devices and components cannot be used to get around prohibitions on advertising for example. Enables the setting of minimum quality and safety requirements for all parts of the product.
Cons	Legislative provisions for vaping liquids are unenforceable as it is difficult to tell if the nicotine in a liquid is manufactured from tobacco.	From a business perspective, limits size of market and ability to advertise non-nicotine parts of products.	From a business perspective, limits size of market and ability to advertise non-nicotine parts of products.	From a business perspective, limits size of market and ability to advertise non-nicotine parts of products. May increase costs to industry and consumers if new requirements need to be met for devices.

Issue 2: Promotion, advertising and sponsorship of vaping and smokeless tobacco products

Under the SFEA, a tobacco product advertisement is defined as ‘any words, whether written, printed, or spoken, including on film, video recording, or other medium, broadcast or telecast, and any pictorial representation, design, or device, used to encourage the use or notify the availability or promote the sale of any tobacco product or to promote smoking behaviour’.

The SFEA’s prohibitions on the promotion of tobacco products include display of products, free samples, discounts, rewards (eg, loyalty points) and the sale of tobacco products co-packaged with other products, as well as standardised packaging. The standardised packaging requirements are set out in the Smoke-free Environments Regulations 2017.

The options considered below are:

Option 1: status quo (prohibit all promotion, advertising and sponsorship of vaping and smokeless tobacco products, including retail display of products, free samples etc)

Option 2: retain the broad prohibition, but with an exemption to allow in-store display, free samples, rewards, discounting, and co-packaging in specialist R18 retail settings of vaping and smokeless tobacco products

Option 3: retain the broad prohibition, but with an exemption to allow point-of-sale display of vaping and smokeless tobacco products in all retail settings

Option 4: allow all promotion, advertising and sponsorship of vaping and smokeless tobacco products (industry’s self-regulatory system of advertising standards applies)

Options 2 and 3 are not mutually exclusive.

Table 2: Comparison of options for promotion, advertising and sponsorship of vaping and smokeless tobacco products

Options	Option 1: status quo	Option 2: Prohibit with exemption for	Option 3: Prohibit with an exemption for	Option 4: No restrictions; industry self regulates
	Prohibit all promotion, advertising and sponsorship	<u>specialist R18 retailers</u> for in-store display, discounts etc	<u>all retailers</u> for point-of-sale display of products	
Pros	<p>Minimises potential for vaping and smokeless tobacco 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, particularly young people.</p> <p>Limits potential for unknown long-term health impact on users.</p>	<p>Provides smokers with opportunity to explore options that best suit them.</p> <p>May encourage vapers and smokeless tobacco product users to try new products which may be more effective or less harmful.</p> <p>Minimises potential for vaping and smokeless tobacco to be seen as normal consumer products.</p> <p>From a business perspective, increases potential for market growth.</p>	<p>Increases smokers’ awareness of less harmful options to smoking.</p> <p>May increase switching from smoking to less harmful alternatives.</p> <p>From a business perspective, increases potential for market growth.</p>	<p>Increases smokers’ awareness of vaping and smokeless tobacco products as less harmful alternatives to smoking.</p> <p>May maximise likelihood that smokers will switch.</p> <p>From a business perspective, maximises potential for market growth.</p>

Cons	Limits smokers' awareness of less harmful alternatives. From a business perspective, restricts potential for market growth. Restricts freedom of expression in relation to commercial activity.	May increase likelihood of non-smokers trying vaping and smokeless tobacco products. Requires a system to identify specialist vape retailers. From a business perspective, restricts potential for market growth. Restricts freedom of expression in relation to commercial activity.	Increases potential that young people may experiment with vaping and smokeless tobacco products. Increases potential for vaping and smokeless tobacco products to be seen as 'normal' consumer products. From a business perspective, restricts potential for market growth. Restricts freedom of expression in relation to commercial activity.	May downplay risks of vaping and using smokeless tobacco products for non-smokers. May increase risks of uptake by non-smokers, particularly young people.
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Issue 3: Identification of specialist R18 retailers

If there were to be differential requirements for generic and specialist R18 retailers, as set out above, then a system would be required to identify specialist R18 retailers. At present, many specialist vape stores have voluntary R18 policies.

The options considered below are:

Option 1: status quo (retailers self-identify as specialist R18 retailers)

Option 2: a notification system

Table 3: Comparison of options for the identification of specialist R18 vape stores

Options	Option 1: status quo	Option 2: Implement a notification system
	Retailers self-identify as specialist R18 vape shops	
Pros	No cost to business or government.	Provides clarity about which stores are eligible to, for example, display products. Facilitates enforcement. Allows for collection of sales data (if this was required to be collected – see Issue 4).
Cons	Difficult to enforce.	Cost to business and government.

Issue 4: Provision of sales data for vaping liquid

The SFEA requires tobacco manufacturers and importers to provide the Director-General of Health, by 31 January each year, the following information:

- 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.

This data is analysed and published on the Ministry's website, together with the raw data provided by manufacturers and importers. 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 data is also used by researchers.

The requirements set out in the SFEA are not relevant to vaping liquid, therefore, the status quo is not considered a viable option. Options considered below are:

Option 1: do not require reporting for vaping liquid

Option 2: set tailored requirements for nicotine vaping liquid only

Option 3: set tailored requirements for nicotine and nicotine-free vaping liquid.

Table 4: Comparison of options for provision of sales data for vaping liquid

Options	Option 1: Do not require reporting for vaping liquid	Option 2: Set tailored reporting requirements for nicotine vaping liquid	Option 3: Set tailored reporting requirements for nicotine and nicotine-free vaping liquid
Pros	No cost to business and government.	Provides relevant information to support monitoring of trends in the supply and use of tobacco products, particularly the switch from smoked tobacco to smokeless tobacco and vaping products.	Provides additional information to support monitoring of trends in vapers switching from nicotine to nicotine-free products.
Cons	Hampers ability to monitor trends if only tobacco data is collected.	Cost to business and government.	Likely small, marginal cost to business and government over option 2.

Issue 5: Use in legislated smoke-free areas

The SFEA prohibits smoking in indoor workplaces and certain public areas, including schools and early childhood centres, aircraft, passenger service vehicles etc. The main rationale for this prohibition is the significant health risks from second-hand smoke to employees in indoor workplaces.

There are no legislated restrictions on where people can vape or use smokeless tobacco. However, many employers have prohibited vaping in the workplace as part of their smokefree policies. Examples include Air New Zealand, Parliament, the Ministry and district health boards. The options considered below are:

Option 1: status quo (no prohibition on vaping and the use of similar smokeless tobacco devices in legislated smokefree areas)

Option 2: prohibit vaping and the use of similar smokeless tobacco devices in legislated smokefree areas

Option 3: issue guidelines to support employers and business owners to determine their own policies.

Table 5: Comparison of options for use in legislated smokefree areas

Options	Option 1: status quo: no prohibition on use in legislated smokefree areas	Option 2: Prohibit use in legislated smokefree areas	Option 3: Issue guidelines
Pros	<p>May provide incentive for smokers to switch if they can vape or use similar tobacco devices where they can't smoke.</p> <p>Businesses able to tailor policies to suit customer preferences.</p> <p>No cost to business or government.</p>	<p>Employers and bystanders not exposed to emissions that they may find unpleasant.</p> <p>May appear less confusing to have a blanket ban on 'smoking-like' activity in legislated smoke-free areas.</p>	<p>As for option 1.</p> <p>May reduce costs to businesses by providing information to support decision-making.</p>
Cons	<p>Bystanders may consider exposure to emissions to be unpleasant.</p> <p>Constrains business' owners choices on the best use of their premises.</p> <p>May be some cost to businesses, employers and local authorities to determine their own policies, especially if consultation is required.</p> <p>May appear inconsistent and confusing if vaping and the use of similar smokeless tobacco devices can be used in some areas but not others.</p>	<p>May expose vapers and users of similar smokeless tobacco devices to second-hand smoke if required to go outside with the smokers.</p> <p>May reduce incentives on smokers to switch.</p> <p>Constrains business owners choices on the best uses of their premises.</p>	<p>As for option 1.</p>

Issue 6: Product safety

Devices sold in New Zealand should comply with the Electricity (Safety) Regulations 2010.

Nicotine vaping liquids should meet requirements under the HSNO, where threshold criteria are met. The minimum concentration of nicotine that needs to be present in vaping liquid to trigger HSNO has been calculated at 0.18 percent. Flavours may also trigger HSNO, depending on the hazard classification of the specific flavouring used and its concentration in the vaping liquid.

In addition, medicines requirements apply to products making a therapeutic claim (eg, for smoking cessation).

Industry may self-regulate against a range of existing standards and consumers may have recourse against faulty products, false advertising etc under the Consumer Guarantees Act and the industry self-regulated system of advertising standards.

There are inherent risks associated with the use of vaping and smokeless tobacco products, which relate primarily to the toxicants present, however, there is also some risk with malfunctioning devices (related to the batteries overheating and exploding). The risks associated with the use of products can be mitigated with a range of controls on product safety, including requirements for the:

- manufacturing of devices, liquids and tobacco products
- quality and safety of ingredients
- labelling and packaging.

Internationally, a range of generic and specific manufacturing standards have been or are being developed for vaping and smokeless tobacco products. These are being assessed for their relevance to the New Zealand context and include:

1. The PAS 54115:2015 standard is published by the British Standards Institute (BSI) and was drawn up in conjunction with the Electronic Cigarette Trade Industry Association.

This is not yet a 'British Standard'.

2. The French Standard Institute, AFNOR, has published three experimental standards:
 - XP D 90-300-1 on requirements and test methods for electronic cigarettes
 - XP D 90-300-2 on requirements and test methods for e-liquids
 - XP D 90-300-3 on requirements and test methods for emissions.
3. The American E-liquid Manufacturing Standards Association has published a standard V.2.3.2 for its members to use.
4. The International Standards Organization (ISO) is in the process of developing standards and test methods for electronic cigarettes, e-liquid, components and accessories.
5. The US Congress is considering a Bill H.R. 2194 to regulate electronic cigarettes, which includes elements of quality measures for vaping devices. Conceivably, meeting these quality measures would be an acceptable means of meeting a quality standard.
6. The Malaysian Department of Standards has published a draft standard on electronic cigarette device, 17S001RO, for public comment.
7. The safety science company UL has published standard UL 8139 for the safety of the electrical, heating, battery and charging systems of e-cigarettes.

The following table compares the high-level options for regulating product safety for vaping and smokeless tobacco products.

Table 6: Comparison of options for regulating product safety for vaping and smokeless tobacco products

Options	Option 1: status quo	Option 2: Identify existing product safety standards for adoption under the Fair Trading Act (Commerce Commission and Customs undertake enforcement activities)	Option 3: Set standards or requirements under the SFEA (new powers will be needed)	Option 4: Develop a group standard under HSNO
Pros	No additional costs to industry or government to implement and comply. No impact on consumers' ability to purchase products they want.	Risks to health mitigated. Smokers have access to locally-sold products they can have confidence in, which may encourage them to shift.	As for option 2. Ministry of Health is the government agency with the best understanding of regulating products to reduce risks to health (eg, medicines). Allows for the development of bespoke standards or requirements.	Risks to health mitigated. Reduces costs to business compared with suppliers having to seek individual approvals.

Cons	<p>Nicotine, which has addictive and toxic properties, is unregulated (except where HSNO thresholds are met).</p> <p>Other constituents of vaping liquids, some of which may be harmful, are unregulated.</p> <p>Child resistant closures are not mandatory.</p> <p>Uneven playing field for industry – some businesses meet best-practice standards; others sell cheaper, lower-quality products.</p> <p>Experience suggests it is unlikely that consumers will seek redress under the CGA.</p>	<p>Costs to industry to implement (depends on specific controls), which may be passed on to consumers.</p> <p>Costs to government and industry to implement and enforce.</p> <p>May reduce consumer choice if some products are removed from the market.</p> <p>Difficulty in identifying international best standards to adopt.</p> <p>Consumers may continue to access cheaper poor quality products over the internet.</p> <p>Enforcement is passive, in response to complaints and product failures.</p> <p>Suppliers must still have a HSNO approval where threshold criteria are met.</p>	As for option 2.	<p>Only a sub-set of vaping liquids that trigger HSNO thresholds will be able to come under a group standard.</p>
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Issue 7: Use of flavours and colours that may attract young people to vaping and smokeless tobacco products

Concerns are often raised in the media about the use of flavours to attract young people to vaping. To-date there is no robust evidence to support concerns that young non-smokers are becoming regular vapers, although experimentation is common.

In the United States, the Federal Drug Administration is moving to prohibit flavours in some types of vaping products in response to product use among high school students.

The options considered below are:

Option 1: status quo (no specific power to prohibit flavours and/or colours, but the product safety provisions could be relied on to some extent

Option 2: include in the SFEA a power to prohibit flavours and colours in vaping and smokeless tobacco products which attract young people to use the products.

Table 8: Comparison of options to regulate flavours and colours that may attract young people to vaping

Options	Option 1: rely on product safety proposals to enable the prohibition of flavours and colours that are harmful	Option 2: include a power to prohibit flavours and colours that attract children and young people to vaping
Pros	Better meets the risk proportionality principle given the lack of evidence for a problem with young non-smokers becoming regular vapers.	Provides a legal mechanism to prohibit any flavour or colour should evidence of a problem come to light.
Cons	Likely to limit ability in future to prohibit any flavour or colour other than for strict safety reasons.	Disproportionate to the known risks associated with vaping. Disproportionate to the regulatory controls on smoked tobacco, a considerably more harmful product.

Issue 8: Product notification

Safety requirements can be implemented with or without product notification and/or pre-market approval.

Product notification would require the manufacturer or importer to notify products to the regulator via a web-based system, prior to marketing. This is proposed to be a light-touch system which would include self-certification that the product complies with regulatory requirements. Notification systems have been implemented in European Union (EU) countries, in accordance with the EU's Tobacco Products Directive.

An alternative would be a pre-market approval system, which New Zealand has for medicines and the United States is implementing for new tobacco products. This option is not considered further as it is considered to be disproportionate with the risks associated with the use of vaping products in particular.

Table 9: Comparison of options for product notification

Options	Option 1: status quo: no requirement to notify products	Option 2: manufacturers and importers to notify products
Pros	No cost to business and government.	Self-certification prompts manufacturers and importers to consider whether the products they propose to sell meet minimum quality and safety requirements. Regulator knows what products are on the market and who is responsible if any action is required (eg, to remedy a breach of regulations or recall an unsafe product). Regulator can communicate directly (eg, changes to regulatory requirements or safety concerns) to manufacturers and importers.
Cons	No mechanism for assuring that product safety requirements are met. Regulator does not know what products are on the market and who is selling them Communication with manufacturers and importers inefficient (eg, via media).	Cost to business and government to implement.

Regulatory approaches in other jurisdictions

Overseas jurisdictions have taken a range of positions on the regulation of vaping and smokeless tobacco products, from banning their sale to regulating them as medicines, tobacco products and consumer products.

3.2 What criteria, in addition to monetary costs and benefits, have been used to assess the likely impacts of the options under consideration?

The criteria used to assess the options for issues 1 to 5 and 7 are:

1. harm reduction: to reduce the harm to individual smokers from tobacco smoking, where smokers switch completely to vaping or smokeless tobacco products
2. harm prevention: to prevent harm to the public from greater access to vaping and smokeless tobacco products:
 - policies should minimise the risk of initiation of nicotine use by non-smokers (particularly children and young people)
3. risk proportionality: regulatory controls should be proportionate to the risks associated with vaping and smokeless tobacco products
4. cost and ease of implementation: for industry and government is reasonable given the potential health harms associated with vaping and smokeless tobacco products.

There is a balance to be struck between harm reduction and harm prevention. Options which make smokeless tobacco and vaping products more accessible for smokers also risk making them more accessible to young non-smokers.

Criteria used to assess options for issues 6 and 8, which are related to product safety are:

1. effectiveness in minimising harm associated with vaping and the use of smokeless tobacco products
2. risk proportionality
3. cost and ease of implementation.

3.3 What other options have been ruled out of scope, or not considered, and why?

Consideration has not been given to changing the following SFEA regulatory controls as they apply to vaping and smokeless tobacco products:

- prohibition on sale, and supply in a public place, to under 18s
- sale via vending machines.

The evidence supports the use of vaping and smokeless tobacco products to reduce the harm from smoking. Non-smokers who start vaping or using smokeless tobacco products will increase their health risks. The primary policy objectives are, therefore, to support smokers to switch to significantly less harmful alternatives while protecting young people in particular from any harms associated with increased access to these products.

There was strong support in public consultation for retaining the prohibition on sales to under-18s and restricting access to sales via vending machines to support this prohibition.

Charging excise on vaping liquid is also not considered (although it was considered and rejected in a RIS completed in 2017 – see <https://www.health.govt.nz/about-ministry/legislation-and-regulation/regulatory-impact-statements/regulation-e-cigarettes-and-emerging-tobacco-and-nicotine-delivery-products>). An argument is being made by at least one industry stakeholder that the excise on smokeless tobacco should be re-considered given the relatively low risk profile of smokeless tobacco products compared with smoked tobacco. This is not being considered at this time.

Section 4: Impact Analysis

Key:

- ++** much better than doing nothing/the status quo
- +** better than doing nothing/the status quo
- 0** about the same as doing nothing/the status quo
- worse than doing nothing/the status quo
- much worse than doing nothing/the status quo

Issue 1: extend coverage of the SFEA to all nicotine vaping liquid and vaping and smokeless tobacco product devices and components

Under the status quo, only the nicotine components that are manufactured from tobacco are regulated, meaning that nicotine that is not manufactured from tobacco (eg, synthetic nicotine), nicotine-free vaping liquids and devices can be sold to minors and used to circumvent laws prohibiting the advertising, promotion and sponsorship of tobacco products.

Table 9: Impact assessment of the options for the scope of products regulated under the SFEA

Comparison of options with the status quo			
Criteria	Option 2: Regulate all nicotine products (whether or not the nicotine is manufactured from tobacco)	Option 3: Regulate nicotine products and nicotine-free vaping liquid	Option 4: Regulate all nicotine products, nicotine-free vaping liquids, and vaping and smokeless tobacco devices and components
Harm reduction	+	0	++
	(gives smokers assurance that all nicotine products meet minimum quality and safety requirements)		(gives smokers assurance that products meet minimum quality and safety requirements in their entirety)
Harm prevention	+	+	++
	(provides protections for children and young people from all nicotine products)	(nicotine-free liquids and devices can be used for example to advertise products to young people)	(comprehensively provides protections for children and young people from vaping and smokeless tobacco products)
Risk proportionate	+	+	++
	(there is no substantive difference between nicotine manufactured from tobacco and nicotine not manufactured from tobacco to justify different treatment)	(nicotine-free liquids and devices can be used for example to advertise products to young people)	(the risks associated with the products relate to the products as a whole, not just to the nicotine component)
Ease and cost of implementation	+	++	--
	(facilitates enforcement – at present enforcement is hampered because it is difficult to tell if the nicotine in a product is manufactured from nicotine or not)	(facilitates enforcement – it is not possible to determine whether a vaping liquid contains nicotine without laboratory testing)	(increased costs to business if product safety requirements for devices are developed which drive up costs)

Issue 2: Promotion, advertising and sponsorship of vaping and smokeless tobacco products

Under the status quo, promotion, advertising and sponsorship of vaping products manufactured from tobacco and smokeless tobacco products is prohibited. This prohibition includes the retail display of products, the giving of free samples, discounts and rewards, and the sale of these products co-packaged with other products.

However, the provisions related to vaping products have not been routinely enforced due to difficulties proving that nicotine vaping liquid is manufactured from tobacco and therefore covered by the SFEA. In reality nicotine vaping liquid is on display in retail stores and advertised (eg, letter drops, billboards, news websites, radio and buses). Product visibility and advertising have noticeably increased in the past 18 months as has become apparent that the law is not being routinely enforced.

Table 10: Impact assessment of options for the promotion, advertising and sponsorship of vaping and smokeless tobacco products compared with the status quo

Comparison of options with the status quo			
Criteria	Option 2: Prohibit with an exemption for specialist R18 vape retailers for in-store display, free samples, discounts, rewards and co-packaging	Option 3: Prohibit with an exemption for all retailers for point-of-sale display of products	Option 4: No restrictions; industry self regulates
Harm reduction	+	+	++
	(increases smokers' access to products as well as specialist advice and support)	(increases smokers' access to products)	(active promotion to smokers, in addition to increasing smokers' access to products)
Harm prevention	0	-	--
	(if confined to R18 stores, it should not increase young people's access to and potential use of products)	(increases young people's access to and potential use of products)	(active promotion could lead to increased use by young people)
Risk proportionate	+	+	-
	(recognises that vaping and smokeless tobacco products are much less harmful than smoking)	(recognises that vaping and smokeless tobacco products are much less harmful than smoking)	(there are risks associated with these products, including addiction, which is of particular concern if accessed by young people; they should not be treated like 'normal' consumer products)
Ease and cost of implementation	-	-	0
	(cost to Government to enforce; compliance costs to business)	(cost to Government to enforce; compliance costs to business)	(cost to business to self-regulate)

Issue 3: Identification of specialist R18 vape shops

If there were to be differential requirements for generic and R18 stores, as recommended above, then a system would be required to identify R18 stores. The status quo is that specialist vape stores self-identify and have voluntary R18 policies.

Table 11: Impact assessment of the options for the identification of R18 vape stores compared with the status quo

Comparison of options with the status quo	
Criteria	Option 2: implement a notification system
Harm reduction	- (may provide a barrier to businesses deciding to sell products, reducing smokers access)
Harm prevention	+ (may reduce the number of businesses selling products, reducing young people's access)
Risk proportionate	- (no system is in place for the registration of retailers of smoked tobacco products, which are considerably more harmful)
Ease and cost of implementation	- (cost to government and business to implement but provides clarity and aides enforcement)

Issue 4: Provision of sales data for vaping liquid

Under the status quo, manufacturers and importers of vaping liquid manufactured from tobacco should comply with the reporting provisions of the SFEA, however, these provisions are not relevant to vaping liquid.

Table 12: Impact assessment of the options for the provision of sales data for vaping liquid compared with the status quo

Comparison of options with the status quo			
Criteria	Option 2: do not require sales data reporting for vaping liquid	Option 3: set tailored reporting requirements for nicotine vaping liquid	Option 4: set tailored reporting requirements for nicotine and nicotine-free vaping liquid
Harm reduction	0 (effective status quo)	+	++
		(facilitates monitoring of the effectiveness of policy, ie, we should see volumes of smoked tobacco decrease and volumes of smokeless tobacco and nicotine vaping liquid increase)	(as for option 3 however, in addition, it facilitates monitoring of any shift from nicotine to nicotine-free vaping liquid)
Harm prevention	0 (effective status quo)	0 (not applicable)	0 (not applicable)
Risk proportionate	0 (effective status quo)	+	+
		(there are health risks associated with vaping and the use of smokeless tobacco products which make reporting and monitoring warranted)	(as for option 3)
Ease and cost of implementation	0 (effective status quo)	-	--
			(marginal additional effort required for manufacturers and importers to include nicotine-free liquids in their reporting)

Issue 5: Use in legislated smokefree areas

Under the status quo, vaping and the use of similar smokeless tobacco devices is allowed in legislated smokefree areas (although it may be prohibited by the employer or business owner).

Table 13: Impact assessment of the options for the use of vaping products and similar smokeless tobacco devices compared with the status quo

Comparison of options with the status quo		
Criteria	Option 2: Prohibit use in legislated smokefree areas	Option 3: Issue guidelines to support business owners, employers and local authorities to make their own decisions
Harm reduction	- (may reduce incentives for smokers to switch)	0
Harm prevention	+ (reduces young people's exposure to vaping and the use of similar tobacco devices; may help to reduce young people's uptake)	0
Risk proportionate	- (no known health effects associated with second-hand emissions)	0
Ease and cost of implementation	- (enforcement costs to government)	+ (may help to reduce businesses costs in developing their own policies)

Issue 6: Product safety requirements

The status quo is that there are no specific product safety requirements unless HSNO applies, where threshold criteria are met. Where HSNO applies, suppliers must have a product approval. For products that do not trigger HSNO thresholds, there are generic requirements (eg, Electricity Regulations and consumer law)

Table 14: Impact assessment of the options for the development of safety requirements for vaping liquids that trigger HSNO thresholds

Comparison of options with the status quo	
Criteria	Option 2 : Develop a group standard under HSNO for vaping liquid where threshold criteria are met
Effectiveness in minimising harm	0
Risk proportionate	0
Ease and cost of implementation	+

Table 15: Impact assessment of the options for the development of quality and safety standards for vaping

Comparison of options with the status quo		
Criteria	Option 2: Enable the setting of standards or requirements under the SFEA for vaping liquid where HSNO threshold criteria are not met, smokeless tobacco products, and devices	Option 3: Identify existing product standards for vaping liquid where HSNO threshold criteria are not met, smokeless tobacco products, and devices for adoption under the Fair Trading Act
Effectiveness in minimising harm	++	+
Risk proportionate	+	+
Ease and cost of implementation	-	-

Issue 7: Use of flavours and colours that may attract young people to vaping and smokeless tobacco products

The status quo is that there are no provisions to regulate colours and/or flavours used in vaping and smokeless tobacco products, although there are proposals to regulate ingredients as part of the product safety proposals set out in issue 6 above.

Table 16: Impact assessment of the options for the regulation of colours and flavours that may attract young people compared with the status quo

Comparison of options with the status quo	
Criteria	Option 2: include a power to prohibit flavours and/or colours that attract young people to vaping and the use of smokeless tobacco products
Harm reduction	+ (provides the ability to prohibit flavours and/or colours should evidence show that they are being used to attract young non-smokers)
Harm prevention	- (flavours are very important for smokers seeking to use a vaping product to quit smoking)
Risk proportionate	- (no robust evidence that flavours and/or colours are attracting young non-smokers to use these products; no regulation of flavours in place for smoked tobacco products, which are considerably more harmful)
Ease and cost of implementation	- (cost to government and business to implement)

Issue 8: Product notification

Currently there are no requirements for products to be notified or registered.

Table 17: Impact assessment of the options for the notification of vaping and smokeless tobacco products compared with the status quo

Comparison of options with the status quo	
Criteria	Option 2: Products must be notified prior to marketing
Effectiveness in minimising harm	++
Risk proportionate	+
Ease and cost of implementation	-

Section 5: Conclusions

5.1 What option, or combination of options, is likely best to address the problem, meet the policy objectives and deliver the highest net benefits?

A key difficulty in proposing a regulatory regime for vaping and smokeless tobacco products is the lack of evidence that would lead us to definitively conclude how these products should be regulated. The World Health Organization and governments around the world are grappling with this problem.

The Ministry's preferred options are set out below. The set of proposals seeks to maximise the potential benefits of vaping and smokeless tobacco products for smokers by removing regulatory barriers. However, we seek to balance this with protections for the public (particularly children and young people), as well as smokers themselves, from the risks that may be associated with the use of vaping and smokeless tobacco products.

The Ministry's preferred options are:

- a. extend coverage of the SFEA to include all vaping liquid (nicotine-free liquid and nicotine liquid that is not manufactured from tobacco), and vaping and smokeless tobacco product devices and components
- b. retain the broad prohibition on promotion, advertising and sponsorship of vaping and smokeless tobacco products, with exemptions for:
 - i. display of products in specialist R18 stores
 - ii. the giving of free samples, discounts, rewards, and the co-packaging of products in specialist R18 stores
 - iii. identifying specialist R18 stores as retailers of vaping products
- c. require specialist R18 vape stores to be notified to the Ministry to take advantage of the exceptions above and facilitate enforcement
- d. set tailored annual sales reporting requirements for nicotine and nicotine-free vaping liquid
- e. develop guidelines to support business owners, employers and local authorities to develop and implement vaping policies for their smokefree areas
- f. establish minimum product safety requirements for vaping and smokeless tobacco products, including as a group standard under HSNO for vaping liquids which trigger HSNO thresholds
- g. provide a power in the SFEA which would enable flavours and/or colours to be prohibited in future should evidence come to light that they are being used to attract young people to vaping and the use of smokeless tobacco products
- h. require vaping and smokeless tobacco products to be notified to the Ministry, via a web-based system, before they can be sold
- i. recover the costs of regulatory scheme from the regulated industry consistent with The Treasury's guidelines.

5.2 Summary table of costs and benefits of the preferred approach

Affected parties (identify)	Comment: nature of cost or benefit (eg ongoing, one-off), evidence and assumption (eg compliance rates), risks	Impact \$m present value, for monetised impacts; high, medium or low for non-monetised impacts	Evidence certainty (High, medium or low)
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Additional costs of proposed approach, compared to taking no action

Regulated parties (business)	<p>Setting minimum quality and safety requirements will add to costs if manufacturers need to make changes to inputs or processes or importers need to change supplier and/or purchase higher cost products.</p> <p>Requiring product notification will potentially delay the time for products to be marketed and add to costs.</p> <p>Bringing all vaping liquid and vaping and smokeless tobacco devices and components under the SFEA imposes new obligations (as above; in addition, prohibitions on advertising, sales to minors will apply as they do for products/product parts manufactured from tobacco).</p>	<p>Costs associated with notification have been estimated at \$1.05m CAPEX (across the first two financial years) and OPEX of \$180,000 in the first year, \$230,000 in the second year and \$60,000 in subsequent years.</p> <p>Costs associated with meeting product safety requirements have not been estimated.</p> <p>There is no information available of current industry product standards or numbers of products on the market which will impact costs to business and actual fees and levies.</p> <p>Consultation with industry is needed to finalise cost recovery proposals, fees and levies.</p> <p>There will also be compliance costs associated with the new regulatory scheme. These have not been estimated but the scheme is designed to be the minimum necessary to meet safety requirements.</p>	Med
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Regulators	New administrative functions including implementation and maintenance of notification system and enforcement of new requirements.	These are costed as above. It is proposed that costs be recovered from industry consistent with Treasury guidelines.	As above
Wider government	n/a		
Other parties	<p>Additional costs to business likely to be passed on to consumers. This may impact vapers if they notice a cost increase, however, this could be mitigated by the rapidly evolving and highly competitive market.</p> <p>Any increases are highly unlikely to be of such magnitude that they discourage smokers from switching, due to the cost differences between smoking and vaping.</p>	<p>Impact uncertain and highly dependent on the number of notified products (the detailed criteria for notification have yet to be decided – eg, whether different nicotine strengths or sizes of refill bottle need to be separately notified).</p> <p>A review of the impact of UK regulation found that there appeared to have been no major and consistent changes in price over the first year since implementation of the EU Tobacco Products Directive.²¹</p>	As above
Total Monetised Cost		\$1.05m CAPEX and OPEX of \$180,000 in the first year, \$230,000 in the second year and \$60,000 in subsequent years to be fully cost recovered.	Med
Non-monetised costs		<i>Low</i>	

²¹ Public Health England. 2018. Evidence review of e-cigarettes and heated tobacco products 2018. <https://www.gov.uk/government/publications/e-cigarettes-and-heated-tobacco-products-evidence-review>

Expected benefits of proposed approach, compared to taking no action			
Regulated parties	Greater certainty over the legal status of and regulatory requirements for vaping and smokeless tobacco products. Notified specialist R18 vape stores able to lawfully display vaping and smokeless tobacco products and offer free samples, discounts etc.	High	High
Regulators	Able to effectively enforce the SFEA as it applies to vaping products. Know what is on the market and who is responsible in order to take action against breaches or products found to be unsafe.	High	High
Wider government	n/a		
Other parties	Consumers will have access to vaping and smokeless tobacco products which meet minimum quality and safety standards. Smokers will have confidence in switching to less harmful, but unfamiliar, products.	High	High
Total Monetised Benefit	Not assessed		
Non-monetised benefits			

5.3 What other impacts is this approach likely to have?

The Ministry considers that effective regulation of vaping products in particular has the potential to contribute towards achievement of Smokefree 2025 and disrupt the significant inequalities that are present in smoking prevalence and smoking related harm.

5.4 Is the preferred option compatible with the Government's 'Expectations for the design of regulatory systems'?

Yes

Section 6: Implementation and operation

6.1 How will the new arrangements work in practice?

Legislative change

Implementation of the proposals requires amendments to the Smoke-free Environments Act 1990 and its regulations (including the development of new regulations). The amendment bill has a priority 5 on the 2018 legislation programme. Subject to Cabinet decisions being made in October 2018, it should be possible to progress the amendment bill through Parliament in 2019.

The Ministry proposes to build transitional arrangements into the amendment bill where necessary. At this stage, we consider six months lead-in, after passage of the Bill, to be an appropriate period of time to meet notification and labelling requirements.

Regulatory powers, functions and duties

New powers and duties will be needed for new functions, including the notification/self-certification regime for vaping and smokeless tobacco products.

After considering comparable overseas legislation (eg, in Canada, United Kingdom and United States), the Ministry recommends additional powers, functions and duties to apply to vaping and smokeless tobacco products as follows:

1. power to require manufacturer's or importer's disclosure of modifications, research and developments to products since notified
2. power to issue guidance, and codes of practice after consultation with stakeholders
3. power to publish statements/notices about the product, including that a product has a prohibited constituent or misleading labelling or advertising
4. 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, or that the product is likely to cause harm to human safety or health
5. power to suspend a product notification
6. power to cancel or reinstate a product notification
7. duty to declare a product has been notified or suspended or withdrawn, and publish this
8. duty to maintain a register/s of vaping and smokeless tobacco products, and further prescribe the details of the registers in Regulations. Certain parts of the register/s would be published on the Ministry's website. The core components would include: product type and description of constituents; importer/manufacturer of the product; product suspensions or withdrawal information (where relevant); and adverse reaction information and statements about the product issued by the regulator
9. 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 duties applying to manufacturers and importers

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

1. to notify or disclose product modifications, research, test results and developments to products since notified
2. 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

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.

Further work to design a flexible, up-to-date offences and penalties regime aligned with similar legislation 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 and Parliamentary Counsel Office.

Recommended protections for people carrying out functions under the SFEA

Section 19 of the SFEA currently protects enforcement officers appointed under s14 of the SFEA, who do any act in pursuance or intended pursuance of their functions, duties or powers under the SFEA 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.²²

Regulation-making powers

New regulation-making powers will be needed, including to prescribe:

1. information requirements and other detail related to product notifications, suspension and withdrawal of notifications
2. information requirements related to annual sales returns and reports
3. fees for any product notification, certificates, audit, etc.

Enforcement

Enforcement of regulatory controls related to the sale and promotion of products, as well as their use in legislated smokefree areas, is the responsibility of smokefree officers appointed by the Director-General of Health under the Smoke-free Environments Act 1990. The Ministry organises regular training for smokefree officers which will incorporate any changes to the SFEA and its regulations.

The Ministry would be responsible for enforcing product safety proposals, including notification of products. As stated above, further work is needed to determine the scope and cost associated with this work.

²² The immunity chief executives of government departments have in s86 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 s19.

Communications

The Ministry would be responsible for communicating changes to stakeholders, including firms and the public.

6.2 What are the implementation risks?

If proposed amendments to the SFEA are not passed then the scheme will not proceed, leading to the status quo continuing and any expenditure undertaken to date on the notification system being written off. Fewer smokers may switch safely to vaping and other less harmful alternatives and there may be an increase in the number of non-smokers, including young people, who take up vaping.

If funding to establish and implement the notification scheme is not approved then the scheme, which represents the minimum solution, is unlikely to proceed, leading to the status quo continuing and any expenditure undertaken to date being written off.

If the proposed notification scheme is not designed or developed effectively then the scheme will not deliver the expected outcomes leading to less reduction in the number of people switching effectively to significantly less harmful alternatives to smoking, and/or an increase in the number of non-smokers who take up vaping in particular.

If there is insufficient capacity or capability available to implement the notification scheme then commencement may be delayed leading to less reduction in the number of people switching effectively to significantly less harmful alternatives to smoking, and/or an increase in the number of non-smokers who take up vaping in particular.

Section 7: Monitoring, evaluation and review

7.1 How will the impact of the new arrangements be monitored?

The Ministry will continue to monitor emerging evidence on vaping and smokeless tobacco products, including their safety and potential impact on smoking prevalence in New Zealand.

Use of vaping products is monitored via the Health Promotion Agency’s biennial Health and Lifestyles Survey and Youth Insights Survey.

The Youth Insights Survey is a nationwide survey of Year 10 students, conducted every two years. It collects data on smoking-related knowledge, attitudes and beliefs. Since 2012 it has collected information on vaping.

The Health and Lifestyles Survey is a nationwide survey, conducted every two years, of the health attitudes and behaviours of adults aged 15 years and over. Since 2014 it has collected information on vaping.

The information collected via these surveys will be reviewed and built upon.

Currently, there are no mechanisms in place to monitor the market for vaping and smokeless tobacco products. The proposal for product notification would provide information on what is available on the market, once fully implemented.

7.2 When and how will the new arrangements be reviewed?

The Ministry considers that a review of the legislation five years after enactment would be useful given the uncertainties around the analysis.