



# Cabinet


## Minute of Decision

*This document contains information for the New Zealand Cabinet. It must be treated in confidence and handled in accordance with any security classification, or other endorsement. The information can only be released, including under the Official Information Act 1982, by persons with the appropriate authority.*

### Report of the Cabinet Social Wellbeing Committee: Period Ended 19 May 2023


On 22 May 2023, Cabinet made the following decisions on the work of the Cabinet Social Wellbeing Committee for the period ended 19 May 2023:

Out of scope

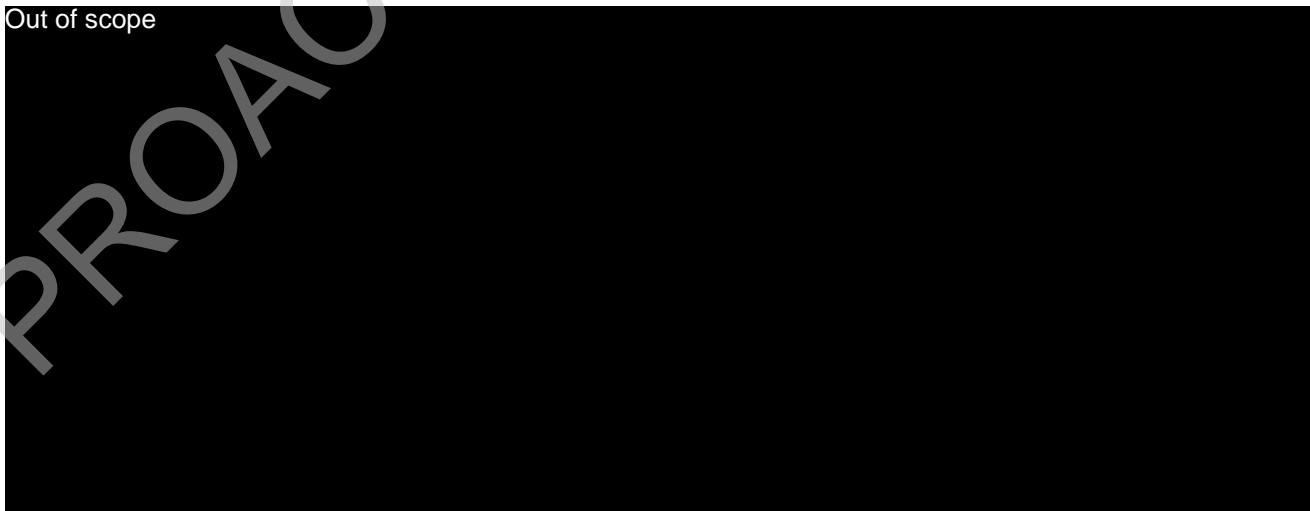


SWC-23-MIN-0051	<b>Establishing the Smoked Tobacco Regulatory Regime</b> Portfolio: Health	CONFIRMED
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Out of scope



Out of scope



Out of scope



Rachel Hayward  
Secretary of the Cabinet

PROACTIVELY RELEASED



# Cabinet Social Wellbeing Committee

## Minute of Decision

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### Establishing the Smoked Tobacco Regulatory Regime

Portfolio                      Health

On 17 May 2023, the Cabinet Social Wellbeing Committee (SWC):

- 1            **noted** that:
  - 1.1        in December 2022, SWC agreed to the public release of the consultation document, *Proposals for the Smoked Tobacco Products Regulatory Regime* [SWC-22-MIN-0257];
  - 1.2        Manatū Hauora | Ministry of Health has publicly consulted on a number of regulatory proposals to establish the Smoked Tobacco Regulatory Regime and bring the new provisions of the Smokefree Environments and Regulated Products Act 1990 into effect;
- 2            **noted** that the majority of submitters supported both the smoked tobacco and vaping proposals in principle, and the proposals have been refined to reflect submission feedback;
- 3            **noted** that Manatū Hauora will draft and publish a written notice setting out the maximum number of retail premises by area that can sell smoked tobacco products, based on the proposal set out in Appendix 2 of the paper under SWC-23-SUB-0051;
- 4            **agreed** to the drafting of Smoked Tobacco Regulations based on the proposals set out in paragraphs 26, 30, 36, 45 and 53 of the paper under SWC-23-SUB-0051;
- 5            **agreed** to the drafting of Vaping Regulations based on the proposals set out in paragraph 50 of the paper under SWC-23-SUB-0051;
- 6            **noted** that Budget 2022 provided \$30.7 million over four years to establish the regulator and regime;
- 7            **noted** that in November 2021, SWC agreed that the Smoked Tobacco Regulatory Regime be cost-recovered from industry through fees and levies [SWC-21-MIN-0192];
- 8            **noted** that the proposed fees are expected to recover the costs of the application process and additional Budget funding is not required to manage this process;

9 **agreed** to set the following fees under the Regulations:

Fee	Amount (ex GST)	Activity
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.
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.

10 **noted** that the Minister of Health intends to submit draft regulations to Cabinet for approval in July 2023;

11 **invited** the Minister of Health to issue drafting instructions to the Parliamentary Counsel Office to give effect to the above decisions;

12 **authorised** the Parliamentary Counsel Office to make necessary consequential changes to the regulations and other minor and technical amendments as required.

Rachel Clarke  
Committee Secretary

**Present:**

Rt Hon Chris Hipkins  
Hon Carmel Sepuloni (Chair)  
Hon Kelvin Davis  
Hon Grant Robertson  
Hon Dr Megan Woods  
Hon Jan Tinetti  
Hon Dr Ayesha Verrall  
Hon Kiri Allan  
Hon Peeni Henare  
Hon Nanaia Mahuta  
Hon Priyanca Radhakrishnan  
Hon Kieran McAnulty  
Hon Barbara Edmonds  
Hon Rino Tirikatene  
Hon Jo Luxton

**Officials present from:**

Office of the Prime Minister  
Office of the Chair  
Officials Committee for SWC

Office of the Minister of Health

Chair, Social Wellbeing Committee

## **Establishing the Smoked Tobacco Regulatory Regime: Report back from consultation and approval to draft Regulations**

### **Proposal**

1. This paper seeks agreement to the policy decisions needed to establish the Smoked Tobacco Regulatory Regime, tighten vaping restrictions, and draft the Regulations to bring these decisions into effect.

### **Relation to Government Priorities**

2. These proposals strengthen the regulation of both smoked tobacco and vaping products. This contributes to the Smokefree Aotearoa 2025 goal and other Government priorities: namely empowering Māori to achieve better health outcomes, improving equity for Māori and Pacific peoples, reducing New Zealanders' risk of developing some cancers, and improving child and youth wellbeing.

### **Executive Summary**

3. The Smokefree Environments and Regulated Products (Smoked Tobacco) Amendment Act 2022 (the Smokefree Act) came into force on 1 January 2023.
4. Regulations are now needed to establish the regulatory regime to oversee and monitor the import, manufacture, sale and supply of smoked tobacco products, and bring the new provisions of the Smokefree Act into effect, particularly the cap of 600 retail outlets and limit of 0.8mg/g of nicotine in the tobacco in smoked tobacco products.
5. On 16 December 2022, Cabinet agreed to publicly consult on the regulatory proposals needed to establish the regime, as well as proposals to tighten vaping regulations to further reduce their appeal to youth [CAB-22-MIN-0589 refers].
6. Public consultation has now concluded with over 2700 submissions received. The majority of submitters supported both the smoked tobacco and vaping proposals in principle, and these have been refined to reflect the feedback. The changes are not significant and further information on consultation feedback is provided in the attached Regulatory Impact Statement.

7. Regulations regarding the smoked tobacco retail scheme must be made by July 2023 to give enough time for retailers to apply to be an approved retailer, and for Manatū Hauora to assess applications, so that approved smoked tobacco retailers are in place by 1 July 2024. This is when the provision prohibiting the sale of smoked tobacco other than by an approved retailer comes into force.
8. This paper seeks agreement on final regulatory proposals outlined in this paper, and to ask the Parliamentary Counsel Office to draft Regulations based on these proposals. A high level summary is provided in Appendix 1. I will provide the Regulations to Cabinet Legislation Committee in July 2023.

## Background

9. The amended Smokefree Act introduced significant changes intended to achieve the following objectives:
  - 9.1 significantly reduce retail availability of smoked tobacco products
  - 9.2 prevent young people from ever taking up smoking
  - 9.3 reduce the appeal and addictiveness of smoked tobacco products.
10. On 16 December 2022 Cabinet agreed to consult on draft proposals to establish the Smoked Tobacco Regulatory Regime and to bring the new provisions of the Smokefree Act into effect [CAB-22-MIN-0589 refers], and some additional proposals related to vaping. These covered:
  - 10.1 the smoked tobacco retail scheme (including approval and decision-making criteria to become an approved retailer)
  - 10.2 testing requirements and approval processes for low nicotine products
  - 10.3 new notification requirements for distributors and retailers
  - 10.4 fees to enable the regime to be cost-recovered
  - 10.5 extending vaping restrictions.
11. Consultation on the draft proposals was primarily undertaken online, with community hui held with Māori and Pacific peoples across the country. Submitters fell largely into the following categories: individuals, retailers, health organisations, councils, academics and the tobacco and vaping industry.
12. Over 2700 submissions were received. The majority of submitters supported the proposals in principle and provided useful feedback on how they could be further refined. Consistent with previous consultation on the Smokefree Aotearoa 2025 Action Plan and the Smokefree Amendment Bill, those with a commercial interest (including small retailers) did not support the proposals.

13. While some tobacco companies provided useful feedback on technical matters such as low-nicotine testing methods, feedback from both the tobacco and vaping industry was focussed on general concerns regarding the Smokefree Act itself (eg, their view that the policies are unworkable, or that the changes will drive an increase in the black market and crime) which have already been decided and passed into law.
14. Manatū Hauora has analysed the consultation feedback and updated the proposals accordingly. I believe the updated proposals will enable the successful implementation of the new provisions of the Smokefree Act.
15. I am seeking agreement on the decisions needed to draft the Regulations that need to be in place by August 2023. I will come back to Cabinet later in 2023 to seek policy approval for the additional regulations needed for the product approval scheme. This will include packaging and product warning requirements for low nicotine products, and importer and manufacturer notifications.

### **Consultation with Māori**

16. The Smokefree Act has specific Te Tiriti o Waitangi provisions requiring the Director-General of Health (Director-General) to consult with Māori when making retail decisions, and the Minister of Health to ensure the risks and benefits to Māori are considered when making regulations regarding the content of smoked tobacco products.
17. With input and advice from Te Aka Whai Ora and the Smokefree Taskforce, Manatū Hauora held a number of hui across the country (both in person and online) to hear Māori views on the draft proposals, and in particular the retail scheme. Participants largely supported the proposals and wanted to see ongoing and meaningful engagement in the decision-making process for where smoked tobacco will be sold, and by whom. There was also a clear desire to ensure that smoked tobacco products are not sold near schools/kura, early childhood centres, kōhanga reo or other locations of importance to Māori such as marae.
18. Manatū Hauora worked with Te Aka Whai Ora to invite Iwi-Māori Partnership Board members to attend the in-person consultations where possible. Some members were able to attend, however, due to the early stages of establishment that many Boards are in, engagement has been understandably limited. Manatū Hauora and Te Aka Whai Ora are continuing to engage with Boards as they are established to ensure that the regulatory regime is implemented in a way that achieves the best outcomes for Māori.

## The regulatory proposals

### Retail scheme

#### *Number of approved premises by area*

19. The Smokefree Act requires the Director-General to determine the maximum number of approved smoked tobacco retail premises by area, with the maximum number not exceeding 600 for all of New Zealand.
20. The consultation document proposed defining areas based on whether they are an urban or rural setting. It also proposed setting a separate maximum number of premises for each area of the country. The document also proposed allocating maximum numbers differently for rural and urban areas, taking into account the different challenges urban and rural areas face.
21. The majority of submitters who provided feedback on this proposal were in support of all proposals. In addition, many stated that retailers should not be approved where they do not currently exist, and many gave useful location-specific details. There was consistent feedback that the indicative rural allocation was too high, and that the proposed allocations in highly populated urban areas such as Auckland may further penalise some communities, particularly in relation to travel time and petrol costs. For Māori and Pacific peoples, many hui and fono participants emphasised the importance of iwi/mana whenua voice and community voice when deciding where retailers are located. The Ministry is continuing to work with Te Aka Whai Ora to ensure that the final allocation reflects community feedback.
22. Specific feedback was also received regarding allocations for duty-free stores and specialist tobacconists. Some duty-free stores requested to be exempt from the retail cap due to the unique nature of their business. In response to this, it is proposed that a specific allocation will be included for a small number of duty-free stores, within the total cap of 600 retailers.
23. The proposed allocation does not require regulations and will be set out as a written notice and published on Manatū Hauora's webpage. Further detail of the updated proposal that takes into account feedback is provided in Appendix 2.

#### *Additional requirements for approval*

24. The Smokefree Act sets out the minimum requirements the Director-General must consider when deciding which premises can sell smoked tobacco products. Further approval requirements can be set in regulations.
25. The consultation document proposed that specific requirements for a 'fit and proper' person be set in regulations, as well as additional requirements to ensure that the retail scheme works as intended (eg, that premises have adequate security, training, sales and delivery systems in place).



26. The majority of submitters who provided feedback on this proposal were in support of the proposed requirements. The proposal has been refined as described below:

Requirements	Description	Updates following consultation
Have appropriate <b>security measures</b> in place	<p>A person must demonstrate that the retail premise has the following:</p> <ul style="list-style-type: none"> <li>- a suitable alarm system, as appropriate for the business</li> <li>- suitable security cameras with recording facilities, as appropriate for the business</li> <li>- suitable external protection to protect premise from theft, as appropriate for the business</li> <li>- secure product storage</li> <li>- a suitable fog cannon system, as appropriate for the business.</li> </ul>	<p><i>No changes have been made.</i></p>
Have appropriate <b>business systems</b> in place	<p><i>Training</i></p> <p>A person must demonstrate that:</p> <ul style="list-style-type: none"> <li>- 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)</li> <li>- appropriate training records, including its effectiveness, will be kept.</li> </ul> <p><i>Sales</i></p> <p>A person must demonstrate that:</p> <ul style="list-style-type: none"> <li>- an accurate record of all smoked tobacco product sales will be kept, including product type, brand, quantity and price</li> <li>- systems are in place to prevent sales to minors/the smokefree generation.</li> </ul> <p><i>Sales - Online</i></p> <p>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 (eg, the identified geographic area that a person can sell within, the use of a specified internet site for sales).</p> <p><i>Delivery</i></p> <p>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.</p>	<p><i>No changes have been made.</i></p>
Be a <b>'fit and proper'</b> person	<p>The Director-General must be satisfied that the person:</p> <ul style="list-style-type: none"> <li>- is over the age of 18</li> <li>- has not had a conviction, in the last 7 years, for- <ul style="list-style-type: none"> <li>• an offence against the Smokefree Act; or</li> <li>• an offence against Part 6 of the Customs and Excise Act 2018; or</li> <li>• an offence against the Sale and Supply of Alcohol Act 2012; or</li> <li>• a crime involving dishonesty (as defined in section 2 of the Crimes Act 1961).</li> </ul> </li> </ul>	<p><i>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.</i></p>

IN CONFIDENCE

	<p>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.</p> <p>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.</p>	
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*Decision-making criteria*

27. The Smokefree 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.
28. Additional decision-making criteria can be set in regulations to rank applicants and determine who will be granted approval in these circumstances. The application process will provide further detail of how these criteria will be used in ranking.
29. The consultation document proposed additional security and business-related criteria (eg, to assess and rank applications). The document also proposed other considerations (eg, legislative compliance history, proximity/location, whether certain businesses are better suited to sell smoked tobacco products than others and requirements for online sales and delivery systems) that the Director-General could use to assess and rank applications.
30. The majority of submitters who provided feedback on this proposal were in support of the proposed decision-making criteria. The proposal has been refined as set out below:

Criteria	Description	Updates following consultation
Proximity and location	<p>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:</p> <ul style="list-style-type: none"> <li>- early childhood centres, Kōhanga Reo, registered schools</li> <li>- Marae.</li> </ul> <p>Further detail will be provided in the application process published on Manatū Hauora’s website.</p>	<p><i>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.</i></p>
Type of business	<p>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.</p>	<p><i>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.</i></p>
Additional security measures	<p>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.</p>	<p><i>No changes have been made.</i></p>

IN CONFIDENCE

	These measures include security staff, de-escalation and conflict resolution training and restricted access to retail premises.	
<b>Additional business systems</b>	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.	<i>No changes have been made.</i>

**Product requirements**

31. The Smokefree 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.
32. The proposed requirements are intended to ensure that smoked tobacco products meet the nicotine limits prescribed in the Smokefree Act and prohibit any constituent that could be used to maintain addictiveness. Ensuring that the addictiveness of smoked tobacco is minimal will likely lead to improved health as people quit or choose less harmful alternatives.
33. The Smokefree Act also sets out the minimum requirements the Director-General must consider before granting approval of a smoked tobacco product for import, manufacture or sale and allows for further approval requirements to be set in regulations.
34. The consultation document proposed requirements for testing methods, constituent limits, 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.
35. Most submitters did not provide feedback on these technical matters, but those that did (mainly academics and tobacco industry members) largely agreed with the proposed requirements.
36. The proposal has been refined as set out below:

<b>Product requirement</b>	<b>Description</b>	<b>Updates following consultation</b>
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.	<i>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.</i>

IN CONFIDENCE

	<p>Current regulation 32(2) is revoked and replaced by new requirements that tobacco should smell of only manufactured tobacco or menthol.</p>	
<p>Testing methods</p>	<p>An importer/manufacture must use an appropriate analytical method, as set out below, to determine nicotine levels in smoked tobacco products:</p> <p>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. The test(s) must be included on the scope of accreditation for that laboratory.</p> <p>Tests should be carried out:</p> <ul style="list-style-type: none"> <li>- using an appropriate chromatography-based analytical test method that uses a gas chromatographic method, which is demonstrated as suitable to test the nicotine content of the product (and any constituents)</li> <li>- using appropriate instrumentation for the method selected, and in appropriate laboratory conditions</li> <li>- using a method which has been shown to be appropriately validated at the accredited laboratory (including for accuracy, precision, specificity, limits of detection, quantification of results, and range).</li> </ul> <p>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.</p> <p>An appropriate test method or methods may be published on Manatū Hauora's website.</p> <p>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.</p> <p>Remove existing requirements of current regulation 63, requiring testing for nicotine emissions, carbon monoxide and tar.</p>	<p><i>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.</i></p>
<p>Product approval/application process (for each brand and variant)</p>	<p>An importer/manufacture must provide the following as part of their approval application:</p> <ul style="list-style-type: none"> <li>- a description of the product type, brand, variant and unique product code (eg, EAN or UPC number)</li> <li>- 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</li> <li>- a full list of ingredients, including any additives</li> <li>- an appendix containing a dossier including full test reports for at least three batches of full-scale manufactured product, information on the testing methodology used, product and packaging images and any other relevant documentation.</li> </ul> <p>An importer/manufacture must provide the following as part of their temporary approval application to</p>	<p><i>Minor changes have been made, for example to require more than one batch to be tested.</i></p>

	<p>import/manufacture a product for research and/or testing purposes:</p> <ul style="list-style-type: none"> <li>- a description of the product type, brand, variant and unique product code (eg, EAN or UPC number) where this is available</li> <li>- a description and purpose for the proposed research and/or testing, including a rationale for requiring the import of a non-compliant product</li> <li>- 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.</li> </ul> <p>An importer/manufacture must provide the following as part of their temporary approval application to import/manufacture a niche smoked tobacco product:</p> <ul style="list-style-type: none"> <li>- a description of the product type, brand, variant and unique product code (eg, EAN or UPC number)</li> <li>- 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.</li> </ul>	
<p>Other product changes</p>	<p>Modify the existing annual reporting and returns requirements for tobacco products as follows: Require an importer/manufacture to have product safety systems in place that enable:</p> <ul style="list-style-type: none"> <li>- investigation and resolution of complaints about the products</li> <li>- recall of a product from sale or supply</li> <li>- notification to the Ministry of Health of any recall.</li> </ul>	<p><i>No changes have been made.</i></p>

37. The consultation document also proposed changes to packaging requirements and product label warnings to reflect low nicotine requirements, as well as requirements for all tobacco products to include information about the product changes.

38. Manatū Hauora is currently undertaking work to finalise packaging and labelling requirements for low nicotine products, as well as requirements relating to smoked tobacco product importers and manufacturers. I will come back to Cabinet at the end of 2023 for approval to draft regulations for any changes required.

**Fees**

39. The Smokefree Act enables the smoked tobacco regulatory regime to be cost-recovered through fees and levies specified in Regulations.

40. The consultation document proposed the structure and level of fees under the regulatory scheme.

41. The majority of submitters who provided feedback on this proposal supported the proposed structure of the fees. Feedback on the level of the fees was mixed. A number of people indicated that the fees were set too low and that application fees should at least be comparable with Specialist Vape Retailer assessment fees. Others suggested that application fees should be staged so

that people who are not approved are charged less. Many considered that registration fees for distributors and general retailers were too low.

42. Taking this into account, as well as relevant guidelines, I propose that the structure and level of fees for the smoked tobacco regulatory regime reflect the consultation proposals in principle, with a change to the smoked tobacco retail application fee from a range of possible fees of \$500 - \$2,200, to \$1475. Refer to paragraph 53 for further detail.

**Notification requirements**

43. The Smokefree 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.
44. 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 Manatū Hauora’s database.
45. The majority of submitters who provided feedback on this proposal were in support of the notification requirements. The proposal is unchanged and set out below:

Notification requirements	Description
Distributor of smoked tobacco products	Provide the following information annually, as part of their notification: <ul style="list-style-type: none"> <li>- the distributor’s contact details (including name, business name, company number, NZBN, address, phone numbers and email addresses)</li> <li>- a declaration that the distributor meets the current requirements of the Smokefree Act (eg, New Zealand resident, manufacturer or importer of notifiable products for sale in New Zealand) and that the details provided are correct.</li> </ul>
General retailer of notifiable products	Provide the following information annually, for each premise, as part of their notification: <ul style="list-style-type: none"> <li>- the retailer’s contact details (including name, business name, company number, NZBN, address, phone numbers and email addresses)</li> <li>- a declaration that the retailer meets the current requirements of the Smokefree Act (eg, New Zealand resident, manufacturer or importer of notifiable products for sale in New Zealand) and that the details provided are correct.</li> </ul>

**Reducing youth vaping**

46. The Smokefree Act regulates vaping products so that people wanting to stop smoking and switch to a less harmful product can access regulated vape products. It aims to balance this with protections to reduce product appeal and availability to those who don’t smoke through restrictions on advertising, packaging, and sales to under 18s. Despite these actions, youth vaping rates have increased significantly in recent years and remain high, particularly for rangatahi Māori who had daily vaping rates of 21.7 percent in 2022.

47. The consultation document proposed the following additional requirements for the manufacture and sale of vaping products to further reduce their appeal, safety risk, and addictiveness to young people:
- 47.1 restricting the way flavour names are described on product packaging
  - 47.2 extending product safety requirements, including reducing nicotine levels in disposable vapes
  - 47.3 introducing proximity restrictions for Specialist Vape Retailers.
48. Feedback on these proposals was extensive with the majority of submitters in support of all three proposals. However, many also wanted to see changes that were more in line with the smoked tobacco proposals. For example, capping the number of retailers, banning general vape retailers and introducing a 'Vapefree Generation' policy. Such changes are outside the scope of the regulation-making powers of the Smokefree Act and I am not seeking a Cabinet decision on these matters.
49. Some submitters raised concerns that a large proportion of reusable vapes, and likely all disposable vapes, have fixed and sealed batteries. The requirement for all vapes to have replaceable batteries will therefore affect these products and potentially impact supply. However, I am of the view that this requirement is necessary. Allowing batteries to be inspected for damage and safely disposed of reduces the safety risk that sealed batteries pose, and especially so when people are wishing to switch to a less harmful product than smoked tobacco. I am confident that importers and manufacturers will adapt to meet these requirements accordingly.
50. I propose that additional requirements for the manufacture and sale of vape products reflect the consultation document in principle, with some changes to reflect consultation feedback as follows:

Youth vaping requirements	Description	Updates following consultation (and timings)
Flavour descriptions	Modify existing packaging requirements for vaping products to include the following: <ul style="list-style-type: none"> <li>- the variant name on a vaping product, and its packaging, must only describe the variant's actual flavour using one or more flavours as prescribed by Manatū Hauora, and published on Manatū Hauora's website.</li> </ul>	<p><i>This proposal is largely unchanged from the consultation proposal.</i></p> <p>All vape products that don't meet the new requirements will not be able to be sold <b>6 months</b> after the regulations come into force.</p> <p>This gives time for manufacturers to update their packaging and retailers to sell through existing product.</p>
Product safety	Modify existing product safety requirements for vaping products to include the following: <ul style="list-style-type: none"> <li>- all vaping products must have a mechanism to prevent the device being activated or accidentally operated by a child</li> <li>- all vaping products must have removable batteries</li> </ul>	<p><i>This proposal is largely unchanged from the consultation proposal.</i></p> <p>a. Single-use vape products that don't meet the new requirements (including child safety mechanisms, removable batteries and reduced nicotine salt</p>

	<ul style="list-style-type: none"> <li>- all vaping products must have the prescribed labels on substance containers, including single-use devices, where the container may be the device itself</li> <li>- the maximum concentration of nicotine salt allowed in single-use vaping products must not exceed 35 mg/mL</li> <li>- single-use vaping devices must display nicotine levels on product labels in mg/mL</li> <li>- 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.</li> </ul>	<p>levels) will not be able to be sold <b>3 months</b> after the regulations come into force.</p> <p>This timeframe recognises that disposable products have a faster turnaround than reusable products and the increasing use of these products by young people, the subsequent safety risk posed by not having child-safety mechanisms or removable batteries, and their addictiveness.</p> <p>b. Reusable vape products that don't meet the new requirements (including child safety mechanisms, removable batteries) will not be able to be sold <b>6 months</b> after the regulations come into force.</p> <p>This timeframe recognises that reusable products have a slower turnaround than disposable products, so manufacturers and importers have more time to update their products, and retailers have more time to sell through existing stock that does not meet requirements.</p>
<p>Specialist Vape Retailers approval requirements</p>	<p>When deciding to give approval to a person to be a Specialist Vape Retailer, the Director-General must:</p> <ul style="list-style-type: none"> <li>- be satisfied that the person has an understanding of their obligations under the Smokefree Act</li> <li>- be satisfied that the retail premises are at least 300 metres distance from the location point for a registered school on the Minister of Education database</li> <li>- be satisfied that the retail premise is further than 300m from a Marae as listed on the Te Puni Kokiri website.</li> </ul>	<p><i>This proposal has been amended to include, in addition to school proximity restrictions, a requirement that applicants must demonstrate an understanding of their obligations under the Smokefree Act (including sales to minors) in response to compliance issues raised in consultation. Options for proximity were considered, including a broader requirement to 'consider' proximity. The proposed option is more certain and easier to interpret for the regulator and potential retailers, however may be a smaller area than some community submitters would prefer.</i></p> <p>Proximity restrictions for new SVRs will come into force <b>immediately</b> when the regulations come into force.</p> <p>This means that no new SVRs will be approved unless they meet the requirements set out in regulations.</p>

**Financial implications**

**Cost recovery**

- 51. Cabinet has already agreed to cost-recover the regulatory regime [CAB-21-MIN 0503 refers].



52. The objective of cost recovery is to make sure reasonable costs associated with the activities of the regulatory regime are recovered from the sector.

53. The proposed fees for regulatory activities are set out below.

Fee	Amount (exc GST)	Activities
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.
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.

#### Budget 2022 funding to establish the Regulator

54. Budget 2022 provided additional funding of \$30.7 million over four years to establish the Regulator and support activities needed to fully operationalise the Smoked Tobacco Regulatory Regime, including:

54.1 communications and stakeholder engagement

54.2 guidance to the retailers, importers and manufacturers

54.3 IT system development, implementation and training

54.4 compliance and enforcement activities.

55. These operating costs are not recovered through fees because they are not directly related to retail application, product approval or participant notification activities.

#### Legislative Implications

56. Regulations are needed to implement the regime. This Cabinet paper seeks agreement to policy decisions required to draft the Regulations.

## Impact Analysis

57. Manatū Hauora'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.

## Te Tiriti and implications for Māori

58. The changes introduced through the Smokefree Act seek to fulfil the Government's Te Tiriti o Waitangi obligations, for example by requiring consultation with Māori and improving equity of health outcomes. These regulations align with the purposes of the Smokefree Act to provide for the regulation of notifiable products in a way that seeks to minimise harm, especially harm to young people and children, and the Minister's requirement to consider the risks and benefits for Māori when regulating smoked tobacco products.
59. Māori have higher smoking rates than other groups of New Zealanders. These proposals, which will impact on all people in Aotearoa who smoke and their whānau are, therefore, more likely to have a positive impact on Māori by reducing smoking related harm.

## Other Population Implications

60. Pacific peoples and those living in New Zealand's most deprived areas also have relatively high smoking rates, and youth vaping rates are highest for young Māori and Pacific peoples. These groups are, therefore, among those most likely to be positively impacted by these proposals.
61. Manatū Hauora has undertaken a number of community hui and fono to ensure that the regulations are developed and can be implemented in a way that contributes to equitable outcomes for Māori and Pacific peoples and that the community voice is at the centre of decision making. This feedback has been incorporated where possible in the regulatory proposals and will be further considered as the retail allocation and process are developed by the Ministry.
62. Disabled people are also likely to be positively impacted by these proposals. This is because disabled adults are more than twice as likely to be daily smokers than non-disabled adults, and almost 3 times as likely to be heavy smokers.

## Human Rights

63. The proposals in this paper are consistent with the New Zealand Bill of Rights Act 1990 and the Human Rights Act 1993.

[Legally Privileged]: s 9(2)(h)

64. s 9(2)(h)

s 9(2)(h)

65. s 9(2)(h)

66.

67.

68.

s 9(2)(h)

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s 9(2)(h)

69. s 9(2)(h)

70.

71.

72.

*Next steps*

73. s 9(2)(h)

s 9(2)(h)

74. s 9(2)(h)

### Consultation

75. The following agencies have been consulted: the New Zealand Customs Service, the Ministry of Justice, New Zealand Police, the Ministry of Education, the Ministry of Business, Innovation and Employment (Commerce and Consumer Affairs), Te Puni Kōkiri, the Ministry for Pacific Peoples, the Ministry of Ethnic Communities, Te Arawhiti, the Parliamentary Counsel Office, the Ministry of Foreign Affairs and Trade, the Ministry for Disabled People, Te Whatu Ora and Te Aka Whai Ora. The Treasury and the Department of the Prime Minister and Cabinet were informed.

### Communications

76. A schedule of communications is planned to advise stakeholders of consultation outcomes following Cabinet decisions, as well as to support any formal announcements when the Regulations are made. Communications will include a press release, website and social media information, newsletters, and other supporting material such as key messages and Q&As.

### Proactive Release

77. I intend to proactively release this paper, subject to redaction as appropriate under the Official Information Act 1982, following Cabinet approval of the Regulations in July 2023.

### Recommendations

I recommend that the Committee:

1. **note** that Manatū Hauora has publicly consulted on a number of regulatory proposals to establish the Smoked Tobacco Regulatory Regime and bring the new provisions of the Smokefree Environments and Regulated Products Act 1990 into effect
2. **note** that majority of submitters supported both the smoked tobacco and vaping proposals in principle, and these have been refined to reflect the submission analysis as described above
3. **note** that Manatū Hauora will draft and publish a written notice setting out the maximum number of retail premises by area that can sell smoked tobacco products, based on the proposal set out in Appendix 2
4. **agree** to the drafting of Smoked Tobacco Regulations based on the proposals set out in paragraphs 26, 30, 36, 45 and 53

5. **agree** to the drafting of Vaping Regulations based on the proposals set out in paragraph 50
6. **note** that Budget 22 provided the \$30.7 million over 4 years to establish the regulator and regime [CAB-21-MIN-0129 refers]
7. **note** that Cabinet has already agreed to cost-recover the activities of the Smoked Tobacco Regulatory Regime [CAB-21-MIN-0192 refers]
8. **note** that the proposed fees are expected to recover the costs of the application process and additional Budget funding is not required to manage this process
9. **agree** to set the following fees under the Regulations:

Fee	Amount (ex GST)	Activity
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.
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.

10. **note** the draft Regulations will be submitted to Cabinet in July 2023 for approval
11. **agree** to authorise the Minister of Health to issue drafting instructions to the Parliamentary Counsel Office to give effect to recommendation 4 and 5
12. **authorise** the Parliamentary Counsel Office to make necessary consequential changes to the regulations and other minor and technical amendments as required.

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Authorised for lodgement

Hon Dr Ayesha Verrall

Minister of Health

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## **Appendix 1: Summary of drafting proposals**

### **Smoked tobacco**

#### **a. Retail scheme**

##### *Additional approval requirements*

From 1 July 2024, only retailers approved by the Director-General of Health (Director-General) will be able to sell smoked tobacco products such as cigarettes (and cigars and roll-your-own). No more than 600 stores will be approved. Currently there are no restrictions on where cigarettes can be sold and who can sell them. It is estimated that cigarettes are sold in approximately 6000 stores.

To be able to sell cigarettes, retail applicants must firstly meet the proposed approval requirements to demonstrate that they are of 'good character', understand their obligations under the Smokefree Act and have systems in place to protect the health and safety of their staff and customers.

##### *Decision-making criteria*

Cigarettes will only be able to be sold in 600 stores, compared to approximately 6000 currently. The Director-General will decide how many of these stores are allowed in certain areas across the country (Appendix 2 sets out the proposed numbers of outlets per region). If the number of retail applicants that meet the proposed approval requirements (see above) exceeds the allocation for region, the proposed criteria will allow the Regulator to rank applicants before making final decisions.

#### **b. Product requirements**

From 1 April 2025, only tobacco products with very low levels of nicotine (less than 0.8 mg/g compared to current levels of around 15 mg/g) can be imported, manufactured or sold. The proposed product requirements set out specific testing standards that will provide greater surety to the Regulator and consumers that cigarettes consistently meet the nicotine levels prescribed in the Smokefree Act. The proposed product requirements will also mean that cigarettes cannot be made with any other ingredient with addictive properties similar to nicotine.

#### **c. Notification requirements**

From 1 October 2023, distributors of smoked tobacco products and vaping retailers will be required to notify the Director-General that they are in business. The proposed notification requirements will allow consistent information to be gathered across both the wholesale and retail sector for both smoked tobacco and vaping products. This information can be used by the Regulator and the National Public Health Service to assist with compliance and enforcement activities.

### **Youth vaping**

The proposed restrictions are intended to make vapes less appealing to young people (by limiting the way flavours can be described), safer (by requiring replaceable batteries and child safety mechanisms) and less addictive (by reducing maximum nicotine levels in disposable vapes). The proposal is also intended to



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ensure that Specialist Vape Retailers are less likely to be allowed to operate near school premises in the future.

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## Appendix 2: Draft retail premise maximum number by area proposal

	Refined scenario*		Difference		Consultation scenario	
	Urban	Rural	Urban	Rural	Urban	Rural
Northland	18	18	+4	-10	14	28
Auckland (including airside- Auckland International Airport)	46	4	+18	-1	28	5
Waikato	52	43	+19	-10	33	53
Bay of Plenty	31	23	+8	-10	23	33
Tairāwhiti	24	20	+8	-12	16	32
Taranaki	13	9	+4	-4	9	13
Manawatū-Whanganui	29	21	+9	-9	20	30
Greater Wellington (including airside- Wellington International Airport)	41	2	+11	0	30	2
Nelson-Marlborough	10	7	+3	-3	7	10
Tasman-West Coast	11	26	+2	-12	9	38
Canterbury (including airside- Christchurch International Airport)	43	22	+9	-14	34	36
Otago-Southland (including airside- Queenstown International Airport)	36	47	+9	-20	27	67
Outlying areas (Chatham Is, Rakiura/Stewart Is, Aotea/Great Barrier Is)		3		+3		
<b>Total</b>	<b>354</b>	<b>245</b>	<b>+104</b>	<b>-102</b>	<b>250</b>	<b>347</b>
<b>Total</b>		<b>599</b>	<b>+104</b>	<b>-102</b>	<b>Total</b>	<b>597</b>

Urban Halo	Rural DT
8 min	28 min
93.30%	87%

Urban Halo	Rural DT
9:30 min	15:30 min
93.50%	85.30%

Estimated reduction (not including additional airside/outlying areas)

\*Allocation of stores in rural regions (ie, where a state highway crosses a regional boundary) has been fine-tuned and numbers updated. New allocations for airside at international airports have been added to the relevant urban region as named areas. New allocations have been created for Rakiura/Stewart Island, the Chatham Islands, and Aotea/Great Barrier Island. These will be named rural areas, rather than being rolled into the regional tally.