# Regulatory Impact Statement: Smoked Tobacco Regulations

## Coversheet

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| Purpose of Document |
| Decision sought: | Analysis produced for the purpose of informing final Cabinet decisions |
| Advising agencies: | Manatū Hauora (Ministry of Health) |
| Proposing Ministers: | Minister of Health, Hon Dr Ayesha Verrall |
| Date finalised: | 9 May 2023 |
| Problem Definition |
| Recent changes to the Smokefree Environments and Regulated Products Act 1990 (the Smokefree Act) require regulations to fully implement the policy changes that will deliver on the Smokefree Aotearoa 2025 Action Plan and its objectives.There is also an opportunity to shift the balance of the regulatory requirements for vaping, with the objectives of improving safety and preventing uptake among children and young people, while maintaining access for people who want to quit smoking to a less harmful, less costly alternative. |
| Executive Summary |
| The Smokefree Environments and Regulated Products (Smoked Tobacco) Amendment Act 2022 (the Amendment Act) came into force on 1 January 2023, with new provisions regulating entry into the smoked tobacco and vaping product markets, providing for the approval of smoked tobacco products, introducing very low nicotine limits, and creating a ‘smokefree generation’. Regulations are needed to stand up a regulatory regime that will oversee and monitor these changes. Manatū Hauora (the Ministry) has publicly consulted on regulatory proposals needed for:* the smoked tobacco products retail scheme
* low nicotine testing requirements
* new notification requirements
* fees to enable the regime to be cost-recovered.

The Ministry also consulted on a small number of proposals to tighten existing vaping requirements through regulations. These proposals respond to public concerns and submissions on the Smokefree Aotearoa 2025 Action Plan (the action plan) and the Smokefree Environments and Regulated Products (Smoked Tobacco) Amendment Bill about vaping.The Ministry received more than 2,700 written submissions on the regulatory proposals. Submissions were received from individuals, academics, healthcare providers, community groups, retailers and tobacco and vaping importers and manufacturers. Targeted in-person and online consultation was also held with Māori and Pacific communities across the country. Feedback was generally either supportive, or supportive but wanting further action in some areas, such as vaping. Those not in support were generally industry and retailer submissions.The Amendment Act has specific Te Tiriti o Waitangi provisions requiring the Director-General of Health (the Director-General) to consult with Māori when making retail decisions and requiring the Minister of Health to ensure the risks and benefits to Māori are considered when making regulations regarding the content of smoked tobacco products. To meet these new requirements, the Ministry convened a number of hui with Māori across the country to ensure that special consideration was given to the potential impact the proposals, and especially the retail scheme, will have on Māori. Feedback on the smoked tobacco and vaping proposals has been considered and incorporated as part of this analysis and reflected in the summary of preferred options.The regulations must be in place by August 2023 for the retail scheme to commence. |
| Limitations and Constraints on Analysis |
| The Amendment Act sets limits for the number of approved smoked tobacco retailers (no more than 600) and the maximum nicotine concentration in smoked tobacco products (0.8mg/g). The scope of the regulatory proposals outlined in this analysis is limited to what is needed to stand up the regulatory regime for smoked tobacco. The vaping proposals are limited by the scope of the regulation-making powers in the Smokefree Act, and previous Cabinet decisions. The timeframe for the development of the regulations is constrained by the commencement dates in the Amendment Act (eg, retailers must apply for approval in October 2023). The extent of consultation with Māori was impacted by the North Island flood events and Cyclone Gabrielle. In addition, formal engagement with Iwi-Māori Partnership Boards has not been possible to date as the Boards are in early stages of establishment.  |
| Responsible Manager(s) (completed by relevant manager) |
| Jane Chambers**Group Manager****Public Health Policy and Regulation****Manatū Hauora**9 May 2023 |
| Quality Assurance (completed by QA panel) |
| Reviewing Agency: | Manatū Hauora |
| Panel Assessment & Comment: | The Ministry of Health’s Papers and Regulatory Committee has reviewed the attached Regulatory Impact Statement and considers it meets the quality assurance criteria. It concisely addresses the range of regulatory options, is clear and complete, has been consulted widely, and the limitations of the analysis are clearly set out.  |

##

# Stage 2: Cost Recovery Impact Statement

### Status quo

Cabinet has agreed that the costs of running the regulatory regime will be cost-recovered through fees and/or levies [CAB-21-MIN-0503 refers]. Costs have been determined to the extent practicable given the uncertainty around some aspects of the scheme (for example the number of applicants). Funding was also provided through Budget 22, and this will contribute to the overall cost model.

The Act allows for fees and/or levies to be set in regulations. The Ministry proposes fees for:

* assessment and approval of applications to be a smoked tobacco retailer
* assessment and approval of smoked tobacco product applications
* assessment and temporary approval of smoked tobacco product applications
* registration fees for smoked tobacco distributors and general retailers of notifiable products (including vaping products).

Regulations setting fees must be made by August 2023 when the smoked tobacco retail scheme commences.

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

It is appropriate for the industry to meet the costs of establishing and managing the regulatory regime (including assessment and registration) as the scheme enables them to continue importing, manufacturing, distributing and selling products.

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

**Table 1:**

|  |  |  |
| --- | --- | --- |
| **Output** | **Type of good** | **Recommendation** |
| Policy advice | Public – to maintain independence of advice to the Minister | Crown pays |
| Assessment and approval of smoked tobacco retailers | Private – the benefits can be directly attributed to those wanting to sell smoked tobacco products | Applicant pays |
| Assessment and approval of smoked tobacco products | Private – the benefits can be directly attributed to those wanting to import and/or manufacture smoked tobacco products | Industry pays |
| Assessment and temporary approval of smoked tobacco products | Private – the benefits can be directly attributed to those wanting to import and/or manufacture smoked tobacco products | Industry pays |
| Registration of smoked tobacco distributors and general retailers of notifiable products (including vapes) | Private – the benefits can be directly attributed to those wanting to sell and distribute smoked tobacco products, and those wanting to sell notifiable products (including vapes) | Industry pays |

*NB: In this table, industry refers to retailers, manufacturers and/or importers of smoked tobacco and notifiable product*

### High level cost recovery model: the level of the proposed fee and its cost components

The scheme will be partially cost-recovered through fees. The proposed fees are as follows:

**Table 2:**

|  |  |  |
| --- | --- | --- |
| **Fee**  | **Amount (excl. GST)** | **Recovering costs for** |
| Assessment fee for applications to be an approved smoked tobacco retailer | $1,475 per premise | Receive and check application; assess and score against published criteria; review; calculate application ranking; send final assessment to applicant; publish on approved smoked tobacco retailer register.*\*Does not include costs for store visit. See options for more information* |
| Assessment fee for smoked tobacco product applications | $13,450 per product | Receive and check application; review product testing results; seek clarifications (if any); review product constituents; undertake internal peer review; prepare product assessment report; undertake final review; send final assessment to applicant; publish on approved products register. |
| Assessment fee for smoked tobacco product applications (temporary approvals for products that cannot meet product requirements) | $2,650 per product | Receive and check application; undertake market scan; review product information; seek clarifications (if any); review any additional information provided; undertake peer review; prepare product assessment report; undertake final review; send final assessment to applicant; publish on approved products register. |
| Registration fee (for smoked tobacco distributors, general vape retailers, and retailers of other notifiable products) | $80 per annum | Receive and check annual registration; seek clarifications (if any); review any additional information provided; publish on participant register where relevant. |

These fee estimates are based on assumptions around the average resourcing required to process each application or registration. Three scenarios have been modelled as shown in table 3. No applications for approved smoked tobacco retailers are included after the first year (2023/24), however it is possible that applications will be sought.

**Table 3:**

|  |  |  |
| --- | --- | --- |
| **Fee Type** | **Volume (2023/24)** | **Volume (outyears)**  |
|  | **Scenario** | **Scenario** |
|  | **Low** | **Med** | **High** | **Low** | **Med** | **High** |
| Applications to be an approved smoked tobacco retailer | 500 | 5,000 | 8,000 | 0 | 0 | 0 |
| Smoked tobacco product applications | 0 | 5 | 8 | 0 | 2 | 4 |
| Smoked tobacco product – temporary approvals | 25 | 50 | 75 | 25 | 50 | 75 |
| Registrations – smoked tobacco distributors, general vape retailers, retailers of other notifiable products | 4,000 | 5,000 | 10,000 | 4,000 | 5,000 | 10,000 |

The money recovered from applications will be directly proportionate to the number of applications received, and cost-recovery therefore directly correlates to the volume of application fees.

Modelled costs and funding for the scenario with a medium volume of applications is presented in table 4 below:

**Table 4:**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Forecast (Medium Scenario)** | **2022/23** | **2023/24** | **2024/25** | **2025/26 and outyears** |
| Establishment and operating costs – estimate incl. regulator and baseline compliance | $ 4,333,000 | $ 9,787,000 | $ 5,518,000 | $ 4,765,000 |
| Forecast income from fees | $ 0 | $ 7,982,500  |  $ 565,500  | $ 565,500  |
| Crown funding | $ 4,333,000 | $ 9,241,000 | $ 5,718,000 | $4,965,000 |
| **Total surplus/deficit)** |  **$ -**  |  **$7,406,500**  |  **$ 765,500**  | **$ 765,500**  |

The operating costs include setting up the smoked tobacco regulator — for example, HR costs and IT system costs, as well as processing applications and some monitoring costs.

Overall, the ongoing surplus/deficit for 2025/26 and outyears is expected to be $765,500 for a medium volume of applications and range between a surplus of $1,439,225 per annum for a scenario where few applications are received and a deficit of $1,793,709 per annum when many applications are received.

Actual retail application volumes will only be known once the retail scheme is underway. All fees will be reviewed as part of the overall review of the Amendment Act and the operation of the scheme no later than 1 January 2029.

## Section 1: Diagnosing the policy problem

### What is the context behind the policy problem and how is the status quo expected to develop?

**Smoked tobacco**

Aotearoa has a goal to reduce daily smoking rates to less than 5% across all population groups by 2025 (the Smokefree 2025 goal). While smoking rates have declined overall, Māori, Pacific peoples, and those living in the most disadvantaged areas continue to have disproportionately higher smoking rates and experience greater health inequities from smoking. Disabled people also have higher smoking rates, with disabled adults more than twice as likely to be daily smokers than non-disabled adults, and almost 3 times as likely to be heavy smokers.

To accelerate progress towards achieving the Smokefree goal, the Government released the Smokefree Aotearoa 2025 Action Plan in December 2021. Legislative change was a key focus area of the action plan and the Amendment Act was passed in December 2022.

**Smoked tobacco**

The Amendment Act introduces measures to achieve the following objectives:

* significantly reducing retail availability of smoked tobacco products (by capping the number of retail stores to a maximum of 600 and restricting where they can be sold and who can sell them)
* prohibiting the sale of smoked tobacco products to those born on or after 1 January 2009 (the smokefree generation policy)
* reducing the appeal and addictiveness of smoked tobacco products (by only allowing the sale of products that meet low-nicotine and other standards)

A regulatory regime is needed to oversee and monitor these changes. It must be stood up in sufficient time for the retail and products restrictions to commence (only approved retailers can sell smoked tobacco products from 1 July 2024, and only low nicotine products can be sold from 1 April 2025).

The new legislative measures, and the regulations needed to implement them, have been designed to address the inequities that smoking causes for Māori and are an integral part of the Crown’s obligations under Te Tiriti o Waitangi. Modelling projected that these legislative changes would significantly reduce the inequity gap in health outcomes between Māori and non-Māori. By 2040, it is estimated that these policies will reduce the gap in all-cause mortality for Māori aged over 45 by 22.9%.

The policies will also support equity in other marginalised communities that have high rates of smoking and vaping, including LGBTQ+ people. Non-heterosexual men, for example, report higher rates of smoking and vaping use than the general population.

#### Vaping

Vaping was first regulated by the Smokefree Environments and Regulated Products (Vaping) Amendment Act 2020, which aimed to provide a balance between ensuring smokers had access to a regulated, less harmful and less costly alternative to smoking, while protecting non-smokers – especially young people – from the risks associated with vaping. However, vaping rates among young people have risen significantly in the past few years.

Vaping rates are higher for Māori, Pacific, people attending low and mid-decile schools and gender-diverse youth than other groups.[[1]](#footnote-2) New Zealand Health Survey data shows that daily vaping by 15 to 17 year-olds increased from 1.7% in 2018/19 to 8.1% in 2021/22.[[2]](#footnote-3) The most recent ASH year 10 survey (2022) found that 10.1% of year 10 students reported vaping daily.[[3]](#footnote-4) Daily vaping rates among Māori youth have increased significantly in this time period, particularly for Māori girls (from 5.2% to 25.2%)[[4]](#footnote-5).

### What is the policy problem or opportunity?

Regulations (and other instruments) are needed to bring a number of provisions of the Amendment Act into full effect and stand up the Smoked Tobacco Regulatory Regime. This includes requirements relating to:

* the smoked tobacco retail scheme, including minimum approval requirements, and decision-making criteria
* low nicotine testing and product requirements
* new notification requirements for distributors and retailers
* fees to enable the scheme to be cost-recovered.

To shift the balance of the vaping regulatory regime towards improving safety and better protecting young people, the Ministry consulted on:

* changing the way vape flavours can be described
* new product safety requirements, including requirements for child safety mechanisms and replaceable batteries, and nicotine levels in disposable vapes
* new proximity restrictions for Specialist Vape Retailers.

### What do the stakeholders think of the problem

Key stakeholders include:

* iwi, hapū and whānau Māori
* people who smoke tobacco and/or vape and their whānau and communities, health sector agencies, health practitioners and researchers
* the tobacco and vaping industries (manufacturers, importers and distributors)
* smoked tobacco and general vape retailers
* Specialist Vape Retailers
* industry bodies.

The Ministry publicly consulted on the regulatory proposals from 4 January to 15 March 2023. More than 2,700 written submissions were received. In addition to online consultation, the Ministry held face-to-face and online hui and fono with Māori and Pacific communities. Hāpai te Hauora also gathered 492 submissions from Māori and Pacific people at cultural events throughout the consultation period. Consultation feedback has been included as part of the options analysis in Section 2.

### What objectives are sought in relation to the policy problem?

The proposed regulations for smoked tobacco products will operationalise the new provisions of the Amendment Act. They will ensure the measures are implemented in a manner that will achieve the objectives of reducing the availability, appeal and addictiveness of smoked tobacco products.

Giving effect to these regulations will support the action plan objectives of eliminating inequities in smoking rates and smoking-related illness and increasing the number of people who successfully quit smoking.

Proposals to tighten existing regulations for vaping products will help to achieve the objective of reducing their appeal to young people and improving their safety.

## Section 2: Deciding upon an option to address the policy problem

### This section analyses options across the following areas:

* *Issue 1*: additional requirements for approval as a smoked tobacco retailer
* *Issue 2*: decision-making criteria for retail applications
* *Issue 3*: testing and other product requirements for low nicotine smoked tobacco
* *Issue 4*: fees
* *Issue 5*: notification requirements
* *Issue 6*: youth vaping- limiting the way flavours are described
* *Issue 7*: youth vaping- addressing safety concerns with single-use products
* *Issue 8*: youth vaping- proximity restrictions.

### What criteria will be used to compare options?

The criteria used to compare options for smoked tobacco (issues 1 to 5) are:

* **Reduces inequity**: will the option reduce inequities in smoking rates and smoking related illnesses, particularly for Māori and Pacific communities?
* **Effectiveness**: does the option support the measure’s objectives (i.e., significantly reduce retail availability of smoked tobacco products; prevent young people from ever taking up smoking; reduce the appeal and addictiveness of smoked tobacco products)?
* **Cost and ease of implementation**: is the option able to be implemented by both Government and industry? Is the cost reasonable to Government and industry?
* **Clear and workable for Aotearoa**: are New Zealanders, including people who smoke and their whānau, and regulated parties, likely to understand or support the intentions, implementation, and enforcement of the option?

The criteria used to compare options for youth vaping (issues 6 to 8) are:

* **Reduces inequity**: will the option reduce inequities in vaping rates, particularly for Māori and Pacific communities?
* **Effectiveness**: will the option support the objectives of shifting the balance towards better protecting young people from the risks associated with vaping (by improving their safety and reducing their appeal and addictiveness), while maintaining access for adults seeking to quit smoking?
* **Cost and ease of implementation**: is the policy able to be implemented within the likely available budget and the necessary timeframe? Is the cost reasonable to Government and industry?

### What scope will options be considered within?

Options are restricted to what can be achieved through the regulation-making powers of the Smokefree Act.

Cabinet agreed at the end of December 2022 to consult on the following proposals needed to establish the Smoked Tobacco Regulatory Regime:

* the smoked tobacco retail scheme
* testing requirements and approval processes for low nicotine products
* new notification requirements for distributors and retailers
* fees to enable the regime to be cost recovered

Cabinet also agreed to consult on tightening vaping restrictions.

### What issues and options are out of Scope?

The following options have not been considered:

* the allocation and distribution of retail premises across the country. As set out in the Amendment Act, the Director-General determines, by written notice, the maximum number of approved premises by area. Regulations are not required to achieve this.
* any changes, including to the way vaping products are regulated, that would require a legislative amendment.

### What options are being considered?

### Retail Scheme

### Issue 1 – Additional requirements for approval as a smoked tobacco retailer

From July 2024, only approved retailers will be able to legally sell smoked tobacco products. Retailers must apply to the Director-General for approval. The Amendment Act sets out the following minimum requirements the Director-General must consider when deciding approvals:

* the applicant, if an individual, must be a fit and proper person
* for an entity, each ‘responsible person’ must be a fit and proper person
* an entity must be carrying on business in Aotearoa and be registered under New Zealand law
* any retail premises must be a fixed, permanent structure and be an appropriate premises from which to operate.

The Ministry consulted on additional approval requirements which would be set in regulations. These covered security, training, sales systems and delivery systems, as well as requirements for the ‘fit and proper’ person test in the Amendment Act. These are intended to ensure that retailers approved to sell tobacco products are responsible business people and have systems in place to protect the health and safety of their staff and customers.

*Consultation feedback*

Feedback included detailed suggestions for the additional approval and ‘fit and proper’ person requirements.

Concerns about security for stores selling smoked tobacco products was raised by many submitters. Many also considered that, for example, security systems should not have to be in place at the time of application as applicants should not have to spend a lot of money to meet requirements, with no guarantee their application will be approved.

Table 5 sets out the proposed additional approval requirements, noting changes made following consultation.

Table 5: Proposed additional requirements for approval as a smoked tobacco retail premise to be set out in regulations

|  |  |  |
| --- | --- | --- |
| **Requirements** | **Description** | **Updates following consultation**  |
| Have appropriate **security measures** in place | A person must demonstrate that the retail premise has the following:* a suitable alarm system, as appropriate for the business
* suitable security cameras with recording facilities, as appropriate for the business
* suitable external protection to protect premise from theft, as appropriate for the business
* secure product storage
* a suitable fog cannon system, as appropriate for the business.
 | *No changes have been made.* |
| Have appropriate **business systems** in place | *Training*A person must demonstrate that: * every staff member is/will be trained in, and understand, their responsibilities under the Smokefree Act, including preventing sales to minors/the smokefree generation (as described in the application process)
* appropriate training records, including effectiveness, will be kept

*Sales*A person must demonstrate that: * an accurate record of all smoked tobacco product sales will be kept, including product type, brand, quantity and price
* systems are in place to prevent sales to minors/the smokefree generation.

*Sales - Online*If a person is permitted to sell online, then they must also demonstrate that systems are in place to ensure conditions of approval are met (e.g., the identified geographic area that a person can sell within, the use of a specified internet site for sales).*Delivery*A person must demonstrate that systems are in place to ensure that smoked tobacco products are not delivered to minors/the smokefree generation, including for online sales where these are permitted. | *No changes have been made.* |
| Be a **‘fit and proper’** person  | The Director-General must be satisfied that the person: * is over the age of 18
* has not had a conviction, in the last 7 years, for-
	+ an offence against the Smokefree Act; or
	+ an offence against Part 6 of the Customs and Excise Act 2018; or
	+ an offence against the Sale and Supply of Alcohol Act 2012; or
	+ a crime involving dishonesty (as defined in section 2 of the Crimes Act 1961).

The Director-General may also have regard to any other matters that the Director-General thinks are relevant, including non-compliance with the Smokefree Act.To ascertain whether a responsible person has a conviction for a crime, or an offence referred to above, the Director-General must ask the Chief Executive of the Ministry of Justice to check whether the person has a conviction of that type. | *Changes have been made to include a 7-year time frame for convictions aligned with clean slate requirements. Several proposals from the consultation document, such as compliance history, are given effect by the ability of the Director-General to have regard to other matters.* |

The options for additional approval criteria are:

#### Option 1 (Counterfactual)

No additional approval requirements are set for smoked tobacco retailers. Retailers are assessed only against the requirements in the Amendment Act.

#### Option 2

Additional approval requirements for smoked tobacco retailers set out in regulations.

**Table 6: Comparison of options**

|  |  |  |
| --- | --- | --- |
| **Options** | **Option 1 (counterfactual):** retailers assessed against requirements in Act | **Option 2:** additional approval requirements set in regulations |
| Pros | Possibly less cost for businesses that are approved (i.e., lower set-up costs to install additional security systems or conduct staff training) | Greater clarity and certainty for retailers when deciding whether to apply, and for the regulator when assessing applicationsMay increase safety for staff and customers in some retail premises if they would not otherwise choose to install safety featuresWould ensure high-quality permanent systems, such as security, training, and business systems (e.g., record keeping)Community confidence that retailers are responsible business people, eg, less likely to sell to minors and adequate security to protect health and safety of customers ,  |
| Cons | Lack of clarity and certainty for retailers when considering an applicationDifficult for regulator to assess applications; could create perception of unfairness and lack of trust in regulator from both industry and communityMay increase crime risk for retailers if lesser security requirements; decreases safety for staff and customersLess certainty that retailers will comply with their legal obligations, such as sales to minorsMay result in poor practices, such as poor record keeping which would hamper compliance actionA less robust scheme may result in ongoing costs to the regulator for compliance purposes | Could exclude certain businesses if too prescriptivePossible financial cost to businesses who are approvedAdditional cost to the regulator (and thus businesses), as it will likely require the regulator to visit and verify that each store meets requirements |

###  Assessment of options

|  |  |  |
| --- | --- | --- |
|  | **Option 1 – Counterfactual: No additional approval requirements in regulations** | **Option 2: Additional approval requirements set in Regulations** |
| **Reduces inequity** | 0Likely to have no impact on equity. | **+**Better systems will reduce the likelihood of underage sales; this may disproportionately benefit young Māori and Pacific peoples who have higher smoking rates than other groups. Security requirements mean that retailers less likely to be disproportionately targeted by criminal offending. |
| **Effectiveness**  | 0Increased risk of compliance breaches, illicit sales, and to safety of staff and customers.  | **+**Better compliance with obligations, reduced risk of illicit sales, and increased safety for staff and customers. Better supports policy objective of significantly reducing retail availability of smoked tobacco products.  |
| **Cost and ease of implementation** | 0Less cost for industry and regulator, but also less certainty regarding who can be approved. | **+**Although industry may incur higher set-up costs, this will provide much more certainty for both industry and regulator, potentially reducing costs in the longer term. Less theft and burglaries will likely reduce costs for industry. |
| **Clear and workable for Aotearoa** | 0Less robust scheme, potentially leading to reduced trust and confidence in the system. | **+**More robust scheme, provides clarity on expectations for businesses. Improved trust and confidence in the sector due to robust security and higher standards for retailers. |
| **Overall assessment** |  | **Preferred option** |

### Issue 2 – Decision-making criteria for retail applications

The Amendment Act requires that the Director-General determine and publish an application process that ensures that the maximum number of approved premises for an area is not exceeded. The process must also include a ranking system for when there are more applicants for an area than the maximum number allows.

Additional decision-making criteria can be set in regulations to rank applicants and determine who will be granted approval in these circumstances. The Ministry consulted on a proposal to set specific ranking criteria relating to proximity and location, the type of business, store security, business systems, and compliance history.

*Consultation feedback*

A large number of submissions supported proximity restrictions for smoked tobacco retailers. Submitters strongly considered that proximity considerations should include kōhanga reo, kura/schools, marae and churches. Some submitters also supported consideration of the type of business, with some recommending that for example alcohol and/or grocery stores not be eligible for approval.

Many submitters considered that local communities should be involved in decision making for retailer approvals. It was also commonly raised that no new tobacco retailers should be approved where there are currently none.

Another concern raised was whether stores would have to invest in ensuring they could meet these criteria prior to applying, when there was no certainty that they would be approved.

Table 7 sets out the proposed decision-making criteria, noting changes made following consultation.

**Table 7: Proposed decision-making criteria for smoked tobacco retailer applications**

|  |  |  |
| --- | --- | --- |
| **Criteria** | **Description** | **Updates following consultation** |
| Proximity and location | An applicant will be ranked according to the proximity of the retail premise in relation to one or more areas of community interest, which are:* early childhood centres, Kōhanga Reo, schools/kura
* marae

Further detail will be provided in the application process published on Manatū Hauora’s website. | *Proposals to rank stores in relation to proximity to areas of community interest is unchanged but has been refined to focus on areas which can be defined through available information.* |
| Type of business | An applicant will be ranked according to the type of business they operate. For example, a retail premise selling alcohol will be ranked lower than a premise that does not. Further detail will be provided in the application process published on Manatū Hauora’s website. | *A change has been made to remove reference to grocery or convenience store items. While a number of submitters, including Māori, would have preferred to exclude retail premises that sold food from consideration this seemed unworkable.* |
| Additional **security measures** | An applicant will be ranked according to the number of additional security measures in place (over and above the minimum approval requirements), as outlined in the application process published on Manatū Hauora’s website. These measures include security staff, de-escalation and conflict resolution training, and restricted access to retail premises. | *No changes have been made.* |
| Additional **business systems**  | An applicant will be ranked according to how they meet any additional business system requirements as outlined in the application process published on Manatū Hauora’s website. These requirements include how stock and supply chains are managed and a business’ capacity to manage fluctuations in demand. | *No changes have been made.* |

The options for decision-making criteria to support the ranking of applications are:

#### Option 1 (Counterfactual)

No decision-making criteria to rank applications set in regulations. Criteria would instead be published on the Ministry website.

#### Option 2

Decision-making criteria to rank applications set out in regulations.

**Table 8: Comparison of options**

|  |  |  |
| --- | --- | --- |
| **Options** | **Option 1 (counterfactual):** no decision-making criteria in regulations | **Option 2:** decision-making criteria set in regulations |
| Pros | Regulator has more discretion to decide who becomes an approved retailer. Regulator has more flexibility to change and update criteria as needed. | Greater transparency and certainty for businesses and the regulator.Clear criteria for application and assessment should reduce the likelihood of needing to make changes during the process.Greater clarity around criteria and process means decision making is more robust. |
| Cons | Decisions may be more arbitraryLess transparency and certainty for businessesA less robust scheme may result in ongoing costs to the regulator for compliance purposes | Application scheme may be disrupted if changes are needed given the longer process to change or update decision-making criteria if needed. |

### How do the options compare to the status quo/counterfactual?

|  |  |  |
| --- | --- | --- |
|  | **Option 1 (Counterfactual) – No decision-making criteria to rank applications set in regulations** | **Option 2 – Decision-making criteria to rank applications set in regulations** |
| **Reduces inequity** | 0Likely to have no impact on equity. | **+**May have some impact on equity. |
| **Effectiveness as a policy** | 0Does not align with policy intent. Increased risk of arbitrary decision making. | **+**More reliably gives effect to policy intent. Criteria applied will be more legally robust, ie, clear and certain law. |
| **Cost and ease of implementation** | 0Easier to change if required. However, it will not undergo scrutiny of the legislative process. | **+**Will provide an extra layer of legislative scrutiny to approving criteria.More difficult to amend criteria if needed. |
| **Clear and workable for Aotearoa** | 0Less transparency and certainty for businesses and the general public. | **+**Greater transparency and certainty for businesses and the general public. |
| **Overall assessment** |  | **Preferred option** |

### Product Requirements

### Issue 3 – Testing and other product requirements for low nicotine smoked tobacco

The Amendment Act limits the nicotine in smoked tobacco products to a maximum level and requires that these products are tested in accordance with regulations before granting approval for import, manufacture or sale, and allows for further constituents to be regulated.

The Ministry consulted on proposed requirements for testing methods, as well as specific information requirements for the granting of product approvals and temporary approvals for research/testing purposes or for the import of a niche product.

*Consultation feedback*

Most submitters did not provide feedback on this proposal. Those who did broadly supported the proposed requirements and wanted testing to be conducted in New Zealand and by independent companies separate to the tobacco industry.

Table 9 sets out the proposed product requirements, noting changes made following consultation.

**Table 9: Proposed product requirements**

|  |  |  |
| --- | --- | --- |
| **Product requirement** | **Description** | **Updates following consultation** |
| Constituents of smoked tobacco products  | Smoked tobacco products must not include any synthetic or naturally occurring chemicals or ingredients that are structurally analogous or have functional similarity to nicotine/synthetic nicotine.All parts of a smoked tobacco product other than tobacco leaf or filler should not contain nicotine, or any other substances, including psychoactive substances that could maintain addictiveness. Current regulation 32(2) is revoked and replaced by new requirements that tobacco should smell of only manufactured tobacco or menthol. | *No changes have been made.**The Minister’s requirement to consider the risks and benefits to Māori of regulating a constituent as required under the Act are met by these requirements which are designed to ensure that the reduction of addictiveness is not circumvented by changes to product design.* |
| Testing methods  | An importer/manufacturer must use an analytical method, as set out below, to determine nicotine levels in smoked tobacco products:Tests should be carried out in a suitable laboratory that is accredited to the most recent version of ISO/IEC 17025 and be independent from the manufacturer or importer of the smoked tobacco product. Tests should be carried out:* using an appropriate chromatography-based analytical test method [that uses/such as] a gas chromatographic method with flame ionisation detection, which is demonstrated as suitable to test the nicotine content of the product (and any constituents)
* using appropriate instrumentation for the method selected, and in appropriate laboratory conditions
* using a method which has been shown to be appropriately validated at the accredited laboratory (including for accuracy, precision and certainty of measurement).

A manufacturer or importer must submit full details of their proposed test methodology to the Director-General for review, including evidence of its validity and the accreditation of the laboratory where the testing took place. An appropriate test method or methods may be published on Manatū Hauora’s website.Testing regimes must ensure that each individual product will be compliant, including all sources of variability. A manufacturer should test a range of samples, and account for any variance in products when setting out their testing methodology. This methodology shall be submitted as part of their product application process.Remove existing requirements of current regulation 63, requiring testing for nicotine emissions, carbon monoxide and tar. | *These proposals have been refined to allow some variation in the method used as long as it is a gas chromatography based, chemical analytical method, that has been submitted for review. Some manufacturers continued to push for the inclusion of ISO emissions testing however this has been removed to ensure no confusion in future.* |
| Product approval / application process (for each brand and variant)  | An importer/manufacturer must provide the following as part of their approval application:* a description of the product type, brand, variant and unique product code (eg, EAN or UPC number)
* a summary of test results for nicotine content of the tobacco and any other constituents required, for at least 3 batches of full-scale manufactured product
* a full list of ingredients, including any additives
* an appendix containing a dossier including full test reports for at least 3 batches of full-scale manufactured product, information on the testing methodology used, product and packaging images and any other relevant documentation.

An importer/manufacturer must provide the following as part of their temporary approval application to import/manufacture a product for research and/or testing purposes:* a description of the product type, brand, variant and unique product code (eg, EAN or UPC number) where this is available
* a description and purpose for the proposed research and/or testing, including a rationale for requiring the import of a non-compliant product
* the volume of product proposed to be imported or manufactured for research and/or testing and the rationale of how this relates to the research purpose.

An importer/manufacturer must provide the following as part of their temporary approval application to import/manufacture a niche smoked tobacco product:* a description of the product type, brand, variant and unique product code (eg, EAN or UPC number)
* evidence that the product is a niche smoked tobacco product, not of mass appeal, not a cigarette, and that no similar compliant product can be sourced.
 | *Minor changes have been made, for example to require more than one batch to be tested.* |
| Other product changes | Modify the existing annual reporting and returns requirements for tobacco products as follows:Require an importer/manufacturer to have product safety systems in place that enable:* investigation and resolution of complaints about the products
* recall of a product from sale or supply
* notification to Manatū Hauora of any recall.
 | *No changes have been made.* |

The options for product requirements are:

#### Option 1 (Counterfactual)

Do not set any product requirements through regulations.

#### Option 2

Set the full range of product requirements proposed through regulations.

**Table 10: Comparison of options**

|  |  |  |
| --- | --- | --- |
| **Options** | **Option 1 (counterfactual):** do not set product requirements in regulations | **Option 2:** set the full range of proposed product requirement in regulations |
| Pros | Easier for industry to achieve compliance Will not overburden one or a small number of testing labsLow implementation cost for industry | Ensures products are not brought to market that undermine the policy intent Greater certainty that the products meet low nicotine standardsGreater certainty to industry that test results are robust and consistent ensuring a level playing fieldSets a clear precedent for industry to participate in the new regulatory regime |
| Cons | May be difficult to carry out complianceLess certainty that products do not exceed maximum nicotine levels | Expense for industry to get products testedReliance on a smaller number of businesses approved to carry out tests  |

### How do the options compare to the status quo/counterfactual?

|  |  |  |
| --- | --- | --- |
|  | Option 1 (Counterfactual) – No additional product requirements set in regulations | **Option 2 – Set the full range of product requirements in regulations** |
| **Reduces inequity** | 0Less certainty that products will not be minimally addictive which would likely have a disproportionate adverse impact on Māori and Pacific people who have higher rates of smoking than other groups. | **+**Greater certainty that products are less addictive and appealing, which will disproportionately benefit Māori and Pacific peoples who have higher rates of smoking than other groups.  |
| **Effectiveness as a policy** | 0This may result in smoked tobacco products being sold that exceed the mandated nicotine limits or are addictive in other ways. Does not meet policy objective to ‘reduce the appeal and addictiveness of smoked tobacco products.’ | **+**Ensures smoked tobacco is consistently and reliably below mandated level (and below the addictiveness threshold) ensuring the policy objective is achieved. Limits ability of industry to increase appeal and addictiveness of smoked tobacco products by ensuring test results are robust and products remain minimally addictive. |
| **Cost and ease of implementation** | 0Less compliance costs to industry. More challenging for the regulator to implement and enforce.  | 0Greater compliance costs for industry. Easier for the regulator to implement and enforce. |
| **Clear and workable for Aotearoa** | 0Unclear process, likely to be less reliable test results. | **+**Provides clarity for industry, the regulator and the public. Reliable test results. Ministry’s technical advisory group supported this option. |
| **Overall assessment** |  | **Preferred option** |

### Issue 4 – Fees

The Amendment Act provides for the recovery of costs associated with establishing and operating the regulatory regime from industry through fees or levies. There is a regulation-making power to set fees and levies for this purpose.

Cabinet has agreed that this regime should be cost-recovered (CAB-21-MIN-0503 refers). This is aligned with the approach for vaping products and broader cost-recovery principles. The proposed fees have been set with reference to the costs of assessing applications, and relevant guidance.[[5]](#footnote-6)

The Ministry consulted on a proposal to set fees in regulations for the following:

* assessment of applications to be an approved smoked tobacco retailer
* assessment of smoked tobacco product applications
* assessment of smoked tobacco product temporary approval applications
* registration of smoked tobacco distributors, general vape retailers, and retailers of other notifiable products.

The assessment fee for applications to become an approved smoked tobacco retailer was included in consultation as an indicative range and has now been finalised at $1,475 based on estimations of application volumes, the level of automation and time taken to process.

*Consultation feedback*

The majority of submitters who answered questions on fees supported the proposals, however some felt the level of fees was set too low or high. Some suggested the fees should cover the cost of the harm smoking causes. Some concerns were raised about the potentially large number of unsuccessful smoked tobacco retailer applicants being charged the same fee as successful applicants.

The proposal consulted on did not seek to recover the cost of verification site visits from the sector as the costs could not be attributed to specific applicants at the time the fees are paid. Current plans are for these site visits to be carried out by Smokefree Enforcement Officers, who are already funded by the Crown.

Comprehensive guidance on the assessment process will be provided to all potential applicants, allowing people to self-select and not apply where they are not likely to be successful.

The options for fees are:

#### Option 1 (Counterfactual)

Do not charge cost-recovery fees.

#### Option 2

Introduce cost-recovery fees through regulations as proposed in consultation.

#### Option 3 (adjusted proposal following consultation)

Cost recovery, but with a small refund to smoked tobacco retail applicants who do not progress to the point of requiring an on-site inspection of their store. The fee for this inspection is estimated at $350, which would be included in the initial fee paid by all applicants.

**Table 11: Comparison of options**

|  |  |  |  |
| --- | --- | --- | --- |
| **Options** | **Option 1 (counterfactual):** do not charge cost-recovery fees | **Option 2:** introduce cost-recovery fees through regulations | **Option 3:** cost recovery, with a partial refund for applicants whose stores are not visited |
| Pros | No cost to industry | Aligns with previous Cabinet decision for the scheme to be cost-recoveredReduces reliance on funding from tax/public moneyAligns with LDAC guidelines for charging fees and levies | Aligns with previous Cabinet decision for the scheme to be cost-recoveredReduces reliance on funding from tax/public moneyAligns with LDAC guidelines for charging fees and leviesOnly those who meet approval requirements pay for site visits |
| Cons | Does not align with Cabinet decision for scheme to be cost-recoveredAdditional costs to Government to fund the regulatory schemeDoes not align with feedback from consultation hui that costs should not be met by the tax payer | Up front cost for businesses may be a barrier to seeking entry for some eligible retailersOngoing costs to the sector for some fee categories – notification and temporary product approvals – may be passed on to consumersAll retailers pay for a site visit, even if they do not benefit from one | Higher up-front cost for smoked tobacco retailer applicants, may be a higher barrier to seeking entry for some eligible retailersHigher overall costs for successful retail applicants, still a significant cost for unsuccessful applicantsOngoing costs to the sector for some fee categories – notification and temporary product approvalsSignificant time and cost to process and return refunds to applicants |

### How do the options compare to the status quo/counterfactual?

|  |  |  |  |
| --- | --- | --- | --- |
|  | **Option 1 (Counterfactual) – Do not charge cost-recovery fees** | **Option 2 – Introduce cost-recovery fees through regulations** | **Option 3 – Cost recovery, with a partial refund for applicants whose stores are not visited**  |
| **Reduces inequity** | 0Likely to have no impact on equity. | **+**Ensures Government does not subsidise business costs for industry that is disproportionately harmful to low socioeconomic communities.  | **+**Ensures Government does not subsidise business costs for industry that is disproportionately harmful to low socioeconomic communities (and other groups who experience greater health inequities from smoking such as disabled people). Offsets some existing Crown costs through additional fees. |
| **Effectiveness as a policy** | 0Public funds covering the cost of industry establishing/seeking to establish businesses. Does not align with previous Cabinet decisions. | **++**Aligns with previous policy and Cabinet decisions and follows precedent set by the comparable vaping regulatory scheme. | **+**Aligns with principle of Cabinet decisions. More complex to implement. Does not follow precedent set by the comparable vaping regulatory scheme. |
| **Cost and ease of implementation** | 0Significant cost for regulator – public interest in not using government money to cover the costs of private businesses, particularly for harmful commodities. No cost to industry. | **+**Up-front cost to industry, minimised cost to the regulator (user pays system). Site visits for shortlisted applicants carried out by existing Enforcement Officers. | **-**Up-front cost to industry, but small refund to some. Cost and significant administrative task for the regulator. Refund process could cost more to administer than revenue from fees. |
| **Clear and workable for Aotearoa** | 0Out of step with similar regimes, would require additional crown funding. | **++**Logical and aligns with cost-recovery models of similar regulatory regimes. Submitters in public consultation supported this option. | **+**Reasons for a refund or not may seem opaque to industry participants, especially those who have a store visit but are not approved. |
| **Overall assessment** |  | **Preferred option** |  |

### Issue 5 – Notification requirements

The Amendment Act requires distributors of smoked tobacco products and general retailers of notifiable products (including vape products) to notify the Director-General of their business. A notification must be made in accordance with requirements set in regulations.

The consultation document proposed that distributors and general retailers are required, on an annual basis, to provide their contact details (including name, business name, company number/New Zealand business number, address, phone numbers and email addresses) when they register on the Ministry’s database

*Consultation feedback*

Many submitters who responded to this question supported the proposal. There were suggestions around how often a business should be required to notify, but very few comments relating to the information requirements proposed.

The options for notification requirements are:

#### Option 1 – Counterfactual

Do not set out requirements for information to be supplied in regulations.

#### Option 2

Set out requirements for information to be supplied in regulations.

**Table 12: Comparison of options**

|  |  |  |
| --- | --- | --- |
| **Options** | **Option 1 (counterfactual):** do not set out requirements for information to be supplied | **Option 2:** set out information to be supplied in regulations |
| Pros | Potentially smaller administrative burden for industry | Consistent information will be received by the regulator, useful for trend analysis Will support compliance work as reliable information is held by regulatorExisting processes in place to receive, compile and analyse this type of information |
| Cons | Information received likely to be inconsistent and not useful for reporting and compliance | High volume of information to be received by regulator, need time resource to process and analyse |

### How do the options compare to the status quo/counterfactual?

|  |  |  |
| --- | --- | --- |
|  | **Option 1 (Counterfactual) – Do not set out requirements for information to be supplied** | **Option 2 – Set out information to be supplied in regulations** |
| **Reduces inequity** | 0Likely to have no impact on equity. | 0Likely to have no impact on equity. |
| **Effectiveness as a policy** | 0Will make the notification process far less useful, in effect making this policy much less successful. | **++**Clear and consistent collection of information enables compliance system monitoring. |
| **Cost and ease of implementation** | 0Information provided is likely to be inconsistent and not useful. | **++**Information provided will be consistent and will support compliance/enforcement and monitoring activities. |
| **Clear and workable for Aotearoa** | 0Will reduce the amount of information Ministry has about the industry, weakening the compliance and monitoring system. | **++**Provides clear and consistent guidance to the sector. Will enable greater targeted compliance work. |
| **Overall assessment** |  | **Preferred option** |

**Youth vaping**

### Issue 6 – Limiting the way flavours are described

The Smokefree Environments and Regulated Products Regulations 2021 (the Smokefree Regulations) set out vaping product packaging and labelling requirements. Overall, the vaping regulatory regime aims to ensure that, while vaping products are available to support smokers to quit, their appeal to non-smokers, and in particular youth, is minimised.

There are no limits on how vaping product flavours can be described. This has resulted in “flavours” that clearly appear to be designed to appeal to young people. For example, flavour descriptions of products notified for sale in New Zealand include ‘gummy bear’, ‘bubble gum’, ‘Ibiza nights’, ‘unicorn tears’ and ‘OMG’.

Limiting the way flavours can be described, by using consistent flavour categories, is likely to reduce appeal to young people, thereby contributing to reducing youth vaping uptake. Recent research shows that most young people use vaping products with descriptive flavours, and that colours or imagery in flavour names can play an important role in attracting new users and establishing use patterns.[[6]](#footnote-7) A US study found that flavour representation on packaging is likely to influence how fun and interesting young people perceive these products to be, and therefore how susceptible they are to using them.[[7]](#footnote-8) However, there is also evidence that flavours are an important element for adults wanting to quit smoking by switching to vapes. We are therefore not proposing to prohibit flavours themselves, but rather limiting the way flavours are described that appear to be clearly directed at appealing to youth.

The Ministry consulted on a proposal to restrict the variant name on a vaping substance and its packaging to only a description of the product’s flavour, and that the flavour be described using 1 or more flavours, as prescribed by the Ministry and published on its website (in the form of a flavour wheel or something similar). Specifically, it proposed to exclude flavour descriptions that appear to target young people. For example, flavours that refer to confectionary or candy would not be permitted. Instead, products would need to describe a generic flavour, such as strawberry.

*Consultation feedback*

Feedback from consultation was extensive. Some stakeholders wanted to limit the actual range of flavours, for example, limiting options to just tobacco and menthol vape products. This is out of scope as limiting flavours in this way would require an amendment to the Smokefree Act.

There were a significant number of submitters who stated specific flavours that they believe should be banned due to their appeal to young people (eg, ones relating to candy, dessert or alcohol). A small number of applicants raised concerns around a lack of evidence on which flavour descriptions appeal to young people.

Many submitters also raised concerns that the use of Te Reo Māori, and Māori imagery, in flavour names, product branding and stores would be inappropriate and a form of cultural appropriation.

Other stakeholders wished to see a more ‘plain packaging’ approach and limit flavour descriptions simply to colours or numbers (eg, banana flavour as yellow or flavour 1, strawberry as red or flavour 2 etc). A more general ‘plain packaging’ approach was considered when the Ministry consulted on the current vaping regulations in 2021, and the pros and cons are set out in the table below (option 3).

The options for limiting the way flavours are described are:

#### Option 1 – Status Quo

No changes to existing packaging requirements. Current requirements for the packaging of vaping products are based on EU/UK requirements adjusted for the Aotearoa context, and there are no specific requirements for the way flavours can be described or depicted.

#### Option 2

Only use permitted flavour descriptions. This option limits how a flavour is described, using a prescribed flavour wheel.

#### Option 3

‘Plain packaging’ approach. This option would limit how a flavour is described to prescribed colours or numbers.

**Table 13: Comparison of options**

|  |  |  |  |
| --- | --- | --- | --- |
| **Options**  | **Option 1 (status quo):**  no change to regulations | **Option 2:** permitted flavour descriptions | **Option 3:** ‘plain packaging’ approach |
| Pros  | No product changes for adult usersNo additional costs to business or government  | Products appear less fun and interesting to youthYoung people less susceptible to using the productsVaping products are unlikely to be seen as exciting consumer productsProduct flavours accurately described | Products appear less fun and interesting to youthYoung people less susceptible to using the productsVaping products are unlikely to be seen as normal consumer products |
| Cons  | Products described in such a way that may be appealing to youthProducts continue to appeal to youth | Compliance costs to industry from adjusting packagingRestricts freedom of expression in relation to commercial activityDoesn’t prevent manufacturers from referencing the description names on their websites (this is somewhat mitigated by the Consumer Guarantees Act which requires that a product must match its description) | Packaging may be less appealing to adults wishing to switch to a less harmful productCompliance costs to industry from adjusting packaging Restricts freedom of expression in relation to commercial activityDoesn’t prevent manufacturers from referencing the description names on their websites (this is somewhat mitigated by the Consumer Guarantees Act which requires that a product must match its description)  |

### How do the options compare to the status quo/counterfactual?

|  |  |  |  |
| --- | --- | --- | --- |
|   | **Option 1 – Status quo** | **Option 2 – Permitted flavour descriptions** | **Option 3 – ‘Plain packaging’** |
| **Reduces Inequity** | 0Māori youth, particularly girls, have highest rate of regular and daily vaping. | **++**Reduced youth appeal likely to reduce inequity gap. | **++**Māori youth, particularly girls, have highest rate of regular and daily vaping, reduced youth appeal likely to reduce inequity gap. |
| **Harm prevention** | 0Product names and packaging currently appear to be designed to appeal to rangitahi. | **++** Reduces appeal to youth and therefore uptake while not limiting access to those who wish to quit. | **+**Reduces appeal to youth but may also impact on appeal to those adults wishing to quit. |
| **Effectiveness** | 0Products maintain current appeal to youth. | **++**Reduce appeal to youth. | **++**Reduce appeal to youth. |
| **Cost and ease of implementation** | 0No change to cost for industry or regulator. | **-**Additional cost to industry. | **-**Additional cost to industry. |
| **Overall assessment**  |  | **Preferred option** |  |

### Issue 7 – Addressing safety concerns with single-use products

The Smokefree Regulations set out product safety requirements that all vaping products must meet for import, manufacture or sale in Aotearoa.

These regulations appear to have limited applicability for single-use vape products (disposable vapes). For example, many disposable vapes do not have the same consumer information on them as reusable vapes and are unable to be traced should an adverse reaction or safety issue occur. Disposable vapes are also a low-cost single-use product, lack child safety mechanisms, have limited opportunities for recycling or safe disposal of batteries and contribute to increasing environmental waste.

Unlike reusable vapes, disposable vapes also have a fixed nicotine concentration that is generally at or close to the maximum allowable levels and therefore potentially highly addictive. This is of particular concern as these products have quickly become the most popular vape product used by young people in the US and UK. Aotearoa appears to be following this trend with the use of disposable vapes by young people increasing from 12% (ever tried vapers) in 2021 to 39% in 2022.[[8]](#footnote-9) For young daily vapers, reusable and disposable vapes are equally most often used. However, reusable vape use dropped from 63.5% in 2021 to 38.5% in 2022, and disposable vape use increased from 9.0% in 2021 to 39.7% in 2022. If this trend continues, disposables will rapidly become the most popular device for daily users as well. Disposable vapes are the most used device for young people across all ethnicities, with the highest rate of use in Pacific and Māori students.

Introducing new product safety requirements will ensure that all vape products, including single-use, are safer to use, and disposable vapes are less addictive. It could also reduce their appeal for young people, as their cost may increase as a consequence.

The Ministry consulted on a proposal for the following additional product safety requirements for all vape products, as well as limiting the allowable nicotine levels in disposable vapes. The requirements as proposed were:

|  |  |
| --- | --- |
| **User safety mechanisms** | all vaping devices must have a mechanism to prevent the device being activated or accidently operated by a child |
| **Removeable/replaceable batteries** | all vaping devices to have a removable battery to enable the battery to be inspected (and therefore prevent risk of battery failure/explosion) |
| **Substance container labelling** | all vaping products must have the prescribed labels on substance containers, including single-use devices, where the container may be the device itself |
| **Nicotine concentrations in non-refillable products** | reduce the maximum concentration of nicotine salts allowed in single-use products from 50mg/mL to 35mg/mL.nicotine levels must be displayed on single-use product labels in mg/mL and a percentage figure for nicotine/nicotine salt concentration is not sufficient |
| **Serial/batch numbers** | require serial/batch numbers on the single-use devices to ensure they can be traced in the event of a reaction |

*Consultation feedback*

Feedback from consultation was extensive. Some stakeholders wanted to ban disposable vapes completely. This is out of scope of this RIS as banning the products would require an amendment to the Smokefree Act.

Many submitters supported the reduction in nicotine levels in disposable vapes and there was consistent support for these levels to be even lower. Others were concerned that disposable vapes would become more expensive/less available and therefore less accessible to those wishing to quit smoking. Industry submitters did not support reducing nicotine levels and argued that different levels for reusable and disposable vapes would be confusing and may impact on people’s ability to successfully stop smoking.

There was some concern from industry around the requirements for removeable/replaceable batteries, due to manufacturers ability to safely implement such changes across all vape products. For example, submissions noted that the majority of vaping devices notified in Aotearoa (both reusable and disposable) contain securely sealed inbuilt batteries and the proposed requirements may inadvertently reduce the supply of reusable vapes on the market for adults wishing to quit smoking, at a time when legislative policies will be encouraging large numbers of adults who smoke to switch to vaping.

The options for addressing product safety concerns and addictive nicotine salt levels in disposable vapes are:

#### Option 1 – Status Quo

No changes to existing product safety standards.

#### Option 2

Additional product safety requirements for reusable and single-use products. This option adds additional product safety requirements to those already place in regulations.

#### Option 3

Reduce nicotine levels in single-use products. This option proposes to limit the allowable maximum concentration of nicotine salt levels in disposable vapes to 35mg per mL.

**Table 14: Comparison of options**

|  |  |  |  |
| --- | --- | --- | --- |
| **Options**  | **Option 1 (status quo):** no changes to regs | **Option 2:** additional safety requirements for reusable and single-use products | **Option 3:** Reduce nicotine levels in single-use products |
| Pros  | No product changes for adult usersNo additional costs to business or government | Reduces likelihood of harm for users and general publicLess accessible to small children (eg, child locks)Potential increased costs to users (less appealing to youth)Adults choosing to switch to a less harmful product can do so safelyLess environmental wasteDisposable vapes may subsequently cost more, and/or be less available. This will make them less likely to be used by young people. | Less addictive for youthLess addictive for non-smokersLower nicotine levels may have lower appeal to youth |
| Cons  | Children and young people at risk of harmIncreased use of disposable products by youthIncreased environmental waste | Potential increased costs to user (less affordable for adults wishing to switch to less harmful product – though reusable vape products are still generally more affordable than tobacco) Compliance costs to industry, as will need to change the manufacturing of their productsPotential impact on existing reusable vape market if some products are unable to comply with the requirements and are removed from the market (reduced consumer choice)Impact on some stop smoking services (as disposable vapes are more affordable to use as a cessation tool)Removeable batteries may be difficult to implement for all vape products | Possibly less effective for adults wishing to successfully switch (noting that nicotine salt level limits in reusable vapes remain unchanged)Possible compliance costs to industryImpact on some stop smoking services (as disposable vapes used as a cessation tool) |

### How do the options compare to the status quo

|  |  |  |  |
| --- | --- | --- | --- |
|   | **Option 1 – Status quo** | **Option 2 – Additional requirements** | **Option 3 – Reduce nicotine levels** |
| **Reduces Inequity** | 0Māori youth, particularly girls, have highest rate of regular and daily vaping. Product safety concerns remain. | **++**Māori youth, particularly girls, have highest rate of regular and daily vaping. Additional product safety concerns will ensure less harm. | **++**Māori youth, particularly girls, have highest rate of regular and daily vaping. Reduced nicotine levels in disposable vapes will make them less addictive. |
| **Harm Prevention** | 0Product safety concerns remain. | **++**Product safety requirements will ensure less harm.  | **++**Less addictive and therefore less appealing to youth. |
| **Effectiveness** | 0No change to current market, product safety concerns remain.  | **++**Product safety requirements will ensure less harm. | **++**May reduce appeal to youth. |
| **Cost and ease of Implementation** | 0No change to current costs. | **- -**Additional cost to industry. Greater compliance burden to ensure new requirements implemented. | **-**Some cost to industry. |
| **Overall assessment**  |  |  | **Preferred option** |

### Issue 8 – Proximity restrictions

Specialist Vape Retailers (SVRs) have been operating since August 2021.

The Smokefree Act sets out the following approval criteria for SVRs:

* the retail premises in which vaping products are sold are a fixed and permanent structure and appropriate premises from which to operate
* at least 70% of total sales are vaping products (or 60% in some defined circumstances).

There is a regulation-making power that enables further approval criteria to be made, including in relation to where a SVR can be located.

There is currently very limited evidence on whether the proximity of SVRs to schools has an impact on youth vaping rates. The 2022 ASH survey of Year 10 students found that the most common source of vapes for this age group is from friends (43% were given by friends). The least common source is buying online or in a shop. Further, the survey also showed no significant relationship between the density of SVRs to a school (within 1.5km proximity) and school vaping prevalence.

Since establishment of SVRs, concerns have been raised in the media, ministerial correspondence and through submissions on the Smokefree Bill regarding the proximity of these retailers to schools/kura and the impact this is having on youth vaping. In light of these growing concerns, the Ministry consulted on a proposal to set proximity restrictions on where a SVR can be located. This would mean that the Director-General would need to give consideration to where a business intends to operate when deciding to give a person approval to be an SVR. For example, the distance from schools, marae and sports grounds or other considerations specific to certain communities. The proposal would only apply to new applications, not existing SVRs.

*Consultation feedback*

A significant number of submitters supported restrictions on proximity to schools, primarily to help reduce youth uptake of vaping. However, some submitters considered that proximity restrictions could unintentionally result in some towns or areas having no SVRs, which would impact on adult smokers’ access to vaping products (although vaping products would still be available from other retail outlets and existing SVRs).

Other common feedback, also seen in recent media coverage, is the clustering of SVRs in small urban centres. There is concern that there are already too many retailers of vape products in proximity of certain sites, and in Aotearoa more generally.

Options for proximity restrictions are:

#### Option 1 – Status Quo

No changes to existing approval requirements.

#### Option 2

The Director-General must take proximity considerations into account. This option does not set out specific distances or locations in the regulations but allows the regulator to give consideration to such matters when considering SVR approvals.

#### Option 2

SVRs must meet proximity requirements. This option would set out in regulations the minimum allowable distance of an SVR to locations of interest such as schools, marae, sport grounds.

**Table 14: Comparison of options**

|  |  |  |  |
| --- | --- | --- | --- |
| **Options**  | **Option 1 (status quo):** no changes to regs | **Option 2:** Director-General must take into account proximity considerations | **Option 3:** SVRs must meet proximity requirements |
| Pros  | No change in access and availability for adults wishing to switch to less harmful products | May address objective of reducing access to youthVaping products are less likely to be seen as normal consumer productsRegulator discretion will allow areas to maintain access to vaping products where set proximity restrictions may otherwise limit this.  | May address objective of reducing access to youthVaping products are unlikely to be seen as normal consumer productsGives certainty to applicants and Regulator |
| Cons  | Potential risk of vaping products seen by youth as a normal consumer product.Public distrust of the vaping regulatory regime. | Evidence on impact of proximity on youth vaping rates unclearMay impact on adults wishing to switch (less accessible). Products would still be available in other retail outlets and existing SVRs.Less certainty to applicants and Regulator. | Evidence on impact of proximity on youth vaping rates unclearMay impact on adults wishing to switch (less accessible). Products would still be available in other retail outlets and existing SVRs.Proximity restrictions may inadvertently limit vape products if set incorrectly.Provisional analysis of Health Survey results show dual use (smoking and vaping) is more prevalent in neighbourhoods with higher deprivation. Therefore, proximity restrictions may impact lower socioeconomic communities more by making vaping products less available. |

### How do the options compare to the status quo

|  |  |  |  |
| --- | --- | --- | --- |
|   | **Option 1 – Status quo** | **Option 2 – Director-General must *take into account* proximity requirements** | **Option 3 – SVRs must *meet* proximity requirements** |
| **Reduces Inequity** | 0Māori youth, particularly girls, have highest rate of regular and daily vaping. | **+** Māori youth, particularly girls, have highest rate of regular and daily vaping. Reduced access is likely to help reduce inequity gap. | **+**Māori youth, particularly girls, have highest rate of regular and daily vaping. Reduced access is likely to reduce inequity gap.  |
| **Harm prevention** | 0Public perception of store location is that it targets youth, eg if they are near schools. | 0 Current evidence on impact is unclear. May limit access to adults wishing to switch.  | 0Current evidence on impact is unclear. May limit access to adults wishing to switch.  |
| **Effectiveness** | 0No changes to regulations, specialist vaping stores can open with no proximity or location restrictions. | **+**May de-normalise vaping. |  **+**May de-normalise vaping. |
| **Cost and ease of implementation** | 0No change to current costs. | **-**Less certainty to applicant and Regulator. | **+**Greater certainty to applicant and Regulator.  |
| **Overall assessment**  |  |  | **Preferred option** |

### What option is likely to best address the problem, meet the policy objectives, and deliver the highest net benefits?

#### Smoked Tobacco

The Ministry’s preferred options to enable the successful establishment of the Smoked Tobacco Regulatory Regime are set out below. These have been refined following consultation.

The preferred options are:

* 1. set additional requirements for approval as a smoked tobacco retailer in regulations, as detailed in table 5.

This option has been refined following consultation to include a 7-year timeframe for convictions in ‘fit and proper person’ requirements.

* 1. set decision-making criteria to rank applicants for smoked tobacco in regulations as detailed in table 7.

This option has been refined following consultation to remove reference to grocery or convenience store items and to respond to concerns that retailers may be approved where they currently did not exist.

* 1. set the full range of proposed product requirement in regulations, as detailed in table 9.

This option has been refined following consultation to allow some variation in the testing methods for low nicotine smoked tobacco.

* 1. set the level of cost-recovery fees in regulations, as detailed in table 2.

This option has been refined following consultation to change the retail application fee to $1475.

* 1. set out requirements in regulations that distributors of smoked tobacco products (and retailers of notifiable products, including vapes) must provide, on an annual basis, their contact details (including name, business name, company number/New Zealand business number, address, phone numbers and email addresses) when they register on Manatū Hauora’s database.

These regulations will support the successful implementation of Smokefree Act’s objectives as well as the Crown’s Te Tiriti o Waitangi obligations by removing the addictiveness of smoked tobacco, and empowering smokers with the choice to continue smoking, quit, or switch to a less harmful alternative.

**Youth vaping**

The Ministry’s preferred options to strengthen vaping regulations are set out below. These have been refined following public consultation and are intended to reduce the appeal of vape products to youth.

The preferred options are:

1. limiting the way flavours are described on packaging and products to accurately reflect their actual flavour. Permitted flavour descriptions will be prescribed on the Ministry’s website.
2. amending vaping product safety standards, as follows:

|  |  |
| --- | --- |
| **User safety mechanisms** | all vaping products must have a mechanism to prevent the device being activated or accidently operated by a child |
| **Removable batteries** | all vaping devices must have a removable battery to enable the battery to be inspected (and therefore prevent risk of battery failure/explosion) |
| **Substance container labelling** | all vaping products must have the prescribed labels on substance containers, including single-use devices, where the container may be the device itself |
| **Serial/batch numbers** | single-use vaping devices must have serial/batch numbers on the device to ensure they can be traced in the event of an incident or adverse reaction |

1. reducing the maximum allowable concentration of nicotine salts in single-use vape products to 35mg/mL and requiring the level to be displayed on the label in mg/mL (not as a percentage).
2. requiring that new SVRs must:
* be further than 300m from the location point for a school on the Minister of Education database
* be further than 300m from a Marae as listed on the Te Puni Kokiri website
* understand their obligations under the Smokefree Act.

This option has been refined following consultation to reflect general concerns around retailers’ understanding of their obligations under the Smokefree Act and to limit proximity restrictions to schools and Marae.

### What are the marginal costs and benefits of the options?

#### Smoked Tobacco Options

The costs and benefits analysed here are for the regulatory regime specifically, but if the regulations described are not in place, the full benefits of the broader Smokefree 2025 policy will not be realised. These were discussed in the 2021 Smokefree Action Plan RIS ([Smokefree RIS](https://www.health.govt.nz/system/files/documents/pages/ris-smokefree-aotearoa-action-plan-nov-2021.pdf)) and included benefits of 550,000 health-adjusted life years (HALYS) for New Zealanders. Modelling predicted at least $5.5 billion of estimated savings to the health system from the action plan.

|  |  |  |  |
| --- | --- | --- | --- |
| **Affected groups** | **Comment***nature of cost or benefit (eg, ongoing, one-off), evidence and assumption (eg, compliance rates), risks* | **Impact***$m value where appropriate for monetised impacts; high, medium or low for non-monetised impacts* | **Evidence Certainty** |
| **Additional costs of the preferred options compared to taking no action** |
| Regulated groups (businesses) | Costs for compliance with requirements – for example new business systems for approved smoked tobacco retailers[[9]](#footnote-10)Costs for product applications and notifications. Costs for smoked tobacco product testing | Fees approx. $5m - $8m for 23/24. Approx. $0.5m pa for following years as per table 3Number of applicants uncertainCosts associated with implementing minimum criteria for approval, such as security, is not clear and may vary for each retailer | Medium |
| Regulators | Costs to the Ministry and Te Whatu Ora for new administrative functions to implement the regulations. For example, analysing new annual reporting data and processing applications to become a smoked tobacco retailer.[[10]](#footnote-11) Includes some compliance and monitoring, does not include costs of enforcement action.Partially cost recovered from fees, however this is dependent on volume of applications. | Cost to regulator: $9.7m for 24/25 and $4.7m for out-years. | Medium |
| Others (eg, wider govt, consumers, etc) | Additional costs to businesses associated with becoming approved under the smoked tobacco regime may be passed on to consumersIt is possible that there may be an increased cost of smoked tobacco that can be attributed to testing or administrative costs. However, this is likely further encourage consumers to quit to switch to a less harmful alternative[[11]](#footnote-12) | Cost to industry: unknownCost to consumers: unknown | Low |
| **Total monetised costs** |  | Compliance cost for businesses: Cost of fees for industry: $5m - $8m for 23/24. Approx. $0.5m for out-years Cost to regulator: $9.7m for 24/25 and $4.7m for out-years Consumer prices: unknown | Medium |
| **Non-monetised costs**  |  | *(High, medium or low)* | Medium |
| **Additional benefits of the preferred option compared to taking no action** |
| Regulated groups | Greater clarity over the regulatory requirements introduced by the Amendment Act | Low | High |
| Regulators | Able to effectively enforce the Smokefree Act as it applies to vaping and smokeless tobacco products.Information is available to monitor overall trends in the vaping market and inform future policy decisions.Does not include the overall benefits of the Amendment Act. See RIS[[12]](#footnote-13). | High |  |
| Others (eg, wider govt, consumers, etc) | Consumers and public can be confident the industry is operating within a robust and clear regulatory framework. | High | MediumHigh |
| **Total monetised benefits** |  |  |  |
| **Non-monetised benefits** |  | High |  |

#### Vaping Options

|  |  |  |  |
| --- | --- | --- | --- |
| **Affected groups** | **Comment** | **Impact** | **Evidence Certainty** |
| **Additional costs of the preferred options compared to taking no action**  |
| Regulated groups | The proposed regulations will impose new obligations and compliance costs related to how vaping products are packaged (flavour descriptions) and manufactured (product safety requirements) | MediumCosts associated with new packaging and product safety requirements | Medium |
| Regulators | The proposed regulations will have implementation and enforcement costs | LowApplications to vaping scheme are fully cost-recovered with importers and manufacturers required to pay a product notification fee | Medium |
| Others (eg, wider govt, consumers, etc) | Any additional costs to businesses may be passed on to consumers. However, the market is highly competitive, and any cost increase will still be significantly less that the costs associated with smoking. Increased costs will also likely deter youth uptake | Low | Medium |
| **Total monetised costs**  |   | Cost to businesses: unknownCost to regulators: none |   |
| **Non-monetised costs**  |   | Low |   |
| **Additional benefits of the preferred option compared to taking no action**  |
| Regulated groups | Products more appropriate for adults wishing to quit smoking and safer to use | High | High |
| Regulators | Greater ability to contribute to overall policy intent of Smokefree 2025 | High | High |
| Others (eg, wider govt, consumers, etc) | Products safer for those wishing to switch to less harmful product. Products less appealing and addictive to youth | High | High |
| **Total monetised benefits**  | Not assessed |  |  |
| **Non-monetised benefits**  | High |  |  |

## Section 3: Delivering an option

### How will the new arrangements be implemented?

#### Timeframe

The new arrangements will be implemented over a timeframe defined by the Amendment Act. All provisions are phased, with implementation dates scheduled to allow time for industry to prepare for changes and the regulatory authorities to establish relevant processes.

From 1 July 2024, smoked tobacco products will only be available for legal sale from approved smoked tobacco retailers as part of the Smoked Tobacco Retail Scheme under the Act.

Once the relevant regulations are in force, the application process for the Smoked Tobacco Retail Scheme will open in the second half of 2023, allowing enough time to process applications and notify applicants of an outcome as early as possible. Stores that do not receive approval from the Director-General of Health to operate as an Approved smoked tobacco retailer can still trade until the middle of 2024.

From 1 April 2025, only smoked tobacco products with very low levels of nicotine (maximum 0.8mg/g) will be approved by the Director-General of Health for sale through the Product Approval Scheme under the Act. Other notification requirements start on October 2023.

A detailed implementation timeline of the Act can be found on the Ministry website.[[13]](#footnote-14)

#### Agencies involved and responsibilities

Administering the regulations under the Act, and monitoring compliance with requirements, is a responsibility shared by the Ministry of Health (Tobacco Regulatory Authority) and Te Whatu Ora (National Public Health Service).

The Tobacco Regulatory Authority (TRA) will receive, process and consider all applications for smoked tobacco retailers, smoked tobacco products, distributors and general retailers of notifiable products, using the pre-existing HARP data management system. This system stores all information regarding vaping retailers nationally and will be adapted to manage the Smoked Tobacco Regulatory Regime.

The National Public Health Service (NPHS) is a delivery agent of compliance activity for smoked tobacco products in New Zealand. NPHS Smokefree Enforcement Officers will work closely with the TRA and Health Enforcement Legal Team to ensure compliance with the Act.

Joint work includes:

* establishing a comprehensive compliance regime
* setting up and operating cross-agency processes to coordinate compliance activities
* monitoring national and online compliance including sector liaison and education
* reporting on compliance activities, establishing enforcement processes, standards and guidance
* sharing intelligence with other enforcement agencies such as Police and Customs, working with Health legal and other agencies to prosecute offences as required
* assessing compliance and enforcement requirements and resource plans relating to future legislative changes.

#### Communication

The Ministry is responsible for developing timely, accurate and accessible guidance on the new regulations for stakeholders, including industry and the public. The Ministry’s website and social media will be updated when regulations are in place.

**Implementation risks**

The regulations set fees for certain services, such as considering applications. The fee levels are based on the Ministry’s assumptions about the number of applications and notifications that will be made. These assumptions are based on the Ministry’s understanding of the market, consultation feedback, and data from implementing the recent vaping regulatory regime. It is possible that the fees are not set at the right level given uncertainties in the assumptions. To ensure that fees are set at an appropriate level, the Ministry will review them as actual information about application numbers becomes available.

There is some concern that some of the Smokefree 2025 policies will increase illicit trade in smoked tobacco products. However, New Zealand’s geographic isolation, low corruption and strong border control limits the opportunities for growth in illicit trade. There are a range of estimates of the current level of illicit trade, but the exact volume is unknown.

Robust regulations will mitigate this risk by supporting monitoring and enforcement. This is additional to existing actions, including research being undertaken by Auckland University to establish a baseline and monitor illicit trade in tobacco through to July 2026, and additional funding in recent Budgets to boost compliance with, and enforcement of, new requirements set out in the Act, including at the border.

### How will the new arrangements be monitored, evaluated, and reviewed?

The Ministry will continue to monitor the regulatory settings, and how these impact smoking rates and the market itself.

The following surveys contain information that are useful for monitoring smoking and vaping prevalence:

* the New Zealand Health Survey (an annual nationwide survey of people aged 15 years and over). In 2023/24, there will also be a module on smoking and vaping
* the annual Action for Smoking 2025 (ASH) year 10 snapshot survey (a survey of between 20,000 and 30,000 year 10 students)
* Youth2000 (a nationwide survey of 7,700-8,500 students from secondary schools, jointly led by several universities)
* New Zealand census.

The Act and regulations put in place mechanisms to support monitoring of the market. For vaping, product notification and annual reporting requirements provide information on what vaping products are on the market, sales information (price and quantity sold), and the number of retailers and distributors.

Similar mechanisms will now provide information to support monitoring of the smoked tobacco market.

The action plan included a commitment to effective monitoring and evaluation. The Ministry has developed a monitoring framework designed to monitor progress towards meeting the 2025 goal, and regular updates will be published. As mentioned above, monitoring trends in the illicit market is underway.

The Ministry will soon seek expressions of interest for the overall evaluation of the legislative measures that sit under the action plan. Effective monitoring and evaluation enables us to measure the impact of these measures and ensure we are on track to reach the goal.

Under the Act, manufacturers, importers and retailers of notifiable products must keep sales records and submit annual returns to the Vaping Regulatory Authority. Smoked Tobacco distributors and approved smoked tobacco retailers will also be required to submit annual returns to the TRA. Gathering this data enables an evidence-based understanding of consumption trends.

The Act contains a specific requirement for the new policy measures to be reviewed no later than 1 January 2029. The information collected above will be necessary to complete the review.

1. <https://www.sciencedirect.com/science/article/pii/S2468266719302415> [↑](#footnote-ref-2)
2. <https://minhealthnz.shinyapps.io/nz-health-survey-2021-22-annual-data-explorer/_w_1275039c/#!/home> [↑](#footnote-ref-3)
3. <https://www.ash.org.nz/2022_topline_youth_smoking_and_vaping_factsheet> [↑](#footnote-ref-4)
4. <https://www.ash.org.nz/ash_year_10> [↑](#footnote-ref-5)
5. Legislation Design and Advisory Committee (LDAC) guidelines set out the circumstances in which charging fees may be appropriate [↑](#footnote-ref-6)
6. <https://academic.oup.com/ntr/article/25/3/524/6995393> [↑](#footnote-ref-7)
7. <https://pubmed.ncbi.nlm.nih.gov/35931419/> [↑](#footnote-ref-8)
8. <https://www.ash.org.nz/2022_topline_youth_smoking_and_vaping_factsheet> [↑](#footnote-ref-9)
9. Businesses can apply based on proposed features and systems, so will only be liable for outlay if approved. [↑](#footnote-ref-10)
10. There may be some additional costs in relation to compliance and enforcement, however these are mainly due to changes to the primary Act, not the Regulations, or will be made easier to manage by the implementation of regulations. [↑](#footnote-ref-11)
11. Any costs relating to the overall restriction of the number of retail outlets, or low nicotine requirements introduced by primary legislation not considered here. [↑](#footnote-ref-12)
12. <https://www.health.govt.nz/system/files/documents/information-release/ris-smokefree-aotearoa-action-plan-nov21.pdf> [↑](#footnote-ref-13)
13. <https://www.health.govt.nz/system/files/documents/pages/serpa_key_dates_timeline.pdf> [↑](#footnote-ref-14)